Performance of the Reflotron in Massachusetts’ Model System for Blood Cholesterol Screening Program

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Introduction

At least a dozen portable cholesterol-testing instruments have been designed for use in community and office settings. These instruments have made mass screenings for this risk factor feasible and thus are now in widespread use for this purpose.

To address questions concerning the reliability of this technology, the National Heart, Lung, and Blood Institute supported three projects entitled the Model Systems for Blood Cholesterol Screening Program (MSBCSP). A primary MSBCSP objective was to test the accuracy, precision, and durability of portable analyzers under the usual operating conditions associated with screenings. This article reports findings from Massachusetts’ MSBCSP concerning the Reflotron, the lengthiest field evaluation thus far reported.

Methods

From October 1987 to January 1989, the Massachusetts Department of Public Health conducted a blood cholesterol screening project in Chelsea, inner-city Boston, Worcester, and Lowell. The project screened 10,428 individuals in community settings using fingerstick samples analyzed by a Reflotron. Venipuncture blood samples were drawn on 972 participants for comparison.

Most screenings were conducted at work sites although other settings were also used. Two Reflotrons were transported to each site. Three levels of quality control (QC) material were analyzed at the beginning of each screening, after every 10th patient sample, and at the end. Values for QC materials were considered out of range based on Westgard’s rules. A reference laboratory at the University of Massachusetts at Lowell, which had met the Centers for Disease Control’s Lipid Standardization Program requirements, analyzed the venipuncture serum samples.

Results

For Reflotrons 1, 3, and 4, the weighted average of all values met the current precision goal set by the National Cholesterol Education Program’s Laboratory Standardization Panel (LSP) for all three QC levels, but it fell short of the 1992 LSP standards for all levels. For Reflotron 2, the weighted average of the values met the current LSP standards for all QC levels, but the 1992 standards were attained for only two levels (see Table 1).

The bias of the four instruments varied from -3.3% to +3.2%. The differences among the Reflotrons were statistically significant (ANOVA F = 25.4, P < .0001). All four analyzers met the current LSP standards; only two met the 1992 standards.

As demonstrated in Figure 1, monthly bias on the Reflotron fluctuated considerably. For example, the bias ranged from -6.0% to +2.9% on Reflotron 1. Similar variations were seen on the other Reflotrons.

Figure 2 plots the differences in individual results between the Reflotron and the reference laboratory. One Reflotron 1 reading was 80% higher than the reference laboratory value, a 2.12 mmol/L difference. At the opposite extreme, another Reflotron 1 reading was 57% lower than the reference value, a difference of -3.41 mmol/L. The other plots demonstrate similar discrepancies. Overall, more than 40% of the Reflotron values differed from the
venous values by upwards of 5%. The frequency of differences greater than 5% varied from 33% to 47% among the Reflotrons.

The Reflotrons incorrectly classified from 9.2% to 18.5% of individuals regarding their blood cholesterol category. For three Reflotrons, misclassification tended to result in false reassurance; for the other Reflotron, misclassification resulted in false warnings. The differences among the Reflotrons were statistically significant ($\chi^2 = 22.0, P < .005$). Overall, 16.3% of individuals were misclassified by the four Reflotrons.

An unanticipated finding was the malfunctioning of the analyzers. Reflotron 2 had to be returned to the manufacturer when its QC results consistently fell out of range. Subsequently, Reflotron 3 had to be returned for similar reasons. On the last two scheduled days for the project, neither Reflotron 1 nor Reflotron 4 analyzed the QC materials within acceptable ranges, resulting in cancellation of the screenings.

**Discussion**

The Reflotron has been marketed aggressively for use in community screening programs. The marketing has focused heavily on the instrument’s relatively low cost, ease of operation, and accuracy. This strategy has resulted in the widespread use of this instrument in blood cholesterol screenings.

As shown in Table 2, the Reflotron has been studied previously using various settings, sample sizes, and methodologies. When placed in the context of these other studies, our results lead to concerns about the widespread usage of the Reflotron. The first concern is that the instrument is not sufficiently precise. Although it does meet current standards, it clearly will not be able to meet the 1992 standards without substantial modifications.

Our second concern is that the Reflotron does not consistently produce accurate results. Accuracy was found to vary greatly over time, both among and within Reflotrons. Our study is the first to show that monthly bias can fluctuate from positive to negative and vice versa for the same Reflotron. This finding is important because it means one cannot simply apply a “correction” factor to screening values based on overall bias.

A disturbing finding is the large individual discrepancies and the frequency of error, which make it difficult to ascertain blood cholesterol levels correctly and to classify individuals appropriately. These inaccuracies occurred despite all four Reflotrons meeting the current LSP standards for precision and accuracy.

Based on our findings and on similar data in two other recent studies, it is likely that screening programs will misclassify many people due to the current level of inaccuracy of the Reflotron. This could result in various adverse effects. For example, those with high or borderline high blood cholesterol levels who were falsely reassured may not have the follow-up that current treatment guidelines recommend. On the other hand, those...
FIGURE 2—Percent difference between results from the four Reflotrons and reference laboratory.

