Proposed international concept for instrument testing

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The current world-wide economic recession has meant that the decision-making process for purchasing new instrumentation has gained more importance and priority for laboratory managers.

The process requires careful consideration of cost and, even more important, comparable data on the reliability and dependability of a particular instrument. At the present time it is often very difficult to obtain objective, comparable data. When a new item of equipment comes on the market a prospective purchaser often has little information about its performance, other than that from the manufacturer, or perhaps a colleague who might have done a trial for the manufacturer. Neither of these sources could be considered independent and it is unlikely that any testing will have followed a carefully designed and internationally accepted protocol. Therefore, many laboratories perform extensive evaluation studies before a purchase decision is made.

Standardization of evaluation studies would improve the comparability of the results reported. Several national and international organizations are involved in standardizing the procedure for instrument testing, especially for evaluations of analytical analysers. Some examples are listed in table 1. These protocols are all similar; therefore, they should be combined into one internationally acceptable recommendation. However, it appears that it is difficult to produce a single document to serve everyone’s purposes. At least three evaluation stages have been identified for an instrument new to the market. Each stage has its own purpose, so a different protocol for each is required (these are presently elaborated by various organizations).

The first stage (see table 2) is completely in the responsibility of the manufacturer. The experiments can either be performed in the factory or in external users’ laboratories. It is common for manufacturers to ask one or several routine laboratories for an evaluation with various goals:

1. To detect weak points, since routine conditions are hard to simulate in a company’s laboratory.
2. To solve possible problems in sample- and data-handling.
3. To obtain an external publication which is considered a useful advertisement.
4. To establish performance criteria.

The American National Committee for Clinical Laboratory Standards (NCCLS) has published several documents for this purpose.

Evaluations organized by a manufacturer are usually regarded as an essential part of a responsible quality-control programme for the production process. External evaluations are presumably less cost-effective than internal studies with comparable expenditure. No time scale can be suggested for stage 1 because modifications of the instrument are often required.

Lists of specifications, which should be provided by the manufacturer, have been worked out and published by the International Federation of Clinical Chemistry’s (IFCC) Expert Panel on Instrumentation (EPI) for analysers and several other types of instrumentation (table 3). It is to be hoped that these guidelines will soon be adopted by manufacturers and customers.

Table 1. Evaluation protocols proposed by various organizations.

<table>
<thead>
<tr>
<th>Proposed evaluation standards</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended scheme for the evaluation of instruments for automatic analysis in the clinical biochemistry laboratory</td>
<td>British Society for Clinical Chemistry [1]</td>
</tr>
<tr>
<td>Protocol for establishing performance claims for clinical chemical methods evaluations of analytical instruments</td>
<td>NCCLS [2]</td>
</tr>
<tr>
<td>Protocol for the evaluation of analytical instruments</td>
<td>German Society for Clinical Chemistry [3]</td>
</tr>
<tr>
<td>Protocol for the evaluation of automatic blood-cell counters</td>
<td>ECCLS [4]</td>
</tr>
<tr>
<td>Provisional guidelines for a short-term assessment for inter-laboratory acceptance of clinical laboratory instrumentation</td>
<td>ICSH (not yet published)</td>
</tr>
<tr>
<td></td>
<td>IFCC (not yet published)</td>
</tr>
</tbody>
</table>

Table 2. Stage 1 evaluation.

<table>
<thead>
<tr>
<th>Primary goal</th>
<th>Establishment of performance criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsibility</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>Production line</td>
<td>Prototype(s) of instruments for the zero/first production line</td>
</tr>
<tr>
<td>Location</td>
<td>No recommendation</td>
</tr>
<tr>
<td>Time required</td>
<td>No recommendation</td>
</tr>
<tr>
<td>Document prepared by</td>
<td>NCCLS</td>
</tr>
</tbody>
</table>

Table 3. Recommendations by the IFCC’s Expert Panel on Instrumentation for listing specifications by the manufacturer.


The principal goal of stage 2 is to verify the specifications which have been set up during stage 1 (table 4). During a 1978 workshop conference organized by the Commission of the European Communities under the title ‘A plan for the use of national resources for evaluating instruments employed in clinical laboratory sciences’, the idea of a co-ordinated multi-centre evaluation trial was proposed as a way of achieving comparability between the results from different laboratories. Such multi-centre evaluations should last for no more than three to six months.
This concept has been adopted by a working group of the German Society for Clinical Chemistry. The document published by this group has been revised by the ad hoc Committee for Instrument Testing [4] of the European Committee for Clinical Laboratory Standards (ECCLS); the concept is summarized in figure 1. Some specifications (safety and technical specifications for example) are verified simply by an auditing of the manufacturer, others by performing experiments in clinical laboratories.

Although special attention was paid to the statistical part of the document, several comments received show that it is difficult to find a proposal which suits all possible users. There seems to be general agreement that classical regression analysis should be abandoned in favour of either standardized principal component analysis [5] or another non-parametric procedure [6]. Further attention has been paid to the presentation and reduction of the numerous data obtained during a multi-centre evaluation.

The concept of three stages more or less reflects the present situation have shown that single-centre evaluations are not always accepted, especially outside the country in which they were performed; and that instrument companies seldom use only one laboratory for their evaluation studies. This situation can be called ‘multiple one-centre evaluations’. The disadvantages are that the time involved before reports from several sites are published is considered to be over long; the data produced on the various laboratories are often not comparable because differences exist in experimental design; the number of evaluations required by European users is usually considered to be too high by the manufacturers; and there is much wastage of personnel and scientific resources.

Therefore, the next step would be to co-ordinate several trials in one multi-centre evaluation. Major advantages of this concept are:

(1) Comparable data on the reliability of new instruments from several laboratories would be produced.
(2) Information about new instruments would be more easily accessible.
(3) The data would be more objective because the results would be more independent of the manufacturer. The degree of objectivity obtained by a multi-centre study cannot be reached by single laboratories.
(4) Unnecessary replication of numerous evaluations would be avoided.
(5) Expert and financial resources would be used optimally.
(6) Instrument improvement would be stimulated.

Advantages (1), (2) and (3) improve the basis for decision-making on purchases; (4) and (5) mean that less manpower and cost would be required from the manufacturer. Advantage (6) creates improved feedback of laboratory experience to the manufacturer. The data are much more meaningful if they are obtained in several laboratories under comparable conditions.

Assuming that the three-stage concept is accepted, the next step should be harmonization of the various protocols already elaborated concerning terminology and basic features to be tested.

This harmonization has already been achieved between the present version of the stage 2 document published by ECCLS and the stage 3 document elaborated by the IFCC's EPI. No attempts have been made to harmonize these documents with the stage 1 documents worked out by NCCLS. This has led to some misunderstandings. The NCCLS documents have been used for stage 2 purposes; similarly, the ECCLS stage 2 protocol could be used as a guideline for stage 1.

Experiences with the present ECCLS protocol have shown that several specific documents are required for each class of instrument, for instance for spectrometers, chemical analysers, blood-gas analysers and so on.

In conclusion, the three-stage concept for testing new instrumentation should generally be accepted and the performance of multi-centre evaluations should be endorsed on a voluntary basis.

References

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