

## The importance of metrological traceability of medical results

For those of us involved in implementing metrological traceability in laboratory medicine, we are well aware that it plays an important role. In the article that follows, Graham Jones describes some of the many different areas of medicine where this traceability is fundamental to good clinical care. Awareness of these scenarios reminds us of the importance of this work, and can help explain this to those whose support is needed for the work. It is also a reminder that we are all patients as well, and we can benefit from traceable laboratory results.

**Graham RD Jones**

**St Vincent's Clinical School, Sydney, Australia**

**Email: [Graham.Jones@svha.org.au](mailto:Graham.Jones@svha.org.au)**

Producing laboratory medicine results with metrological traceability is a key goal of pathology laboratories, and the JCTLM aims to promote and support these efforts. However in order to gain the benefits of metrological traceability for medical results, it is necessary that in addition to the patients' results, all results that are associated with these results are also traceable. This can be best understood by recognising that all clinical results are interpreted by comparison. This comparison can be with specific results, for example a previous result from the same patient, or values based on multiple measurements, for example a population reference interval or clinical guideline. For valid interpretation of clinical results, the measurements used for the comparators must be unbiased relative to the measurements of a patient's results. This is achieved by metrological traceability of both the results and the comparators (see table 1 for examples of comparators).

Once Traceable results are achieved and widely implemented, there are many things that can be achieved. Conversely if results are not traceable, the activities below will not be able to be performed with safety and reliability.

### Using results from different laboratories

Patients can be seen in different health care settings by choice or by circumstance. In order for results from different laboratories to be interpreted against each other ("is the patient getting better, getting worse, or staying the same"), the results from all the involved laboratories must be traceable. This may include laboratories in different hospitals, laboratories serving general practice, and laboratories in different parts of a country or in different countries.

### Combined medical records

Many countries, states or regions, or health care organisations are placing results from different laboratories into central data locations ("common medical records") to support health care as patients move or receive health care in different locations. With traceable results these databases can function well to monitor patients.

### Cost savings

If a test from another source is not known to be the same as where a patient is being treated, it is common to repeat tests at a local laboratory to ensure correct medical decisions are being made. With traceable results from all laboratories this is not required and faster, more cost-effective care can be provided.

### Clinical Guidelines

Many national and international clinical groups prepare guidelines for doctors about how to diagnose and manage certain medical conditions. Often these include reference to laboratory results. Common examples would be for testing of plasma glucose to diagnose diabetes or measure cholesterol for heart disease risk. These guidelines can only use all the available evidence if the research studies used traceable assays and can only usefully include numbers for diagnosis or as treatment targets if laboratories can all produce traceable results.

### Applying clinical evidence

We have the aim of applying the latest clinical evidence to medical decisions. Research is now done in all parts of the world, and is readily available by relevant search engines, but conclusions based on laboratory results can only be applied to our patients if we know that both the laboratory we use, and

the laboratory where the research was done, both are using traceable assays. The issue is a global one if we want access to global research information.

### Big Data

Medical research now can involve the combing of clinical and other data from different locations looking for trends and relationships. This type of research is particularly valuable as it covers “real world” settings and can bring vast amounts of data to address problems with much less cost than doing other types of studies. However this is only possible, or at least is significantly simplified, if all the laboratory results in these projects are giving the same results, i.e. they are all traceable.

### Common reference intervals

As well as getting the same results on a laboratory report with traceable results, it is also then possible to provide the same reference intervals. These are a vital tool to help with rapid assessment of laboratory results and variability in these intervals has as much effect on interpretation and variation in the results themselves. The use of traceable results allows the setting of high quality reference intervals for common use across a state or country, removing another source of unnecessary variation in results and their interpretation.

In summary, the full benefits of traceable results are only realised if they are provided by all laboratories, in clinical practice and research, in hospitals and family practice, in all countries of the world. This is truly a global issue requiring local, national and global actions.

Table 1. Interpretation of patient result by comparison

Comparison scenario	Example clinical questions	Comparison results
Comparison with a previous result from the same patient	Is my patient getting better or getting worse? Is my treatment working?	The previous result may be from the same laboratory; or from a different laboratory with the same or different method
Comparison with a population reference interval	Is this result expected for a person of this age and sex without disease?	Reference intervals are derived from many measurements of healthy subjects using the same or different methods, at a previous time and place.
Comparison with a clinical decision point	Does this result diagnose this disease?	Data for a clinical decision point is taken from many measurements with associated clinical outcome data. Examples include diagnosis of diabetes and managing lipid disorders.
Comparison with a doctor's experience	Do these results look like those I have seen with this disease in the past?	The doctor's experience is based on results from the laboratory serving his/her clinical practice.