Influence of geography on the performance of quality control testing in the Australian Government’s point of care testing in general practice trial

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Abstract

Objective: To investigate the influence of geography on quality control (QC) testing in the point of care testing (PoCT) in general practice trial.

Design and methods: Within-practice imprecision for QC testing for HbA1c, urine albumin:creatinine ratio, lipids and international normalised ratio was calculated for each geographic region.

Results: There was no significant difference between the region of testing and within-practice imprecision, except for triglyceride and HDL cholesterol.

Conclusions: PoCT was conducted to an equivalent analytical standard across geographic regions.

Keywords: Point of care testing; Geography; Quality control; Imprecision

Introduction

During 2005–2007, the Australian Government funded a trial of point of care testing (PoCT) in general practices in Australia. The clustered randomised controlled trial, the largest of its type conducted in Australia, involved 53 general practices and 4968 patients with a range of chronic conditions including diabetes, hyperlipidaemia or coagulation disorders. The trial methodology, rationale, recruitment and baseline patient characteristics have been reported elsewhere [1]. The principal aims of the trial were to determine the safety, clinical effectiveness, cost effectiveness, and satisfaction of PoCT in general practice.

The participating general practices were recruited from three different geographic regions, encompassing urban, rural and remote locations that were categorised according to the Australian Government’s Rural, Remote and Metropolitan Area (RRMA) classification system. The 17 urban practices were from the Adelaide region, the capital city of South Australia. The 16 rural practices were principally from the Bendigo region and surrounding country towns in the state of Victoria. The 20 remote practices were centred on the town of Dubbo and surrounding districts in New South Wales. Practices from each region were randomised to an intervention group that conducted PoCT for patient management (30 practices in total comprising 8 urban, 9 rural and 13 remote practices) and a control group that used their local laboratory for pathology testing (23 practices: 9 urban, 6 rural and 8 remote). A secondary research question from the trial was to determine the influence of geographic location on the capacity to conduct PoCT effectively in the general practice setting.

A quality management framework underpinned the conduct of PoCT in the intervention practices. This framework focused on training and competency assessment for device operators, internal quality control testing and external proficiency testing [2]. This paper reports on, and assesses the difference between, the imprecision obtained for quality control testing by intervention practices across the three geographic regions.

Methods

The following point of care (PoC) tests [and devices] were measured during the Trial: haemoglobin A1c (HbA1c) and
Results

The total number of QC tests performed for each PoC test was 1026 (HbA1c), 3072 (ACR), 3063 (lipids) and 553 (INR).

Table 1 summarises the median within-practice imprecision by geographic region and compares the observed performance with the analytical goals for imprecision set for this Trial.

For HbA1c, urine albumin, urine creatinine, urine ACR, total cholesterol and INR, there were no significant differences in the median imprecision between urban, rural or remote practices for all QC levels and lot numbers tested.

For triglyceride, there were no significant differences in the median imprecision between urban, rural or remote practices except for QC Level 1 lot number 5082 and QC Level 2 lot number 5230. For Level 1 lot number 5082, rural practices had a significantly lower within-practice imprecision for triglyceride compared with urban or remote practices (rural: 3.3 [2.1, 3.9], urban: 4.3 [3.5, 5.0], remote: 4.5 [3.5, 5.1]; median [25th, 75th percentiles], p = 0.03). For Level 2 lot number 5230, urban practices had significantly lower within-practice imprecision for triglyceride compared with rural or remote practices (urban: 3.7 [1.7, 5.6], rural: 5.1 [4.6, 7.4], remote: 6.1 [5.9, 8.2]; median [25th, 75th percentiles], p = 0.03). Although regional differences were observed with these two QC levels and lot numbers, it should be noted that the median within-practice imprecision across all regions remained within the desirable analytical goal of 7.5% for this analyte.

For HDL cholesterol, there were no significant differences in the median imprecision between urban, rural or remote practices except for QC Level 1 lot number 5230 where urban sites had significantly lower within-practice imprecision compared with rural or remote practices (urban: 5.1 [4.5, 8.0], rural: 6.5 [6.1, 7.9], remote: 8.8 [6.4, 10.2], p = 0.05). The median within-practice imprecision for HDL cholesterol obtained by rural and remote practices was also outside the analytical goal of 6% for this analyte.

