The Royal College of Pathologists
Pathology: the science behind the cure

The regulatory landscape for pathology services

Pathology services work in a highly regulated environment that aims to ensure that laboratories provide a safe working environment for staff and are capable of delivering a consistent, accurate and safe service to patients.

Although the UK Accreditation Service (UKAS) is the main vehicle for accreditation, the Medicines and Healthcare products Regulatory Authority (MHRA), Health and Safety Executive (HSE) and Human Tissue Authority (HTA) impact on laboratory work, with professional guidance provided by The Royal College of Pathologists (RCPath), Association for Clinical Biochemistry and Laboratory Medicine (ACB), British Society for Haematology (BSH), British Infection Association (BIA) and others. They do this through key performance indicators (KPIs), key assurance indicators (KAIs) and formal guidance documents. NHS Improvement (NHSI) is seeking to quantify some aspects of laboratory performance to provide to patients and commissioners with assurance on the clinical value of the services, e.g. Pathology Quality Assurance Dashboard (PQAD) and Getting It Right First Time (GIRFT).

This document provides an overview of the main regulatory organisations impacting on pathology services, seeking to clarify where there are areas of overlap and synergy.

1 United Kingdom Accreditation Service (UKAS) www.ukas.com

By means of The Accreditation Regulations 2009 (SI 2009 3155), the United Kingdom Accreditation Service is appointed as the national accreditation body (NAB) for the UK (see https://www.gov.uk/government/publications/conformity-assessment-and-accreditation-policy-the-uks-quality-infrastructure)

Accreditation within the health and social care sector provides reassurance to patients, commissioners and health and social care providers that the service that is being provided has been independently evaluated against recognised standards. It seeks to validate and recognise success, as well as drive up the quality and consistency of service by aspiring towards excellence and the sharing of good practice, with quality patient outcomes at its core. Indeed commissioners recognise there is a need to drive up the quality of care for patients, whilst delivering efficiency and productivity (www.ukas.com).

Currently, three UKAS healthcare accreditation schemes are approved for use within the CQC hospital inspection methodology. Clinical Pathology Accreditation (CPA), the Imaging Services Accreditation Scheme (ISAS), and Physiological Services (IQIPS) are formally recognised as part of the CQC inspection programme.

UKAS acquired Clinical Pathology Accreditation as a wholly owned subsidiary and is now moving towards completion of the transition to ISO 15189:2012. In March 2017, approximately 75% of laboratories had been assessed to this standard, with the expectation that 100% of laboratories will have been assessed by March 2018.

ISO 17043 applies to external quality assurance (EQA) schemes.

ISO 22870 applies to point-of-care testing.

The clauses in the ISO 15189 standard specify the criteria that should be met to achieve accreditation. These clauses cover organisational aspects, staffing, estates and the technical aspects of delivering laboratory services. As a general principle, professional organisations provide guidance on the criteria that should be met for satisfactory performance against the standard and UKAS assesses laboratories in a peer-review process that evaluates whether or not the laboratory meets the performance criteria.

ISO 15189 is written as a generic standard to cover all medical laboratory services. Given the wide range of pathology specialties, conformity with the standard is not always straightforward. UKAS are committed to working with the professional organisations to provide guidance to laboratories on the approaches to meeting the standard.

2 Medicines and Healthcare Products Regulatory Agency (MHRA) is involved through the regulation of in-vitro diagnostics and the use of blood components for transfusion

www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

The MHRA is responsible for:

- ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy
- ensuring that the supply chain for medicines, medical devices and blood components is safe and secure
- promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines.

The MHRA defines a medical device as any instrument, apparatus, appliance, software, material or other article used alone or combined for humans to:

- diagnose, prevent, monitor, treat or alleviate disease
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- investigate, replace or modify the anatomy or a physiological process
- control conception.

Clearly, many aspects of diagnostic pathology will be covered by this definition. In most instances, conformity is ensured by the manufacturer of laboratory equipment, reagents, etc. and validated by the award of a CE mark, but if laboratories create their own tests, they may be subject to MHRA compliance. Diagnostic kits used in point-of-care testing are also covered. Interestingly, software algorithms used to elucidate molecular genetic data may be subject to this guidance.

3 HSE regulates the safe working environment for staff and the public

All working environments in the health service, including laboratory areas, should be safe for staff and patients. Infectious risks need to be appropriately handled and any suspected breaches of the regulations are closely investigated.

4 Human Tissue Authority (HTA)

The HTA was created by the Human Tissue Act, which came into force in September 2010. The HTA provides a series of codes of practice that cover post-mortem work, transplantation

and research using human tissues. Organisations are licensed by the HTA with a Designated Individual, who has statutory responsibility for activities carried out under each licence.

Like UKAS, HTA provides a list of standards that need to be met and organisations need to provide evidence of conformity with the standards (www.hta.gov.uk/hta-codes-practice-and-standards-0).

There is some overlap between UKAS and HTA in the accreditation of mortuaries and post-mortem related work. UKAS and HTA are working to minimise this overlap and, if possible, provide a single inspection process covering both sets of standards.

5 NHS Improvement

Pathology Quality Assurance Dashboard (PQAD)

This is a limited series of metrics that are intended to provide assurance to Trust Boards about their pathology services. The metrics are currently in a pilot phase and appear to provide a limited range of assurance indicators with definitions that are subject to local determination. They are therefore of limited, if any, value when comparing organisations.

Getting It Right First Time (GIRFT)

The GIRFT project explicitly aims to improve patient pathways, improve the experiences of patients and improve clinical outcomes. In the pilot phase, with orthopaedic surgery, it has demonstrated that significant savings can be made through attention to quality.

