

Pathology inspection is changing

Pathology inspection is changing, yet there appears to have been little discussion about whether it is for the better or not. Perhaps professionals do not want to put their head over the parapet for fear of identifying themselves as not believing in the orthodoxy that all inspection is good, so increased inspection must be better.

Firstly some context; Clinical Pathology Accreditation (CPA) has been inspecting laboratories for a number of years, but in 2009 it became part of the United Kingdom Accreditation Service (UKAS), with the intention of moving all UK laboratories to the new standards by 2018. The UKAS standards are a step increase from the CPA standards, and will present a huge challenge to all Pathology laboratories in the UK, at a time when resources are at a premium.

The new standards, apart from being ambiguously written, have the potential, I believe, to have a detrimental impact upon this vital, if not well known, service.

There seems to have been little risk assessment as to the impact of the changes on the service.

In these times of scarce resources any change should have clear evidence of benefit to the patient, especially where it will require a huge input in resources, especially in staff time.

Any laboratory's practise has to be evidence based, but when it comes to inspection it appears that there is no such requirement.

What is the impact of putting all this resource into inspection instead of using it to transform services?

Examples of the impact upon resources include:

Standard operating procedures (SOPs) need to be written for all pieces of equipment, and then the staff have to demonstrate competency in using any equipment, then signed off to ensure that they are competent, and then rechecked that they are still competent in an agreed timescale.

This includes such specialist equipment as fridges and freezers.

All equipment needs to have a service history. Incubators, for example, as well as having to be monitored by a temperature monitoring system purchased from an accredited supplier, will also need to be serviced at regular intervals.

Private companies will be queuing up to offer this service, and, I suspect, at a premium price.

Of course any engineer who works on equipment has to be accredited as well.

There are, in my view, other more serious impacts:

There is an undermining of any faith or trust in the professionalism of the workforce. Everything has to be checked, and then rechecked.

Introducing new techniques into the laboratory will become almost impossible as a process of validation and evaluation will need to be undertaken.

Many discoveries in Pathology have come from that wonderful process called serendipity; we wouldn't have penicillin without it. Sometimes doing something slightly differently can lead to a better methodology. Not following process is anathema to the UKAS inspector.

Then there is the impact upon senior staff; any UKAS inspection will lead to a number of non-compliances (most laboratories seem to end up with 100 to 150), and these will need to be "fixed" within 12 weeks.

This becomes an almost herculean task, and why would you want to be a Head of a

department where you know every three years or so you will have an inspector appear to give you a whack with a big stick?

The final insult is the resourcing of the inspection process. Each laboratory has to pay a fee to be inspected, and there has been a special transition charge to help move from CPA to UKAS. UKAS also needs staff from the laboratory system to act as inspectors.

There is no payment for performing inspections; the only cost is to the host Trust of the inspector, who has to release them to undertake these inspections.

In summary, laboratories had been inspected by CPA for a number of years, and this had led to an increase in standards and this has undoubtedly been of benefit to the patient. UKAS is now taking this inspection regime to another level with little evidence of the benefit, or harm, to patients.

Let's stop inspecting for inspecting sake, but instead make it relevant to the patient.

Officinarum procurator