Discussion

Intuitively the scope, application and clinical utility of PoCT would be expected to correlate with an increasing degree of remoteness. Remote health services in general have poorer access to goods and services (notably laboratory services as well as housing, education, transport), and poorer health status with higher mortality rates and a significantly higher burden of both acute and chronic disease [6,7]. However there are few

Table 1

Summary of the median within-practice imprecision by geographic region, and comparison with analytical goals for imprecision set for the trial.

| Test           | Units | Lot no. | Imprecision goal (CV%) set for trial | Median within-practice imprecision (CV%)
<table>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QC level 1 Urban</td>
</tr>
<tr>
<td>HbA1c</td>
<td>%</td>
<td>27</td>
<td>4%</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28</td>
<td>4%</td>
<td>2.6</td>
</tr>
<tr>
<td>Urine albumin</td>
<td>mg/L</td>
<td>28</td>
<td>10%</td>
<td>5.8</td>
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<tr>
<td>Urine creatinine</td>
<td>mmol/L</td>
<td>28</td>
<td>6%</td>
<td>3.3</td>
</tr>
<tr>
<td>Urine ACR</td>
<td>mg/mmol</td>
<td>28</td>
<td>12%</td>
<td>5.0</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>mmol/L</td>
<td>5082</td>
<td>5%</td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5230</td>
<td>5%</td>
<td>2.3</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>mmol/L</td>
<td>5082</td>
<td>7.5%</td>
<td>4.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5230</td>
<td>7.5%</td>
<td>3.8</td>
</tr>
<tr>
<td>HDL-C</td>
<td>mmol/L</td>
<td>5082</td>
<td>6%</td>
<td>6.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5230</td>
<td>6%</td>
<td>5.1</td>
</tr>
<tr>
<td>INR</td>
<td>nil</td>
<td>800042</td>
<td>10%*</td>
<td>7.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>800049</td>
<td>10%*</td>
<td>6.5</td>
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</tbody>
</table>

* An imprecision goal for INR was not set for this Trial, but a CV% of 10% was considered acceptable performance by the trial’s device management group.

* na = not applicable, as there was only one level of QC available from the manufacturer for INR testing.
published studies that have investigated the influence of geography on the effectiveness of PoCT [8,9]. A study of Aboriginal patients with type 2 diabetes in rural South Australia and Western Australia observed a statistically significant reduction in HbA1c after the introduction of PoCT and high levels of community acceptance of PoCT among clinical staff, device operators and patients with diabetes [8]. In a remote Victorian town of Ouyen, PoCT was introduced into the general practice setting as part of a multidisciplinary approach to improving diabetes care within the region. Long-term reductions in HbA1c and high levels of stakeholder satisfaction were similarly reported in this community [9].

In 2002, a review of the role and value of PoCT in general practice in Australia concluded that rural and remote communities could be the main beneficiaries of PoCT but that further work was required to determine its clinical and cost effectiveness [10]. This review was a major catalyst for the Australian Government to fund the PoCT in general practice trial. One objective of the trial was to assess the impact of geography on the efficacy of PoCT from multiple perspectives including analytical quality, clinical efficacy, rates of adverse events, cost, and stakeholder satisfaction. This paper focuses specifically on the influence of geographic location on analytical quality, as assessed by the results of an internal quality control program.

The results show that PoCT for quality control testing was conducted to an equivalent analytical standard by practices across geographic regions, as evidenced by the statistical observation that there was no significant difference between the region of testing and the median within-practice imprecision (using Kruskall Wallis tests). This observation was valid for all tests and QC lot numbers except triglyceride (Level 1 LN 5082 and Level 2 LN 5230) and HDL cholesterol (Level 1 LN 5230).

This is an important finding because it proves that geographic isolation does not impede the capacity of remote device operators to conduct PoCT to an analytical standard that is safe for patient care. Having stated this, it is important to acknowledge that staff turnover in remote health services is a constant problem, making health programs including PoCT services difficult to sustain [6,7]. This is particularly relevant to nursing staff, the health professionals generally responsible for performing PoCT in the general practice setting. PoCT services need to be robust in the face of such change and the capacity for a PoCT model to deliver on-going education, training and support services is critical for sustainability. The quality management framework implemented for the PoCT in general practice trial was able to achieve this.

Acknowledgments

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References