The External Quality Assessment of Laboratories Investigating Toxicology Cases

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INTRODUCTION

It is a requirement of external accreditation bodies that laboratories participate in an external quality control scheme if there is one in existence (1). For specialist workloads such as toxicology, this can be difficult owing to the variety of drugs and chemicals that may be taken accidentally or in overdose situations.

The United Kingdom National External Quality Assessment Scheme (UKNEQAS) Steering Committee for Drugs offers such a scheme in Clinical Toxicology to aid those laboratories routinely undertaking specialist analytical procedures.

Following a review of the scheme returns, the Steering Committee noted that the performance of some laboratories needed to be markedly improved. It was therefore decided to develop a method of analysing and scoring the returns made by scheme participants to attempt to improve the quality of results being generated and used for clinical treatment and patient management.

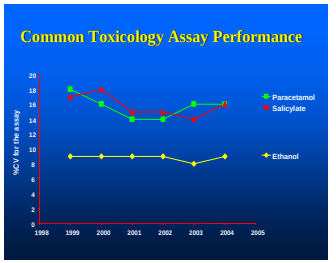
METHODS

The UKNEQAS scheme circulates 4 distributions per year, three involve relatively common drugs with the fourth involving the rarer analytes and posing a more difficult analytical and interpretive problem. Participants are asked to analyse the specimen(s) provided. They also comment on the drug(s) and concentration(s) determined, and outline any advice that would be given to requesting source. In this way the scheme reflects the "true" situation faced by the laboratories performing this work.

A scoring system was developed to aid in the assessment of the returns made to the organisers, as follows: -

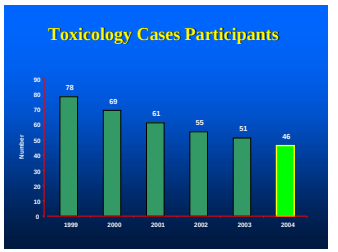
- A maximum of 5 marks for drug identification irrespective of the number of analytes or matrices
2) A maximum of 5 marks for drug quantitation judged against the consensus mean
3) A maximum of 5 marks for other useful information to outline the scope of the analysis performed
4) A maximum of 5 marks for data interpretation
5) A maximum of 10 penalty marks for missed critical analytes, or for incorrect or misleading reports

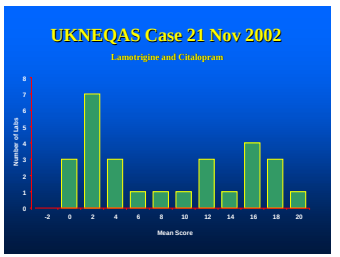
RESULTS



It was found that the returns for the routine and automated analyses were consistent, but showing little or no improvement over time.

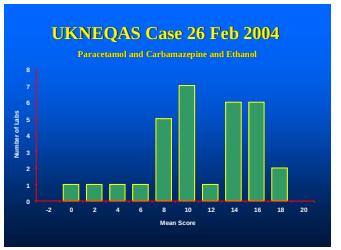
The number of scheme participants declined by around 5 per year following the inception of the scoring scheme.

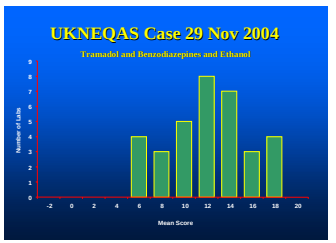




The initial application of the scoring approach resulted in a bi-modal distribution of analytical laboratories participating in the scheme.

There was a gradual shift as performance got steadily better over time, but with a few analytical laboratories still not performing too well.





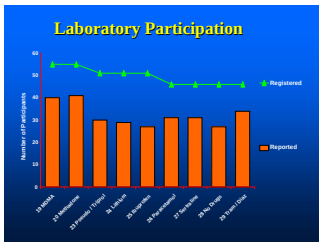
Eventually the scheme led to a significant improvement in the performance of those laboratories still enrolled.

DISCUSSION

The UKNEQAS Toxicology Cases Scheme has provided a mechanism for laboratories to fulfil their obligation with respect to requirements for external accreditation in this specialist area. It has also been demonstrated that the scheme provides an educational, not punitive, mechanism for laboratories to improve the quality of their analytical and interpretive results.

Two obvious questions are raised by the data presented, namely: -

1) Why has the number of participants fallen over time, and are these laboratories still performing this work outside of the scheme.



2) What will be the impact on the scheme following the introduction of compulsory external accreditation for all laboratories.

REFERENCES

1.Clinical Pathology Accreditation (UK) Ltd. (2003) Standards for the Medical Laboratory. Version 1.02. www.cpa-uk.co.uk

* Members of UKNEQAS Steering Committee for Drug Assays:

David Bullock, Steve George, David Holt, John Ramsey, Grace Sweeney, Brian Smith, Steve Smith, Alison Thomson, Ian Watson, John Williams & John F Wilson