The extension of this programme from clearly defined clinical specialties and pathways to the cross-cutting specialties of pathology; imaging and critical care poses a number of challenges. For pathology, the diversity of pathological specialties, the speed of technological evolution and the varied points of impact of clinical opinions from pathology on almost all clinical pathways will focus attention on how NHS organisations place value on pathology and, in particular, how the quality of pathology services impacts on patient experience and outcomes. Pathology services usually work across primary, secondary and tertiary sectors. It is therefore important that the impact of any proposed changes in services is considered across all sectors.

This provides an opportunity, within a unified pathology service, to consider how quality is maintained as patients move between sectors. For example, if a valid result is generated by point-of-care testing in a patient's home, then that test does not necessarily need to be repeated in hospital. Focusing on the delivery of clinical value across a pathway should allow the same metrics to be used as the services evolve and adapt to new technologies; value becomes independent of both the precise type of test and place of testing.

GIRFT methodology suggests that we need verifiable, routinely collected data from provider organisations that can be related to professionally agreed outcomes, so that variables in the cost of service delivery (staff, estates, consumables, procurement) can be optimised to reduced unwarranted variations. Demand management and moderating the requests from clinical teams for unnecessary investigations is an important part of the process.

6 Health Education England (HEE), General Medical Council (GMC), General Dental Council (GDC) and the Health and Care Professions Council (HCPC)

The GMC and HCPC are the professional regulators for doctors and for healthcare scientists respectively. The GDC regulates some dentally qualified pathologists who are primarily involved in oral histopathology and oral microbiology. While they have many roles, these organisations hold the registers of medical and health and care professionals who meet their standards for their training, professional skills, behaviour and health. HEE, through the Deaneries, monitors the training of pathologists and clinical scientists and is therefore involved in both the standards of training and education, and in workforce planning for the future. In 2016, HEE implemented a register of educational and clinical supervisors who have met specific training requirements.

7 Quality Surveillance Programme (QSP), formerly National Peer Review Programme

https://www.qst.england.nhs.uk/

The mission of the Quality Surveillance team is to improve the quality and outcomes of clinical services by delivering a sustainable and embedded quality assurance programme for all cancer services and specialised commissioned services within NHS England. The national programme of biennial self-assessment of cancer services was in place until December 2016, and it is expected that the new QSP will emerge during 2017.

8 External Quality Assurance (EQA)

There are two aspects to EQA of laboratory services:

- technical EQA, which assures the services provided by a laboratory
- interpretative EQA (iEQA), which seeks to assess the clinical advice provided by individuals, usually consultants.

Following the Pathology Quality Assurance Review, there has been considerable debate about the future organisation of schemes and the standards that should be applied to EQA schemes of both types. Currently there are a wide variety of different schemes with different governance processes and standards. The College is seeking to rationalise this process through the Joint Working Group on EQA and the Quality Assurance Management Group (which involves all relevant professional organisations).

9 Role of The Royal College of Pathologists

The primary role of the College in this context is to define standards for the delivery of clinically safe and appropriate medical, dental and veterinary pathology services. It fulfils this role (working with other organisations including the Institute of Biomedical Science [IBMS] and Association for Clinical Biochemistry and Laboratory Medicine [ACB]) through:

- the publication of advice and guidance to laboratories and pathologists,
- the development of appropriate curricula, training programmes, assessments and examinations, which aim to ensure that scientists and pathologists have relevant skills and attitudes for professional practice.
- support for continuing professional development and appraisal, which are integral to this purpose.

Relevant College documents include *Codes of Practice for Pathology Services*, guidance on the performance of autopsies and cancer reporting datasets.

The College view is that, as currently delivered, accreditation by UKAS provides assurance that a wide range of organisational, technical and (as appropriate) medical activities related to pathology services meet the basic requirements for a safe, patient-focussed, clinical testing and advisory service that will normally deliver work to a level agreed with clinical users. Accreditation does not guarantee that everything is perfect or will always work perfectly. Rather, accreditation provides reassurance that, as and when errors/incidents occur, there are robust governance processes to manage the situation and apply appropriate corrective and preventative actions. The criteria currently used by the assessment teams, which include medical and scientific peers, promote continuous quality improvement but do not overtly recognise excellence. It may be that professional organisations could develop appropriate metrics to define 'excellence' in the future.

10 Key performance and assurance indicators

The College, ACB and IBMS published a series of key performance indicators (KPIs) in 2011 (revised in 2013), which sought to define a panel of metrics that would assist laboratories in formalising their reporting of activity/performance to their organisations. There is current debate around which of the original KPIs could or should be rebadged or revised as key assurance indicators (KAIs). In principle, KPIs measure activity while KAIs assess clinical value. Regardless of the semantics (which are important), KPIs/KAIs map onto specific clauses in the ISO 15189:2012 standard and are therefore useful in supporting laboratories to demonstrate conformity with the standard.

The ongoing challenge is to define metrics that demonstrate clinical value rather than activity. Current laboratory information systems can easily capture activity data, but links to electronic patient records and multi-disciplinary team (MDT) systems are very variable and data on clinical value cannot be automatically retrieved by laboratories. Clinical value takes time and effort to demonstrate. The 'big data' approach may provide part of the solution through linking different databases.

Summary

Laboratory accreditation through CPA/UKAS provides the foundation for clinical quality assurance. HTA provides similar assurance for mortuary work. Professional organisations provide the advice and guidance that define appropriate levels of laboratory and professional performance.

The regulatory landscape is continually evolving and this document will be revised periodically to reflect these changes.

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