TABLE 2—Previous Studies of the Reflotron

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Date</th>
<th>Sample Size (n)</th>
<th>Coefficient of Variation (%)</th>
<th>Setting</th>
<th>Correlation Coefficient (r)</th>
<th>Bias (%)</th>
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<tbody>
<tr>
<td>Koch³</td>
<td>1987</td>
<td>109</td>
<td>2.3–3.8</td>
<td>lab</td>
<td>0.95</td>
<td>“significant negative bias”</td>
</tr>
<tr>
<td>Von</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schenck⁴</td>
<td>1987</td>
<td>256</td>
<td>5.4–9.4</td>
<td>lab/M.D. office</td>
<td>0.92–0.95</td>
<td>“acceptable”</td>
</tr>
<tr>
<td>Rohac⁵</td>
<td>1987</td>
<td>98</td>
<td>2.5–2.9</td>
<td>lab</td>
<td>0.96</td>
<td>+0.5%</td>
</tr>
<tr>
<td>Sanguini⁶</td>
<td>1988</td>
<td>29</td>
<td>not reported</td>
<td>lab</td>
<td>0.98</td>
<td>“small negative proportional bias”</td>
</tr>
<tr>
<td>Sedor⁷</td>
<td>1988</td>
<td>204</td>
<td>3.4–4.0</td>
<td>lab</td>
<td>0.95</td>
<td>“usually within 5%”</td>
</tr>
<tr>
<td>James⁸</td>
<td>1988</td>
<td>30</td>
<td>not reported</td>
<td>field</td>
<td>0.92</td>
<td>–3.0</td>
</tr>
<tr>
<td>Phillips¹⁰</td>
<td>1988</td>
<td>80</td>
<td>1.1–1.8</td>
<td>lab</td>
<td>0.97</td>
<td>+4.1</td>
</tr>
<tr>
<td>Burke¹¹</td>
<td>1988</td>
<td>83</td>
<td>2.0–2.9</td>
<td>lab</td>
<td>0.97</td>
<td>+4.5</td>
</tr>
<tr>
<td>Boerman¹²</td>
<td>1988</td>
<td>86</td>
<td>1.6–3.4</td>
<td>lab</td>
<td>0.96</td>
<td>–2.2</td>
</tr>
<tr>
<td>Prior¹³</td>
<td>1988</td>
<td>98</td>
<td>1.8–4.8</td>
<td>lab</td>
<td>0.92</td>
<td>not identified</td>
</tr>
<tr>
<td>Seffel¹⁴</td>
<td>1988</td>
<td>117</td>
<td>0.7–1.0</td>
<td>lab</td>
<td>0.98</td>
<td>+6.0</td>
</tr>
<tr>
<td>Rastam¹⁵</td>
<td>1988</td>
<td>304</td>
<td>3.1–4.7</td>
<td>lab/field</td>
<td>0.92–0.93</td>
<td>+4.1 to +4.9</td>
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<tr>
<td>Pearson¹⁶</td>
<td>1988</td>
<td>345</td>
<td>9.1–9.9</td>
<td>field</td>
<td>not reported</td>
<td>–1.1</td>
</tr>
<tr>
<td>Bachorik¹⁷</td>
<td>1988</td>
<td>1288</td>
<td>2.0–4.3</td>
<td>field</td>
<td>0.92–0.96</td>
<td>–0.8 to –7.8 (pooled data for 8 Reflotrons)</td>
</tr>
<tr>
<td>Lefebvre¹⁸</td>
<td>1988</td>
<td>486</td>
<td>“within 5.0”</td>
<td>field</td>
<td>not reported</td>
<td>–1.8 to –10.5</td>
</tr>
<tr>
<td>Assmann¹⁹</td>
<td>1988</td>
<td>85</td>
<td>1.5–2.5</td>
<td>field</td>
<td>not reported</td>
<td>–0.2</td>
</tr>
<tr>
<td>Bachorick²⁰</td>
<td>1990</td>
<td>290</td>
<td>4.0–7.1</td>
<td>lab</td>
<td>0.89</td>
<td>+6.0 (pooled data for 50 Reflotrons)</td>
</tr>
<tr>
<td>Kaufman²¹</td>
<td>1990</td>
<td>96</td>
<td>13.3</td>
<td>lab</td>
<td>not reported</td>
<td>+5.2 to +6.3</td>
</tr>
</tbody>
</table>

who were falsely warned may visit their physicians unnecessarily, incurring additional tests, costs, and anxiety.

The frequent breakdown of the Reflotrons is also worrisome. For analyzers to be useful to screening programs, they must be precise, accurate, and durable. Our Reflotrons were not sufficiently durable to be considered optimal.
The public's enthusiasm for blood cholesterol screening programs is likely to continue for quite some time. Such programs have the potential to improve awareness and control rates for high blood cholesterol substantially. To provide the quality of blood cholesterol measurements that this important public health problem warrants, however, requires either improvements in the Reflotron or the use of other, more reliable analyzers.

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References