Upsala J Med Sci 91: 201–204, 1986

Analytical Quality

Bo Sörbo

Department of Clinical Chemistry, Linköping University, Linköping, Sweden

We are all aware that the concept of analytical quality implies that laboratory results are reliable, i.e. are precise and accurate. We thus try to maintain a high standard in these respects with internal and external quality control and put a lot of effort and money in these activities. However, we often neglect another aspect of analytical quality, and that is the factor of time. Although, we ought to control the turn-around-time of our tests, how often is that done? We must realize that an unacceptable delay in the delivery of our excellent analytical results to the clinical ward will result in bedside clinical chemistry taking over even if not being precise and accurate.

However, returning back to precision and accuracy raises the question: What can we demand of bedside clinical chemistry in these respects? There are optimists who claim that it is desirable and possible to perform bedside clinical chemistry with the same precision and accuracy as conventional clinical chemistry in the laboratory but this is not a realistic attitude. On the other hand, our clinical collegues sometimes claim that the high precision obtained in the laboratory with conventional wet-chemical methods is not required in clinical practice, especially if the results are used for monitoring therapy and not for diagnostic purposes. This is probably true to some extent, but how imprecise may results from bedside clinical chemistry be? The determination of blood glucose is probably the method which has received most attention in this respect. It has thus been proposed (5) that a blood glucose value deviating less than 20% from the true values is acceptable from a clinical point of view, but no real arguments for this proposal were presented. If we use Tonk's criteria (9) for blood glucose a CV (coefficient of variation) of $\pm$ 13% would be permissible.

As a working hypothesis I considered the possibility that a result for blood glucose obtained under bedside conditions should be permitted to be within $\pm$ 4 CV from the true mean. Looking at the reports from our external quality control during the last 6 months I found that the CV for normo- and hyperglycemic

values was about 5%, giving a permissible range of ± 20% as suggested by other authors. However, for hypoglycemic values the CV was about 10% and a range of ± 40% is certainly not acceptable even for bedside clinical chemistry.

Nevertheless, what is the "state of the art" with respect to analytical quality of bedside clinical chemistry? The results of interest here are not those obtained by well-trained laboratory technicians when they evaluate the methods in the laboratory but those obtained by nurses and doctors in the clinical wards. Gibb et al (6) thus reported that determinations of serum creatine kinase with a seralyzer in a coronary case unit by the medical staff were of the same quality as those obtained in the central laboratory i.e. the CV was 5-9%. On the other hand Clark & Broughton (3) found that determinations of serum urea with a Seralyzer had a CV of ± 4% if performed by trained laboratory technicians, whereas the results obtained by non-laboratory personnel were much more imprecise with a CV of ± 16%. The latter results are probably unacceptable from a clinical point of view. Furthermore, it was found in a recent study from Upsala (2) that laboratory technicians working in primary care units obtained results for blood hemoglobin of satisfactory precision, whereas non-laboratory personnel produced much inferior results, especially if no external quality control was available. Other reports at this meeting provide further evidence for bedside clinical chemistry being of a higher quality if performed by laboratory technicians and I shall not expand further on this subject.

What should then be done in order to improve the quality of bedside clinical chemistry as performed by non-laboratory personnel? Firstly, it should be stressed that bedside clinical chemistry should be directed and supervised by a clinical chemistry laboratory. The laboratory should thus in advance evaluate both the methods and the instruments desired by the wards or primary care units. Otherwise, the latter may experience unpleasant surprises as illustrated in a recent report (8). A special care baby unit intended to determine serum bilirubin in a bedside manner and purchased a bilirubinometer for this purpose. Comparison of the results obtained with this instrument with those obtained in the main laboratory of the hospital revealed, however, that the bilirubinometer gave too low results on highly icteric sera. This was due to an inherent non-linearity of the instrument, which had totally escaped the attention of the ward personnel responsible for the purchase of the instrument. Furthermore, the central laboratory should provide preventive maintenance of the instruments used for bedside clinical chemistry, even if most of the errors are not caused by the instruments but by the operators of the latter.

