Investigation of potential quality improvements when using BD Vacutainer® Barricor™ for samples collected from Primary Care.

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Introduction

- Laboratory services to primary care are often compromised by restricted transport and delayed sample separation which can lead to un-reportable results. This can add extra stress on GP surgeries and patients alike.
- The newly introduced BD Vacutainer® Barricor™ tube has a novel mechanical separator which can lead to improved plasma sample quality post-centrifugation and potentially reduce analytical errors.

Aim

This study aimed to compare the performance of the new BD Barricor™ tube with current BD Vacutainer® SST™ tubes used in GP surgeries throughout the Trust.

Material & Methods

- Patients attending a local GP surgery were consented to provide an additional blood sample (Barricor™) in addition to the standard SST™ sample.
- These Barricor™ samples were separated immediately (within 10 min) on-site by centrifugation at 4000g for 3 min using a Drucker Apex 6 Centrifuge.
- Both Barricor™ and SST™ samples were then transported to the laboratory and processed under the same conditions.
- Both samples were transferred for analysis as close together as possible, after appropriate processing (including centrifugation) of the SST tube.
- Centrifugation lag times were calculated for SST tubes vs. Barricor™ and results of each compared.
- Comparison data was collected for a number of common analytes and statistical differences were assessed using the 2-sample T-test for either equal or unequal variances, after performing the F-test.
- The clinical impact of moving to from using SST to Barricor for various analytes was assessed.

Acknowledgements

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Results

- Matched SST and Barricor tests results were analysed for statistical and clinical significance.
- Result ranges, differences and the affects of delayed centrifugation for many of the commonly requested tests from primary care are summarised in Table 1.
- As expected, a number of analytes show a statistical difference between serum (SST) and plasma (Barricor). However, in the majority of cases this was not deemed to have any negative clinical impact.
- In some cases samples were received in the lab the next morning after samples had been collected at the GP surgery. In such cases some of these results breached the lab rules for delayed reporting and these results are withheld.
- The majority of analytes (inc. urea, creatinine, Ca, Alb, ALP, TBl, ALT, ALP, HDL, Trig, Chol, CRP, Fe, Ferritin, FT4, TSH & PSA) showed good correlation between results from the SST and Barricor tubes and there would be no significant change in quality if moving to the Barricor for these samples.
- In addition, there was no significant change by quicker centrifugation for these tests.
- Delayed separation had a negative impact on potassium (increased results) [Fig. 1], and chloride (decreased results) [Fig. 2]. However, the increases in potassium were smaller than had been expected considering the transit delays involved.
- Serum folate [Fig. 3] and phosphate [Fig. 4] results also showed a slight decrease with separation delay, though the numbers of delayed samples were small for both these groups.

Conclusions

- The use of BD Barricor™ over the current SST sample collection tube resulted in no significant difference for the majority of analytes investigated.
- However, use of Barricor™ tube has the potential to reduce repeat testing for unreportable potassium and phosphate results and therefore reduce the negative impact of delayed analysis for these tests.
- Folate results were higher when using the Barricor™ and further investigation is required to assess if the use of Barricor™ with refrigerated storage and protection from light has the potential for further improvements.
- The use of the Barricor™ tube has the potential to provide quality improvements for some primary care tests and to facilitate test consolidation.
- Cost-benefit analysis work is on-going to evaluate the efficiencies of using Barricor™ in line with reduced re-bleeding and reducing GP sample collections.

Table 1: Summary of result ranges, differences, effects of delayed separation and clinical impact of using Barricor™ over SST™ for some of the commonly requested tests from Primary Care.

