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CONTENTS

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The Zimbabwe External Quality Assessment Scheme (ZEQAS) in clinical chemistry: results of the pilot programme

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SUMMARY

A pilot programme for assessing laboratory performance in clinical chemistry laboratories in Zimbabwe is described (ZEQAS). Twenty four laboratories providing patient care services participated. Eight lyphilised bovine sera were distributed over one year.

Consensus values and the spread of interlaboratory agreement were calculated for each of 12 analytes and compared with results previously obtained in a large mature national EQA scheme in the UK (UK NEQAS). For all analytes except phosphate, the mean consensus value obtained in ZEQAS was between 94 and 108 pc of the UK target, although the spread of results in ZEQAS was generally two to threefold greater for individual analytes than in UK NEQAS.

It is concluded that the ZEQAS consensus values for the analytes surveyed provide a valid target against which individual laboratory performance can be assessed. The wide spread of results from individual laboratories suggests there is considerable scope for improving interlaboratory agreement. This is being addressed by the continuing programme, with increased interaction and production of local specimens.

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INTRODUCTION

Laboratory results have an important role in the provision of optimal health care whether for screening, diagnosis, prognosis or monitoring of disease. To fulfill this role, results must be accurate (ie. precise and unbiased) and comparable between different laboratories.

Clinical laboratories seek to achieve these goals through quality assurance programmes which include pre-analytical (specimen handling), analytical, and post analytical (interpretive) elements of performance.[2] Assessment of analytical quality requires internal quality control (IQC) and external quality assessment (EQA). Internal quality control is primarily useful for assessing in real time when the test results from an individual laboratory can be released for patient care. The main focus in IQC is on reproducibility (precision) of results. In contrast, EQA examines comparability of results between laboratories and can provide valuable information on systematic bias of results.[1-2] EQA is necessarily retrospective and requires an overall target value against which individual laboratory results can be compared.[3-6]

In Zimbabwe, clinical chemistry laboratories routinely employ IQC and some participate in commercial EQA schemes organised internationally. However, such EQA schemes are not ideal for a developing country such as Zimbabwe because:

1. The time interval for feedback of the data analysis to participating laboratories is too long to be practically useful in stimulating improved performance.
2. Since the EQA centre is remote, participants find it difficult and expensive to seek advice and assistance.
3. Commercial schemes cannot provide impartial advice with knowledge of local conditions.
4. International commercial schemes are expensive and require scarce foreign currency.
5. International commercial schemes cannot provide information focused on the quality of performance over a whole country.
6. Local priorities cannot be addressed since the scheme design is inflexible.

The Zimbabwe EQA scheme in clinical chemistry was initiated to survey the comparability of results between clinical laboratories. The scheme aims to stimulate improved performance by encouraging good practice and discovering unsatisfactory procedures. As a first step, reliable and valid target values for analytes in the material distributed are required.

To test the validity of ZEQAS consensus values (derived from a relatively small number of laboratories) as targets, they were compared with those obtained from the same material in a mature and large clinical UK scheme. The initial surveys also provided valuable baseline information on the state of the art in Zimbabwe, against which future progress can be assessed.

MATERIALS AND METHODS

Participants: Twenty four clinical chemistry laboratories were recruited into the ZEQAS. Three private laboratories participated, the others being Public Health Laboratories attached to Government hospitals at provincial level and above.

Specimens: A total of eight distributions constituted the pilot phase of the ZEQAS over a period of one year. Each distribution included a different lyophilised bovine serum supplied from the UK National External Quality Assessment Scheme (UK NEQAS) based at Queen Elizabeth Medical Centre, Birmingham. These specimens covered a wide range of normal and pathological concentrations for all analytes. All materials had been previously distributed in the UK NEQAS, and data analysed based on returns from the 650 participants, yielding results from 300 to 650 laboratories, depending on analyte. Locally produced liquid specimens[7] were also distributed in the scheme, but data are not considered here.

Distribution of specimens: Vials containing lyophilised specimens for reconstitution with five or 10 ml water were labelled with the distribution number, reconstruction instructions and the latest date for receipt of results by the organisers. Each vial was placed in an addressed envelope before transfer to the Public Health Laboratories (PHL) at Parirenyatwa Hospital for onward delivery by courier, car or post as appropriate. The specimens reached their destination within 24 hours.

Analysis of specimens and reporting results: The specimen was reconstituted in distilled or deionised water (five or 10 ml) before analysis. The reconstituted specimen was treated and analysed in the same way as patients' specimens. The results of the analyses were returned to the organising centre by post. After data

processing, individual laboratory reports were returned to the participants together with the next specimen for analysis. Each laboratory received an individual confidential report comparing its results with the overall data. No laboratory received information on the performance of another identifiable laboratory, though reports showed grouped and mean data for all participants.

