Quality of plasma cholesterol measurements in primary care

Peter M G Broughton, David G Bullock, Robert Cramb

Abstract

Three surveys were made of the quality of plasma cholesterol measurements performed with a commercial desktop analyser (BCL Reflotron) in primary care. Each survey included three specimens, and results were received from 37, 61, and 69 participants. Although many participants obtained satisfactory results, 8.6% of the results differed by 1.0 mmol/l or more from the target values, and the overall between instrument dispersion of results was 1.3 times that between hospital laboratories. It was found that common sources of error were poor technique and the use of outdated reagent strips. Users of such instruments outside the laboratory need help and advice with training, and guidelines for this are provided. The main recommendations are that users should establish contact with a local clinical chemistry laboratory for training and support and should participate in external quality assessment schemes.

Introduction

The association between increased plasma cholesterol concentration and the risk of coronary heart disease is now well recognised, and guidelines for the management of patients have been published.^{1,2} At the same time measurement of plasma cholesterol concentrations by a doctor, nurse, or other non-technical personnel has become easier with the introduction of at least five desktop instruments that can provide a result on a capillary blood specimen within a few minutes.³ Such instruments are being used increasingly in community health programmes for preventing coronary heart disease and for opportunistic screening in primary care.^{4,5} The drama of seeing the test performed and being given a rapid result seems to have a powerful effect in motivating the patient to comply with dietary or other advice which can be given during the same visit.

Though several recent reports indicate that most of these instruments are satisfactory when used by trained laboratory staff, it should not be assumed that they are equally reliable when used by non-technical personnel. Indeed, there is evidence that the quality of measurements made in primary care is often inferior to that obtained by laboratories.^{6,7} We therefore decided to survey the present state of the art for cholesterol measurements that are made outside the laboratory.

Method and results

Three surveys were made of cholesterol assays performed with the Boehringer Reflotron (BCL Ltd, Lewes, Sussex) outside laboratories in the United Kingdom, mostly in general practice and occupational health departments. Participants were recruited with the help of the manufacturers or by personal contact.

In each survey participants received three specimens of liquid serum for analysis of cholesterol and were asked to return the results to us, with the lot number of the reagent strips used, within two weeks. Participants were then sent a report with a histogram (figure) and the mean, coefficient of variation, and range of results obtained on each specimen. In addition, the three

Part of report returned to participants, showing frequency distribution of serum cholesterol results for specimen 3A/3C

results obtained by each participant were displayed on a graph against the mean values from all participants (which were taken as the target values; table). When results were clearly discrepant a comment was added advising the participant to contact the manufacturers for help.

The table gives a summary of the results. On average half of the participants' results were within 0.3 mmol/l of the mean, but 8.6% differed by 1.0 mmol/l or more. The overall dispersion of results in these surveys—that is, the average difference from the mean—was 1.3

Mean, coefficient of variation, and range of serum cholesterol results obtained by participants in three surveys

	Mean (mmol/l)	Coefficient of variation (%)	Range (mmol/l)
Survey 1 (37 returns):			
A	7.73	3.94	6.94-10.9
B	4.15	11.98	2.72- 4.97
C	7.41	5.48	6.29-11.00
Survey 2 (61 returns):			
A	8.25	5.56	6.66-11.4
B	8.77	9.24	7.41-12.9
C	6.99	5.06	5.73- 8.77
Survey 3 (69 returns):			
A/C	6.91	4.24	4.78- 8.70
B	9.14	6.40	7.41-11.60
Average	7.76	5.52	4.25

Note: Mean and coefficient of variation after exclusion of results more than 2 standard deviations from initial mean; specimen 1B excluded from averages. Specimens 3A and 3C were duplicates and their results are combined.

Wolfson Research
Laboratories,
Department of Clinical
Chemistry, Queen
Elizabeth Medical Centre,
Birmingham B15 2TH
Peter M G Broughton,
FRCPATH, deputy director
David G Bullock, PHD,
principal biochemist
Robert Cramb, MRCPATH,
consultant chemical
pathologist

Correspondence to: Dr
Bullock.

Br Med J 1989;298:297-8

times that of cholesterol assays made in UK laboratories, as determined in the UK External Quality Assessment Scheme for General Clinical Chemistry.⁸

All specimens used were reconstituted lyophilised serum except specimen 3A/3C (see table), which was a serum specimen (negative for hepatitis B surface antigen and for antibodies to human immunodeficiency virus) obtained with the approval of the ethical committee from a patient with hyperlipidaemia. For this specimen the mean result obtained by participants (6.91 mmol/l) agreed closely with that obtained by four reference laboratories (6.94 mmol/l).

Discussion

In each survey a few participants consistently failed to obtain results which agreed with the majority of the results. The commonest causes of error appeared to be poor technique and the use of reagent strips that had passed their expiry date.

Most of those who performed the test were nurses with little or no laboratory experience or awareness of the need for quality assurance, and few seemed to have any contact with a recognised laboratory. Based on this experience we prepared guidelines (see appendix) to help inexperienced users. Our main recommendations are that users should (a) establish contact with a local clinical chemistry laboratory for help in training, quality control, etc, and for advice in following up patients who have had a lipid disorder; (b) join an external quality assessment scheme; and (c) contact the manufacturers if results are unsatisfactory.

Most specimens used in these three surveys were reconstituted lyophilised serum, which can show matrix effects with the reagent strips used with this instrument.⁹ Thus these must not be used for comparisons of accuracy with that of conventional laboratory methods: fresh human serum must be used for this. The Reflotron results for the fresh serum specimen agreed closely with those obtained by the reference laboratories which, with other published evidence,⁹⁻¹¹ suggest that the instrument is accurate when used with patients' specimens but inaccuracies have arisen with

some batches of reagent strips and from poor operator technique.

