Automatic Detection of Spironolactone – Related Adverse Drug Events
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Abstract
Due to increasing reports of spironolactone associated life-threatening hyperkalemia, we implemented a rule in our automated event detection system to monitor serum potassium results in patients receiving spironolactone. In 2004, 419 (10.49\%) of 3995 admissions at 3 BJC HealthCare hospitals were identified as having hyperkalemia while on spironolactone. For a 9-month period in one facility, 33 of 52 automatically detected potential ADEs had been validated by pharmacists through manual chart review to have spironolactone as a contributing factor (PPV=63.5\%).

Introduction
The 1999 Randomized Aldactone Evaluation Study (RALES) demonstrated that spironolactone significantly improves outcomes in patients with severe heart failure. Recent research also identified an increased risk of hyperkalemia associated with spironolactone therapy, and suggested closely monitoring renal function and serum potassium to reduce the risk.\textsuperscript{1}

Previous studies showed that computerized event monitoring could detect certain types of adverse drug events (ADEs) more effectively and efficiently than manual chart review and passive reporting.\textsuperscript{2} BJC HealthCare has used an automatic event detection computer program, called EventDetector, to screen for ADEs since 2003. In this study, we implemented rules in the existing framework to identify hospitalized patients with elevated serum potassium while receiving spironolactone. Additionally, we verified the results of automatic detection against manual chart review at one hospital.

Methods
Using EventDetector, we retrospectively evaluated data from 1/1/2004 to 12/31/2004 to identify hospitalized patients who were on spironolactone therapy and had hyperkalemia (serum potassium $\geq$ 5.2 mmol/L).

In November 2004, pharmacists of Hospital B carried out a study to identify patients admitted from 1/1/2004 through 9/30/2005 with hyperkalemia attributed to spironolactone through chart review. The comparison of the findings between EventDetector and manual chart review are presented.

Results
From 1/1/2004 to 12/31/2004, 5802 spironolactone drug orders in 3995 admissions were screened in one teaching hospital (Hospital A) and two community hospitals (Hospitals B and C). Table 1 shows the results per hospital. Hyperkalemia was identified in 419 (10.49\%) patient admissions receiving spironolactone therapy. The median age of all the patients was 65 and the median daily dose was 25mg.

Table 1: Incidents found by automated screening

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Admissions on Spironolactone</th>
<th>Hyperkalemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital A</td>
<td>1897</td>
<td>207 (10.91%)</td>
</tr>
<tr>
<td>Hospital B</td>
<td>827</td>
<td>74 (8.95%)</td>
</tr>
<tr>
<td>Hospital C</td>
<td>1271</td>
<td>138 (10.86%)</td>
</tr>
<tr>
<td>Totals</td>
<td>3995</td>
<td>419 (10.49%)</td>
</tr>
</tbody>
</table>

From 1/1/2004 to 9/30/2004 at Hospital B, 52 (7.85\%) out of 662 admissions receiving spironolactone were found having hyperkalemia, of which 33 (63.5\%) had been validated through manual chart review to have spironolactone as a contributing factor. Chart review caught 5 events not in the results of automatic detection. In all 5 cases, the high potassium level was obtained after the drug order for spironolactone was closed so that they were not screened by EventDetector.

From our study, we also found voluntary reporting system is not a good tool to detect this type of ADE. Only 1 incident was reported during the study period.

Conclusions
Using an automated system to monitor the potassium level of patients receiving spironolactone is an effective and efficient way to detect potential spironolactone-related ADEs. This method may make timely intervention possible by alerting clinical staff to abnormal lab values in patients taking spironolactone.

References

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