Data processing and assessment of performance: A microcomputer employing a modified MUMPS programme (developed and donated by the Wolfson Research Laboratories, Queen Elizabeth Medical Centre, Birmingham, UK) was used for scheme administration and statistical analysis of the data. Laboratory results received by the organisation on or before the due data were processed and files updated accordingly. The results, in molar SI units, were entered into the computer by two people independently.

The results were analysed and assessed using consensus values for each analyte. The consensus values were recalculated means obtained after elimination of outliers by truncation of values greater than 3SD from the untrimmed mean.[6,8] Reports also showed data classified according to the method used, but these were not used as targets.

RESULTS

The ratio of consensus values, $\frac{\text{ZEQAS}}{\text{UK NEQAS}} \times 100$ pc were calculated for each analyte and each specimen. The average ratios in Table I show that there is excellent agreement between the ZEQAS and UK NEQAS for most analytes. The ZEQAS results for phosphate show over estimation (108,7pc) whereas those for glucose and urea indicate a rather wide variation of results, due to the spread of inter laboratory agreement (Table II) and the small number of participants.[8-10]

The inter-laboratory agreement for each analyte in the sample distributed was quantified by calculating the coefficient of variation (CV, pc) of the results from the laboratories. Table II compares inter laboratory agreement in the ZEQAS and UK NEQAS. Taking the UK NEQAS values as a target obtained from more than 300 laboratories, the ZEQAS performance shows between two and threefold greater spread of results. Only sodium, potassium, glucose and total protein have average CV values below 10. The greatest variation

Table I: Comparison of consensus values in ZEQAS and UK NEQAS of the eight lyophilized specimens.

Number of participants: Zimbabwe = 24; UK = 300 to 620

Analyte	ZEQAS/UK NEQAS Average (pc)	Range*	SD
Sodium	99,6	98,4 — 101,0	1,09
Potassium	99,5	97,2 — 102,0	1,57
Urea	95,7	90,0 — 98,2	3,29
Glucose	94,4	88,0 — 98,7	3,32
Calcium	96,7	87,0 — 109,0	6,68
Phosphate	108,7	91,0 — 132,6	12,89
Urate	103,4	97,1 — 113,8	6,26
Creatine	97,8	89,0 — 103,0	5,84
Bilirubin	107,2	92,0 — 108,0	5,21
Total protein	97,7	94,8 — 100,8	2,85
Cholesterol	96,9	88,0 — 107,0	5,55

** Range of ratios obtained for all distributions.*

Table II: Comparison of Interlaboratory Agreement (Average CV, pc for each analyte in the eight samples distributed) obtained in ZEQAS and UK NEQAS.

Number of participants: Zimbabwe = 24: UK = between 300 to 620 depending on analyte.

Analyte	ZEQAS Average CV, pc	SD	UK NEQAS Average CV, pc	SD
Sodium (mmol/l)	2,28	0,7	1,40	0,2
Potassium (mmol/l)	3,28	0,8	2,44	0,3
Urea (mmol/l)	11,04	0,3	4,60	0,9
Glucose (mmol/l)	8,04	3,4	4,04	0,4
Calcium (mmol/l)	19,78	5,0	3,16	0,4
Phosphate (mmol/l)	19,78	5,6	4,75	0,4
Urate (mmol/l)	14,44	4,3	6,20	0,5
Creatine (mol/l)	11,60	9,5	8,40	0,5
Bilirubin (mol/l)	17,74	9,0	8,40	1,3
Total protein (g/l)	7,44	1,4	3,24	0,4
Cholesterol (mmol/l)	12,60	4,6	4,35	0,1

relative to UK NEQAS was found for calcium, phosphate and cholesterol, though the high CV for cholesterol in ZEQAS is due in part to use of chemical and enzymic methods which have differing specificity.

DISCUSSION

The UK NEQAS has been operating successfully for over 20 years, and this is frequently used as the reference for other schemes.[8,9] In this pilot ZEQAS, the UK procedures for statistical calculations were adopted and consensus values for UK NEQAS were used as targets, against which to compare the ZEQAS results.

The results demonstrate that there is close agreement between the consensus values obtained from ZEQAS and UK NEQAS despite the relatively small number of participants in the Zimbabwe scheme (24), compared to the UK scheme (300 to 620 depending on analyte). Difference for glucose and phosphate may be due to changes in specimen composition if the delay between reconstitution and analysis is excessive: the large between laboratory CV for phosphate supports this possibility. The inter laboratory agreement, however, leaves substantial scope for improvement. It is important to emphasise that no counselling of laboratories was done during this pilot programme.

It is concluded that the consensus values in the ZEQAS have been validated as suitable targets against which individual laboratory performance can be assessed. Since this pilot programme, ZEQAS has been expanded and operated independently of the UK NEQAS, with a system for providing advice and assistance to participants with apparent performance problems. Future publications will report on the validation of locally produced liquid bovine serum specimens and changes in laboratory performance over time in ZEQAS.

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