

They can be helpful and will be discussed in a later module, but they are still simply a good attempt to interpret stats information.

Who defines what is considered 'good enough' quality?

At a seminar many years ago I asked that question, concentrating on the 'who' part. The general reaction was that 'experts' must decide. Okay so far, but now let's define what is meant by 'expert'. This is not as easy as it looks.

When the original Accreditation Committee sat in South Africa, in roughly 1994, I recall some debate about how the length of time that samples and pathology records should be retained. About twenty 'experts' sat around the table, deliberating and talking endlessly about factors that affect the storage and retention of, say, histology sections, or blood samples, or even QC records. This continued until it became obvious that the 'experts' had no idea how long such items be retained. Everyone spoke about what happened 'in my lab' but none of us knew what was correct, or appropriate or even legally required.

This story illustrates several things, including the well-known fact that experts will often disagree, as well as the reluctance of such experts to confess they do not know the answer!

The same situation applies to deciding what is and what is not acceptable quality. The patient illustration earlier is important here, as it shows that we each carry around somewhere in our experience, an idea of what is good enough for each test. Generally this is a combination of knowledge about the performance of this test in our own lab experience; plus a feeling for what variations patients will have – a feeling that is based to some extent on the reference ranges we use, the wider the range, the more patient variation there will be, roughly speaking.

Three sets of acceptable performance standards will be discussed, namely CLIA'88, Biological Variation, and the Acceptable Standards used by Thistle QA in South Africa.
CLIA'88

The USA law entitled the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) was one of the first ever to attempt to define minimum standards for all laboratory tests. There have been many subsequent changes and alterations to this law, and these changes are well discussed by James Westgard (www.westgard.com).

Four categories exist in CLIA'88 regulations, from waived to high complexity, but only three are relevant to us here, as follows.

Waived tests have the lowest quality requirement. Such tests include Faecal Occult Blood (FOB), urine pregnancy tests and various dipstick or tablet urine tests.

Moderate complexity tests comprise about 75% of all tests performed in labs today. CLIA'88 includes much more than traditional stats QC procedures, namely, calibration,

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