<table>
<thead>
<tr>
<th>Analyte (no. of results) [units]</th>
<th>Data Range</th>
<th>Difference Range (SST – BAR)</th>
<th>Statistical Difference</th>
<th>Effects of delayed separation</th>
<th>Clinical impact of using BAR vs. SST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (n = 418) mmol/l</td>
<td>SIT: 129 - 148</td>
<td>-4 to + 5</td>
<td>Yes (p = 0.003)</td>
<td>BAR results lower</td>
<td>Minor: Slight increase in Na with delay. No significant impact.</td>
</tr>
<tr>
<td>Chloride (n = 414) mmol/l</td>
<td>SIT: 90 - 112 BAR: 92 - 113</td>
<td>-5 to + 3</td>
<td>Yes (p = 0.003)</td>
<td>BAR results higher</td>
<td>Minor: Slight fall in Cl with delay. No significant impact.</td>
</tr>
<tr>
<td>Potassium (n = 618) mmol/l</td>
<td>SIT: 3.2 - 6.1 BAR: 3.0 - 6.0</td>
<td>-0.7 to + 1.9</td>
<td>Yes (p = 0.001)</td>
<td>94 SST results (15%) N/R vs. 1 BAR (0.2%) N/R</td>
<td>Clinical improvement with BAR – potential reduction in repeat samples</td>
</tr>
<tr>
<td>Urea (n = 619) [mmol/l]</td>
<td>SIT: 1.2 - 24.7 BAR: 1.2 - 24.5</td>
<td>-0.8 to + 1.2</td>
<td>No (p = 0.54)</td>
<td>No change.</td>
<td>No significant impact.</td>
</tr>
<tr>
<td>Creatinine (n = 619) [µmol/l]</td>
<td>SIT: 21 - 356 BAR: 50 - 348</td>
<td>-14 to + 16</td>
<td>No (p = 0.70)</td>
<td>No change.</td>
<td>No significant impact.</td>
</tr>
<tr>
<td>CO2 (n = 473) [mmol/l]</td>
<td>SIT: 18 - 37 BAR: 19 - 39</td>
<td>-6 to +7</td>
<td>Yes (p = 0.001)</td>
<td>BAR results higher</td>
<td>Minor. No significant impact.</td>
</tr>
<tr>
<td>Phosphate (n = 66) [mg/dL]</td>
<td>SIT: 0.56 - 1.36 BAR: 0.57 - 1.41</td>
<td>-0.24 to + 0.08</td>
<td>No (p = 0.29)</td>
<td>4 results (6%) not reportable with SST</td>
<td>Potential reduction in repeat samples</td>
</tr>
<tr>
<td>Calcium (n = 219) [mmol/l]</td>
<td>SIT: 1.99 - 2.78 BAR: 1.9 - 2.79</td>
<td>-0.13 to + 0.25</td>
<td>Yes (p = 0.031)</td>
<td>BAR results lower</td>
<td>No change. No significant impact.</td>
</tr>
<tr>
<td>Albumin (n = 533) [g/L]</td>
<td>SIT: 17 - 55 BAR: 17 - 52</td>
<td>-3 to + 4</td>
<td>Yes (p = 0.001)</td>
<td>BAR results higher</td>
<td>No change. No significant impact.</td>
</tr>
<tr>
<td>Folate (n = 109) [µg/L]</td>
<td>SIT: 2.3 - 19.3 BAR: 3.3 - 19.8</td>
<td>-3.9 to + 1.2</td>
<td>Yes (p = 0.04)</td>
<td>BAR results higher</td>
<td>Slight fall in SST with time Possibly less patients diagnosed with folate deficiency</td>
</tr>
</tbody>
</table>

The following analytes were also investigated and no significant differences were found between results from SST and Barricor™ (number of samples and p values are shown in brackets): B12 (n = 118, p = 0.76); ALP (n = 513, p = 0.13); TBl (n = 506, p = 0.93); AST (n = 508, p = 0.72); ALT (n = 380, p = 0.29); GOT (n = 513, p = 1.0); Total cholesterol (n = 355, p = 0.48); HDL (n = 293, p = 0.7; Ti(g) (n = 305, p = 0.74); CRP (n = 218, p = 0.52); Iron (n = 133, p = 0.39); Ferritin (n = 126, p = 0.83); FT4 (n = 330, p = 0.23); TSH (n = 329, p = 0.90). PSA (n = 40, p = 0.97).

Key: SST = Vacutainer® SST™ tubes; BAR = Barricor™ tube; N/R = Not reportable

Fig. 1: Difference between Barricor & SST results (SST-Barricor) vs. centrifugation delay for potassium results

Fig. 2: Difference between Barricor & SST results (SST-Barricor) vs. centrifugation delay for chloride results

Fig. 3: Difference between Barricor & SST results (SST-Barricor) vs. centrifugation delay for folate results

Fig. 4: Difference between Barricor & SST results (SST-Barricor) vs. centrifugation delay for phosphate results