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Reporting unit size and measurement uncertainty: current Australian practice in clinical chemistry and haematology

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Summary

In this study we aimed to compare the reporting unit size used by Australian laboratories for routine chemistry and haematology tests to the unit size used by learned authorities and in standard laboratory textbooks and to the justified unit size based on measurement uncertainty (MU) estimates from quality assurance program data. MU was determined from Royal College of Pathologists of Australasia (RCPA) – Australasian Association of Clinical Biochemists (AACB) and RCPA Haematology Quality Assurance Program survey reports. The reporting unit size implicitly suggested in authoritative textbooks, the RCPA Manual, and the General Serum Chemistry program itself was noted. We also used published data on Australian laboratory practices. The best performing laboratories could justify their chemistry unit size for 55% of analytes while comparable figures for the 50% and 90% laboratories were 14% and 8%, respectively. Reporting unit size was justifiable for all laboratories for red cell count, >50% for haemoglobin but only the top 10% for haematocrit. Few, if any, could justify their mean cell volume (MCV) and mean cell haemoglobin concentration (MCHC) reporting unit sizes. The reporting unit size used by many laboratories is not justified by present analytical performance. Using MU estimates to determine the reporting interval for quantitative laboratory results ensures reporting practices match local analytical performance and recognises the inherent error of the measurement process.

Key words: Clinical chemistry, haematology, reporting interval, reporting unit, significant figures.

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INTRODUCTION

Excessive use of significant figures in numerical data gives a spurious impression of laboratory imprecision to clinicians. Inappropriate reporting unit size has previously been demonstrated in clinical chemistry but not to our knowledge in routine haematology reporting.[1,2] Measurement uncertainty (MU) estimates are a requirement of the latest ISO 15189 standard and are increasingly used in the clinical laboratory.[3] We have previously argued that MU estimates can be used to set the appropriate reporting unit size for quantitative analytes.[4] In this paper, we compare the reporting unit size used by Australian laboratories for routine chemistry and haematology tests to the unit size used by learned authorities and in standard laboratory textbooks and to the justified unit size based on MU estimates from quality assurance program data.

MATERIALS AND METHODS

Contemporary laboratory reporting practice

Data on MU and reporting unit sizes was taken from a recent study of reporting practices in Australian haematology laboratories described elsewhere.[5] In brief, Australian laboratories enrolled in the Royal College of Pathologists Quality Assurance Programs (RCPA QAP) were invited to participate in an internet survey (using the SurveyMonkey website) in December 2012. Responses were received from 85 laboratories (a 17% response rate). Amongst the data collected were the details of reference intervals for full or complete blood count panels, from which reporting unit sizes were inferred. Data on reporting unit sizes for a limited number of common analytes (creatinine, ferritin, thyroid-stimulating hormone and sodium) in 24 Asia-Pacific laboratories has been previously described.[1]

Contemporary authoritative reporting practice

The reporting unit size used in the reference intervals and data entry sheets (for quality assurance data entry) from the sources below were recorded:

1. Textbooks: Tietz Textbook of Clinical Chemistry[6] and Practical Haematology by Dacie and Lewis.[7]
2. Website: RCPA Manual of Use and Interpretation of Pathology Tests (www.rcpamanual.edu.au).[8]
3. Data entry sheets: General Serum Chemistry and Haematology Quality Assurance Programs from RCPA – Australasian Association of Clinical Biochemists Quality Assurance Program (RCPA-AACB QAP).

It is understood that these are not explicit unit size recommendations but could be interpreted as such by some laboratories. The quality assurance data entry sheets are intended to capture all possible reporting formats from participating laboratories but their uncensored design may inadvertently have a permissive, if not prescriptive, effect on laboratory reporting choices.

Contemporary laboratory performance

Summary data from the latest RCPA-AACB QAP and the RCPA Haematology QAP end-of-cycle reports was examined to assess the imprecision performance of the best, 50th percentile and 90th percentile laboratories in the survey. The design and data analysis of the quality assurance program has been described elsewhere.[1] In brief, the surveys are comprised of duplicates of linearly related samples, which enable the individual laboratory's imprecision to be calculated at the end of the testing cycle via the standard error of the estimate Sy.x from least-squares linear regression on each laboratory's dataset. These surveys consist of a relatively small number of samples per cycle, however the variation in laboratory imprecision from cycle to cycle is small and therefore we feel confident that these data represent a robust estimate of performance. The strength of the RCPA-AACB QAP process in using repeated analysis of material to calculate individual laboratory assay imprecision may result in more reliable estimates of true assay imprecision than consensus imprecision figures.[9]

Determination of appropriate reporting unit size

Appropriate reporting unit size was calculated as follows:[4]

$R = k.SDa / 1.9$

Where $SDa = S$ y.x from quality assurance data and $k = 2$.

We have used the median imprecision (50%) from the QAP surveys to determine *R*. Some laboratories can achieve a better imprecision but *R* values

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should be harmonised across all laboratories. Ideally *R* should equal k.SDa/1.9. Use of values greater than this risk masking statistically significant changes from the reader while values less than this risk over-interpretation in less knowledgeable readers. Of these two risks, the first is greater as it is irremediable, while the second can be overcome by education of clinicians, making calculated minimum change values available to clinicians, automated flagging of significant changes, etc.