Another important responsability of the central laboratory is to provide

written instructions for performing bedside analytical methods which may be understood by non-laboratory personnel. The written material provided by suppliers of instruments, kits and test strips often leaves much to be desired in this respect. The central laboratory should also be responsible for the training of non-laboratory personnel and furthermore evaluate their ability to perform even simple bedside tests. An ambitious training program for blood glucose determinations with a visually read test strip was recently described (10). Unfortunately I think that this elaborate training program is too complicated for most of our laboratories. But another simple measure, which should not be neglected, is to examine the color vision of those who intend to perform test strip analysis by visual reading, as otherwise large errors may result. This applies especially to diabetics who use test strips for self-control (7). The necessity of training all personnel performing bedside clinical chemistry has been stressed in the "Guide-lines" adopted by the English clinical chemists (1). Furthermore, they stress the importance of retraining the personnel involved. Unfortunately, I think it is fair to say that this aspect has not yet received the attention it should in Scandinavia.

Last, but not least comes quality control. The central laboratory should insist on supervising the internal quality control of bedside analytical methods but should also be responsible for an external quality control system. Technical problems have earlier prevented external quality control of blood glucose determinations by test strips, but satisfactory control methods are now available. Unfortunately, the quality control of the methods used by patients for self-control has often been neglected. I feel often uncomfortable about the unduly enthusiasm showed by clinical collegues, who put reflectometers and test strips in the hands of their patients with very little instructions and no quality control at all. The clinical chemists must thus engage themselves much more in these matters than they have done up to now.

What has been said in the foregoing may give the impression that I have a negative attitude to bedside clinical chemistry. However, I whole-heartedly share the opinions so ably expressed by two British collegues (4): "Clinical biochemistry now has the potential to move nearer the patient. Whether clinical biochemists accompany it is largely a matter for themselves. There will be those who make things happen, those who watch things happen, and those who wonder what has happened." Let us not wonder what has happened to the quality of bedside clinical chemistry!

REFERENCES

1. Andersson, J.R., Linsell, W.D. & Mitchell, F.M.: Guidelines on the performance of chemical pathology assays outside the laboratory. Br. Med. J. 282:743, 1981.

2. Bengtsson, P.G., Ronquist, G. & Holmgren, C.: Nytt analyssystem för hemoglobinbestämning på olika vårdnivåer i ett primärvårdsområde. Läkartidningen 81:642-644, 1984.

3. Clark, P.M.S. & Broughton, P.M.: Potential applications and pitfalls of dry reagent tests. Ann. Clin. Biochem. 20:208-212, 1983.

4. Evans, S.E. & Buckley, B.M.: Biochemists nearer the patient? Br. Med. J. 287:1399-1400, 1983.

5. Fairclough, P.M., Clements, R.S., Filer, D.V. & Bell, D.S.H.: An evaluation of patient performance and their satisfaction with various rapid blood glucose measurement systems. Diabetes Care 6:45-49, 1983.

6. Gibb, I., Barton, J.R., Adams, P.C., Pratt, D., Dean, C.R. & Tarbit, I.F.: Rapid measurement of creatine kinase activity in a coronary care unit using a portable benchtop reflectance photometer. Br. Med. J. 290:1381-1383, 1985.

7. Lombrail, P., Cathelineau, G., Gervais, P. & Thibault, N.: Abnormal color vision and reliable self-monitoring of blood glucose. Diabetes Care 7:318-321, 1984.

8. Mount, J.N. & Slavin, B.: Bedside biochemistry. J. Clin. Pathol. 37:715-716, 1984.

9. Tonks, D.B.: A study of the accuracy and precision of clinical chemistry determinations in 170 Canadian laboratories. Clin. Chem. 9:217-233, 1963.

10. Williams, J. & Freedman, Z.: Evaluation of hospital staff nurse performance of Chemostrip bG testing. Diabetes Care 7:398-399, 1984.