

Impact of New Technology in Clinical Chemistry

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Recently a British colleague stated that "clinical chemistry is now under attack". New techniques allow in principle every doctor or even every patient to perform advanced clinical chemistry analyses outside professional laboratories.

Some years ago we were enthusiastic for the big automated instruments. They made it possible to get 20 or even more results simultaneously from a small serum sample. However, many "abnormal" results gave costly follow-up studies without much benefit for the physician or the patient. Today clinicians prefer selective laboratory results depending upon the clinical need for information. Clinical chemistry is often of great value as a diagnostic aid and even more in the follow-up of disease. However, we must be aware of the fact that laboratory investigations only rarely are of value in screening procedures because of the low prevalence of disease. There are at least 32 reasons for ordering tests (1). The clinical demand for laboratory investigations, not the new technology, must be the main reason for the ordering of tests.

Clinical chemists must take an active part in the evaluation of the new techniques. Modern laboratories perform well-documented, analytical work with computer-controlled techniques. However, this is not the only need for clinical chemistry (Table I).

Table I Needs for clinical chemistry

- 1 Test selection and strategy
- 2 Patient instructions
- 3 Specimen collection
- 4 Specimen handling
- 5 Choosing the best method and instrument
- 6 Analysis
- 7 Guarantee of quality
- 8 Evaluation of results
- 9 Science, teaching
- 10 Economy

Our speciality must initiate discussions concerning which tests that are best suited in different clinical situations. Test strategy is depending upon the prevalence of disease, the specificity and sensitivity of the tests and the precision of the method used. Clinical chemists must give advice regarding test selection and not just perform tests without sound reasons.

Often the production of a laboratory is expressed only as the number of tests performed. This is a very unsatisfactory way of presentation. It should be substituted by evaluation of the effects of laboratory tests in diagnostics and follow-up of diseases.

The patient should be informed before laboratory testing as this sometimes is necessary in order to get the correct result. Detailed information must be given for example to persons before a glucose tolerance test. When performing serum triglyceride determinations fasting and alcohol abstinence for 12 hours is necessary etc.

All personnel involved in blood sampling must be aware of the necessity to use the correct technique. Thus, muscle contractions in the arm during blood collection can falsely elevate the serum potassium values up to 80 %. Furthermore, the correct handling of specimens is important, e.g. the separation of serum within two hours for potassium determination.

Choosing the best analytical technique as well as documentation and guarantee of quality are professional duties for clinical chemists. Quality assessment is a must. It includes continuous internal quality control as well as regular external quality registration. The term external quality control should be avoided for psychological reasons. Great progress has been obtained by modern technology with increased analytical specificity and well-controlled quality.

Clinical chemists are also responsible for a correct presentation and evaluation of the results. The need for scientific research, evaluation and education is obvious.

Economy is an important factor with great impact on our work. Taxes for refund that are given from insurance companies to hospitals or between laboratories and wards can be very important. Refund systems may result in great commercial success for the new techniques nearer the patient e.g. in USA and Germany. However, in Belgium, where no refund is given, no single machine has been sold. In Sweden it seems improbable that amateurs will use the new instruments uncritically just as an aid to earn money. However, if the new techniques are easily available there is a risk of overconsumption and misuse of analyses.

There are special problems with the usage of new instruments by untrained people. Even if an instrument is robust and well functioning when used by

trained laboratory personnel under optimal conditions, the performance can be very unsatisfactory when used by the untrained staff (2). In primary health care there is a risk that many different, more or less untrained persons will be involved. It may be necessary to issue some type of driver's licence to achieve maximum security. Even after training some persons may not be well suited to drive cars or new instruments.

Of course, the manufacturers are responsible for the homogeneity and stability of the reagents. The laboratory results obtained by the new techniques must be compared with the standard routine analytical performance at the responsible hospital laboratory. If the same analyte concentration gives different results with different instruments there will be a risk for mistakes. This risk is obvious if the reference intervals for the same analyte differ between primary care using their special instrument and in the central hospital with another instrument. Clinical chemical expertise is thus needed for harmonisation and continuous control of the analytical performance in primary health care as well as in hospitals. This also means that we are responsible for regular information and education. In regular conferences with those clinical doctors who order the tests we discuss which analysis can be recommended in different clinical situations. We also give courses to the staff performing the routine laboratory work in primary health care. In our experience this type of education is extremely important. Even in simple laboratory routine work the personnel involved needs regular information in order to produce acceptable results with documented quality. The ideal situation seems to be that well-educated specialists in clinical chemistry are given the responsibility for education and quality assessment in a regional area.

Before we decide on introducing the new instruments we must know if there is a clinical need for them (3). The performance and long term quality must be known as well as the economy of the new techniques. The Swedish Society for Clinical Chemistry is pleased to have this opportunity to discuss the new situation with our clinical colleagues from primary health care, representatives from the authorities and manufacturers of reagents and instruments.

References

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