RESULTS

Table 1 shows the reporting unit magnitude for 40 clinical chemistry analytes based on the standard deviations for the 50th and 90th percentile rankings of the more than 500 laboratories enrolled in Cycle 94 (10 January–18 April 2013) of the General Serum Chemistry QAP. The table also shows the reporting unit size (where available) used for the reference intervals from the RCPA Manual[8] and Tietz Textbook of Clinical Chemistry[6] and for the data entry sheets from the General Serum Chemistry Program. This table also includes the suggested *R* value as calculated above. There are two cases where we have not followed the criteria and these are troponin T (TnT) and creatine kinase (CK) where the SDa from the QAP represents performance across a wide range of concentrations but there are critical decision points where the reference interval reflects the MU.

Comparing these results to those from 2007, the proportion of analytes where the justifiable unit size based on analytical performance is less than or equal to the unit size suggested by authorities has improved with an increase from 2007 to 2014 of 22/38 to 27/37 (RCPA), 12/39 to 22/39 (Tietz) and 6/40 to 15/41 (QAP), respectively. For the 50th percentile laboratories, the respective improvements were more modest at 9/38 to 11/37 (RCPA), 3/39 to 4/39 (Tietz) and 0/40 to 1/41 (QAP). There was a similar pattern for the 90th percentile laboratories of 3/38 to 7/37 (RCPA), 1/39 to 2/39 (Tietz) and 0/40 to 0/40 (QAP).

Table 2 shows the reporting unit magnitude for seven haematology parameters based on the standard deviations for the 50th and 90th percentile rankings of the more than 500 laboratories enrolled in Cycle 22 (1 July–10 Dec 2013) of the RCPA Haematology QAP. Table 2 also shows the reporting unit size (where available) used for the reference intervals from the RCPA Manual[8] and Dacie and Lewis Practical Haematology Textbook[7] and for the data entry sheets from the Haematology program. We also include the calculated *R* value as above.

Table 1 Justified reporting unit size based on performance in RCPA General Serum Chemistry QAP Cycle 94, together with unit size taken from various authorities

Analyte	Unit	Suggested reporting interval	Unit size from 50% QAP SD	Unit size from 90% QAP SD	RCPA unit size[8]	Tietz unit size[6]	QAP unit size
ALT	U/L	1	3.5	5.4	1	1	1
Albumin	g/L	1	1.0	1.6	1	1	0.1
ALP	U/L	1	10.0	17.9	1	1	1
Amylase	U/L	1	6.1	11.6		1	1
AST	U/L	1	5.7	9.2	1	1	1
Bicarbonate	mmol/L	1	1.0	1.6	1	1	0.1
Bilirubin	μmol/L	1	2.0	3.3	1	1	1
Calcium	mmol/L	0.01	0.04	0.07	0.01	0.01	0.01
Chlorine	mmol/L	1	1.3	2.1	1	1	1
Cholesterol	mmol/L	0.1	0.10	0.16	0.1	0.01	0.01
Creatine kinase	U/L	1	13.9	29.8	1	1	1
Creatinine	μmol/L	1	6.8	10.7	10	1	1
Ferritin	μg/L	1	8.7	15.0	1	1	1
GGT	U/L	1	2.8	6.3	1	1	1
Glucose	mmol/L	0.1	0.33	0.51	0.1	0.1	0.1
HDL-Chol	mmol/L	0.01	0.04	0.06	0.1	0.01	0.01
Iron	μmol/L	0.1	0.6	1.1	1	0.1	0.1
LD	U/L	1	9.3	15.3	1	1	1
Magnesium	mmol/L	0.01	0.04	0.05	0.1	0.01	0.01
Osmolality	mmol/kg	1	4.2	6.6	1	1	1
Phosphate	mmol/L	0.01	0.03	0.05	0.1	0.01	0.01
Potassium	mmol/L	0.01	0.06	0.11	0.1	0.1	0.1
Protein	g/L	1	1.4	2.2	1	1	1
Sodium	mmol/L	1	1.4	2.2	1	1	1
Triglyceride	mmol/L	0.01	0.04	0.06	0.1	0.01	0.01
Urate	mmol/L	0.01	0.009	0.014	0.01	0.01	0.001
Urea	mmol/L	0.1	0.34	0.58	0.1	0.1	0.1
Cortisol	nmol/L	1	26.3	41.5	1	1	1
Free T4	pmol/L	1	1.12	1.8	1	0.1	0.1
TSH	mU/L	0.1	0.46	0.84	0.1	0.01	0.1
Troponin I	μg/L	0.01	0.068	0.84			0.01
Troponin T	ng/L	1	22.9	43.3			0.1
Carbamazepine	mg/L	0.1	0.42	0.73	1	1	0.1
Digoxin	μg/L	0.1	0.10	0.14	0.1	0.1	0.1
Gentamicin	mg/L	0.1	0.36	0.59	1	1	0.1
Paracetamol	mg/L	1	3	7	1	1	1
Phenytoin	mg/L	1	1.0	1.8	1	1	0.1
Salicylate	mg/L	1	7	11	1	1	1
Theophylline	mg/L	0.1	0.7	1	1	1	1
Valproic acid	mg/L	1	3.5	6.5	1	1	1
Vancomycin	mg/L	1	1.4	2.4		1	0.1

ALP, alkaline phophatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma glutamyl transferase; HDL-Chol, high density lipoprotein cholesterol; LD, lactate dehydrogenase; TSH, thyroid stimulating hormone.