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Haemolysis; How big an issue in Primary Care?

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Introduction:

In vitro haemolysis is a major issue for Clinical Chemistry laboratories causing assay interference through a number of mechanisms; erythrocyte release and spurious elevation or dilution of analytes, spectrophotometric and chemical assay interference.[1]

Serum indices (SIs) are semi-quantitative, pre-analytical quality indicators and include measurement of the haemolysis (H) index. The H-index is a crude measure of haemoglobin content and a surrogate for haemolysis.[3] SIs are automatically measured on all sera analysed on the Roche Cobas® 8000 analyser series. Manufacturers pre-define SI limits for each assay such that if limits are exceeded assay results are considered inaccurate and withheld.

Haemolysis is common to specimens originating from Primary Care (*e.g.* transport time, delayed analyses), and the Emergency Department (ED) (*e.g.* urgency/frequency of phlebotomy, technique used, staff profile taking blood).[2] However, sample number originating from ED are small relative to Primary Care. The issue of haemolysed samples in Primary Care may, therefore, appear more worthwhile to address.

We wished to evaluate (1) the numbers of haemolysed samples received and (2) the potential clinical impact of haemolysed samples on Primary Care and ED compared to the Intensive Care Unit (ICU), where phlebotomy services would be considered optimal.

Methods:

H-indices measured in Primary Care, ED and ICU specimens were retrospectively retrieved from the laboratory information system over ten-weeks. Roche assay H-index cut-offs for Potassium (54 µmol/L), Iron (125 µmol/L), Amylase (310 µmol/L) and Creatinine (497 µmol/L) were applied to the H-indices to clinically contextualise the degree of haemolysis observed in each location. These H-index cut-offs span the analytical range of the Roche H-index measurement (3-745 µmol/L). Comparisons of the Primary Care, ICU and ED data which exceeded each of the four H-index cut-offs were conducted using statistical tests for independent categories.

Results:

The majority of samples received to the lab came from Primary Care patients (77.9%) followed by specimens from ED (18.8%) and ICU (3.3%). A minor number were considered unsuitable for analysis (**Table 1**).

Table 1. Numbers of samples with H-index measured by source location over a ten-week period.

Location	Specimens with H-index (number)	Unsuitable samples (number)
ED	9,726	11
ICU	1,720	4
Primary Care	40,365	14

H-index results mean little to clinicians. Given the variable impact haemolysis has on different analytes it is difficult to associate H-index values with mild, moderate and gross haemolysis. In an effort to place H-index results into a more clinical context we examined the H-index cut-off values for potassium, iron, amylase and creatinine (**Table 2**).

The H-index cut-offs for all four tests were exceeded more frequently in ED (Potassium; 6.6%, Iron, 2.9%, Amylase, 0.7%, Creatinine, 0.3%) than in specimens from either Primary Care or ICU (Potassium; 0.5%, Iron, 0.1%, Amylase, 0.0%, Creatinine, 0.0%; **Table 2**).

Table 2. H-index measurement of samples received from ED, ICU and Primary Care examined by Roche test method -associated H-index cut-off.

Analyte	Assay H-index cut-off (µmol/L)	> H-index		
		ED Number (%)	ICU Number (%)	Primary Care Number (%)
K	54	645 (6.6)	9 (0.5)	214 (0.5)
Iron	125	282 (2.9)	1 (0.1)	48 (0.1)
Amylase	310	64 (0.7)	0 (0.0)	4 (0.0)
Creatinine	497	25 (0.3)	0 (0.0)	2 (0.0)

Primary care and ICU data which exceeded the four H-index cut-offs were compared using the Fisher exact probability test with Bonferroni correction; there was no statistically significant difference (p-values >0.05). The number of requests failing the four H-index cut-offs in ED and Primary Care were examined using the Chi-squared test of independence with Bonferroni correction; significant statistical differences were observed (p values <0.05).

Conclusions:

- From this evaluation it is evident that the degree of haemolysis observed in Primary Care samples is comparable to that observed in ICU, a clinical location where phlebotomy practice is good.
- The data clearly demonstrates that haemolysis is a greater issue in ED, compared to Primary Care or ICU.
- As there is no difference in specimen transport between ICU and ED our data supports the view that trained phlebotomists should be available in ED and for longer periods.

Bibliography:

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