External quality assessment of tests done in primary care presents several technical and organisational difficulties but is especially valuable to users who may be unaware of the need for quality assurance or of the techniques used for this. This is likely to become more important as cholesterol and other measurements become more widespread and other instruments come into general use.

We are now making regular two monthly external quality assessment surveys for cholesterol, using mainly fresh human sera. Any non-laboratory user in the UK wishing to join the scheme is invited to contact us; there is no charge for participation.

PMGB and DGB acknowledge financial support from the Department of Health.

- 1 Shepherd J, Betteridge DJ, Durrington P, *et al*. Strategies for reducing coronary heart disease and desirable limits for blood lipid concentrations: guidelines of the British Hyperlipidaemia Association. *Br Med J* 1987;295:1245-6.
- 2 European Atherosclerosis Society. The recognition and management of hyperlipidaemia in adults: a policy statement of the European Atherosclerosis Society. *Eur Heart J* 1988;9:571-600.
- 3 Koch TR, Mehta U, Lee H, *et al*. Bias and precision of cholesterol analysis by physician's office analyzers. *Clin Chem* 1987;33:2262-7.
- 4 Anggard EA, Land JM, Lenihan CJ, *et al*. Prevention of cardiovascular disease in general practice: a proposed model. *Br Med J* 1986;293:177-80.
- 5 Jones A, Davies DH, Dove JR, Collinson MA, Brown PMR. Identification and treatment of risk factors for coronary heart disease in general practice: a possible screening model. *Br Med J* 1988;296:1711-4.
- 6 Drucker RF, Williams DRR, Price CP. Quality assessment of blood glucose monitors in use outside the hospital laboratory. *J Clin Pathol* 1983;36:948-53.
- 7 Bloch MJ, Cembrowski GS, Lembesis GJ. Longitudinal study of error prevalence in Pennsylvania physicians' office laboratories. *JAMA* 1988;260:230-5.
- 8 Lewis SM, Jennings RD, eds. *United Kingdom external quality assessment schemes. Annual report 1987*. London: Department of Health and Social Security, 1988.
- 9 Boerma GJM, van Gorp I, Liem TL, Leijnse B, Bellm J, Carstensen CA. Revised calibration of the Reflotron cholesterol assay evaluated. *Clin Chem* 1988;34:1124-7.
- 10 Price CP, Koller PU. A multicentre study of the new Reflotron system for the measurement of urea, glucose, triacylglycerols, cholesterol, γ -glutamyl-transferase and haemoglobin. *J Clin Chem Clin Biochem* 1988;26:233-50.
- 11 Phillips S, Wyndham L, Shaw J, Walker SF. How accurately does the Reflotron dry-chemistry system measure plasma total cholesterol levels when used as a community-screening device? *Med J Aust* 1988;149:122-5.

(Accepted 9 January 1989)

Appendix

Guidelines for measuring cholesterol outside the laboratory

(1) Before starting any cholesterol measurements contact the head of the clinical chemistry department in your local district general hospital who may be able to advise on selection of equipment and help with training of staff and regular quality control. Ask whether he or she can provide a backup service for dealing with patients found to have raised cholesterol concentrations.

If you expect to do fewer than half a dozen cholesterol assays a week it is unlikely that your results will be consistently reliable or the effort worth while. It might be better to send the specimens to a recognised laboratory.

(2) Make sure that the instrument is installed according to the manufacturer's instructions on a stable flat surface with an adjacent power point. Check on all safety aspects. If the instruction manual has been lost or mislaid request another from the manufacturer.

(3) No one should use the instrument unless they have been properly trained, preferably by the manufacturer's representative or staff of the local clinical chemistry department; maintain a list of authorised users. Special quality control specimens (obtainable from the manufacturer) should be analysed repeatedly until everyone is

satisfied that the instrument is performing satisfactorily and that the operator is using it correctly. Repeat these tests at regular intervals.

(4) All results should be recorded in a notebook or file kept with the instrument. Record the date, patient's name, age and sex, the result, the batch number of reagents or strips used, and the operator's name. Quality control results should be noted here, together with the results of any confirmatory cholesterol assays made on that patient. These records will not only increase the operator's confidence in the results but may be essential evidence if a patient's result is later queried or challenged.

(5) Capillary blood specimens should be collected with proper hygienic technique into heparinised tubes. All contaminated waste material must be disposed of safely. After cleaning the patient's finger with a swab it is essential that any alcohol on the skin is allowed to dry before puncturing the skin and collecting the specimen. Contamination of the specimen can cause incorrect and misleading results.

(6) Check that reagents or strips have not passed their expiry date, and discard any that have. Reagents or strips from different batches should not be mixed.

(7) The instrument should be cleaned after use and any blood spillages cleaned using a suitable disinfectant, such as 70% isopropanol. Keep the instrument covered when not in use, and maintain it according to the manufacturer's instructions.

(8) Join an external quality assessment scheme. This is particularly useful in providing an independent check on the performance of your instrument and operator and in showing how this compares with other users.

(9) The general practitioner or doctor concerned should arrange for all plasma cholesterol results above 6.5 mmol/l to be confirmed by a recognised laboratory before treatment is started. Similarly, the effect of treatment should be monitored by regular cholesterol assays made by the same hospital laboratory.

(10) The European Atherosclerosis Society recommends that patients with confirmed cholesterol concentrations of over 7.8 mmol/l should be considered for referral by their doctor to a hospital lipid clinic for specialist advice.

(11) Finally, remember that you are responsible for the cholesterol assays you do or supervise: you may be held accountable for any incorrect results.