Accuracy and Precision of Cholesterol, Triglycerides and HDL-Cholesterol Methods: A Retrospective Assessment of Quality

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ABSTRACT

Introduction: Accuracy-based proficiency testing programs utilize comparable samples and reference laboratory results to assess accuracy and precision of routine clinical methods. The Institute for Quality Management in Healthcare (IQMH) provides ISO 17543-2003 accredited Proficiency Testing (PT) programs for lipids. Ten years of data was evaluated to determine average bias and imprecision, and then compared to desirable performance targets based on biological variation.

Methods: Twenty-nine surveys distributed between June 2005 and December 2014 were included. PT samples consisted of single donor sera from healthy donors with no additions. Two challenges were distributed in each survey. Participants’ results were assessed against the Centers for Disease Control and Prevention’s certified methods. Robust statistics based on ISO 17543-2003 were used to calculate peer group means and standard deviations to eliminate outliers’ effects.

Results: Cholesterol (CHOL) was assessed across all PT samples with 370 peer groups; average method bias: −0.22% (range: 10.4%–6.5%); average CV: 1.6% (range: 0.4%–11.3%). For triglycerides (TRIG), 302 peer groups; average method bias: −3.25% (range: −23.8%–12.2%); CV: 2.8% (range: 0.4%–14.8%). HDL-Cholesterol (HDL-C) 372 peer groups, average method bias: 0.7% (range: −4.6%–10.4%); CV: 4.0% (range: 0.7%–40.2%).

Nearly five per cent of method bias estimates were within the desirable limits for CHOL, 95% for TRIG and 68% for HDL-C. Nearly five per cent of the peer group CVs were within the desirable CV limits for CHOL, 95% for TRIG and 68% for HDL-C. All-methods’ means (AMMs) correlated very well with reference laboratory results and differences between AMMs and reference results varied between −48 to 80 mg/dl.

Group CVs were within the desirable limits of 9.6% and 10%, respectively. At the low triglycerides concentrations peer group CVs tended to be higher while peer group biases tended to be lower than at the high triglycerides concentrations.

Triglycerides were assessed in 362 peer groups; average method bias: −3.26% (range: −23.8%–12.2%); CV: 2.8% (range: 0.4%–14.8%). Ninety-five per cent of the peer group biases and 99% of peer group CVs were within the desirable limits of ±10%.

Conclusions: Overall biases and CV for CHOL, TRIG were within the desirable limits based on biological variation. However peer group biases and CV values exceeding these limits were noted for some reference laboratory results. All-methods’ means (AMMs) correlated very well with reference results and differences between AMMs and reference results varied between −48 to 80 mg/dl.

INTRODUCTION

Proficiency testing (PT) is also known as external quality assessment, can be defined as the evaluation of the analytical performance of the laboratory tests in terms of interlaboratory comparisons. Generally, a proficiency testing survey consists of sending a set of simulated clinical samples from a PT provider to the participating laboratories for testing. Proficiency testing provides feedback to the laboratories on their performance.

The Institute for Quality Management in Healthcare (IQMH) conducts accuracy based PT Programs for lipids. In this study, we retrospectively reviewed the results of this PT program to compare analytical performance of the state of the art of routine clinical laboratory methods with the optimum and desirable target method performance goals based on biological variation.

MATERIALS AND METHODS

Twenty-nine PT surveys distributed between June 2005 and December 2014 were included. PT samples consisted of single donor sera from healthy donors with no additions from Intermountain Blood Bank (Memphis, Tennessee). Each unit of blood is collected into sterile plastic bags. After collection, red cells are separated and removed then the plasma is held at room temperature for a minimum of 48 hours to allow coagulation. Serum is re-centrifuged to remove any residual visible material and stored and shipped at −15°C to −20°C to Dynacare Laboratories (Brampton, ON) where serum is assayed and shipped to participants. Homogeneity and stability testing performed using the algorithm recommended in ISO 17543-2003.

Each blood donation is tested and flagged negative for HIV, Hepatitis B and C. Two challenges were distributed in each survey. Participants’ results were assessed against the Centers for Disease Control and Prevention’s certified methods at Northwest Lipid Metabolism and Diabetes Research Laboratories (Seattle, WA). Robust statistics based on ISO 17543-2003 were used to calculate peer group means and standard deviations to eliminate the effects of outliers. Desirable and optimal and performance specifications based on biological variation for bias and imprecision were obtained.1

RESULTS

Cholesterol (CHOL) was assessed across all PT samples with 370 peer groups; average method bias: −0.22% (range: 10.4%–6.5%); average CV: 1.6% (range: 0.4%–11.3%). Cholesterol concentration of the survey materials ranged between 175–365 mg/dl (3.0–6.4 mmol/L). 95% of the peer group biases and 95% of the peer group CVs were within the desirable performance targets of 4.1% and 3.0%, respectively (Figure 1). All methods showed a very good correlation with reference results (Figure 2).

Triglycerides were assessed in 372 peer groups; average method bias: −3.25% (range: −23.8%–12.2%); CV: 2.8% (range: 0.4%–14.8%). Nearly five per cent of the peer group biases and 99% of peer group CVs were within the desirable limits of ±10% and ±15%, respectively. At the low triglycerides concentrations peer group CVs tended to be higher while peer group biases tended to be lower than at the high triglycerides concentrations.

Overall biases and CV for CHOL, TRIG were within the desirable limits based on biological variation. However peer group biases and CV values exceeding these limits were noted for some reference laboratory results.

CONCLUSION

Overall biases and CV for CHOL, TRIG were within the desirable limits based on biological variation. However peer group biases and CV values exceeding these limits were noted for some reference laboratory results.

References

1 ISO/IEC 17043:2003 Conformity assessment—General requirements for proficiency testing.

Figure 1. Peer group CV and bias for cholesterol. Triglycerides and HDL-Cholesterol (red line) represent the desirable performance limits for CV and bias based on biological variation.

Figure 2. Relationship between all-methods’ mean and reference results.