Diagnostic equipment outside the laboratory

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SUMMARY A questionnaire was circulated to clinical biochemistry laboratories in the North West Thames region of the United Kingdom requesting information on extralaboratory equipment. Data on the types and numbers of instruments in use, their relationship with the laboratory, and quality assurance procedures were obtained. Laboratories were prepared to maintain equipment over which they had no responsibility for purchase, training of users, or use. The quality assurance of these instruments gave even greater cause for concern. Although internal quality control procedures were performed on many of the instruments, laboratories were involved in only a minority of these procedures. Quality control procedures and training of users were undertaken on site in less than 50% of blood gas analysers and bilirubin meters and in less than 25% of glucose meters. External quality assessment procedures were non-existent for all of the instruments in use with the exception of glucose stick meters in two laboratories.

There has been widespread concern expressed both by individuals and professional bodies regarding the analytical quality of results obtained from instruments used outside clinical biochemistry laboratories by non-laboratory staff. Several publications have documented their poor performance and the inferior quality of results obtained using these techniques.1-4 Much effort has been invested by members of the profession, both in the United Kingdom and abroad, in establishing guidelines on analyses outside the laboratory.5-8 Commercial development of a wide range of instruments capable of chemical, haematological, microbiological and immunological tests seems likely to ensure that this trend towards extra-laboratory testing will continue. It is not clear from the published guidelines with whom the responsibility for quality of performance lies, nor who will bear the cost consequences of funding extralaboratory testing, but it is essential that professional laboratory staff become involved with all aspects of this new growth area of clinical practice.

We therefore felt it an appropriate time to determine the number and types of instruments in use in the North West Thames region and the current involvement of clinical biochemistry laboratories in the purchase, training, maintenance and quality assurance of such instruments. This paper describes the results of a questionnaire designed to answer these problems. It should be emphasised that the aim of this study was not to analyse the quality of results produced by such instruments nor to argue the advantages or disadvantages of extra-laboratory testing, but simply to uncover the scale of the problem in the North West Thames region.

Methods

In September 1986 a questionnaire was circulated to the 22 clinical biochemistry laboratories in the North West Thames region. The questionnaire was in two parts, the first part requesting the presence or absence of instruments performing biochemistry analyses outside the laboratory, with suggestions as to the type of instruments that might be in use being given (table 1). The second part of the questionnaire required more detailed answers for each type of instrument in use, covering their numbers, locations, users, and details on their purchase, maintenance, and any quality assurance procedures carried out (table 2).

Table 1 Part of questionnaire circulated to biochemistry laboratories in the North West Thames region

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your hospital/district have instruments performing biochemistry analyses outside the laboratory?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Do you have: glucose stick meters</td>
<td>Yes/No</td>
</tr>
<tr>
<td>other stick meters</td>
<td>Yes/No</td>
</tr>
<tr>
<td>blood gas analysers (including fetal pH)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>instruments for sodium/potassium</td>
<td>Yes/No</td>
</tr>
<tr>
<td>bilirubin meters</td>
<td>Yes/No</td>
</tr>
<tr>
<td>others?</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

*If yes to any of the above, please complete part 2 of the questionnaire for each type of instrument.*

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925
Table 2  Part 2 of questionnaire circulated to biochemistry laboratories in North West Thames region

<table>
<thead>
<tr>
<th>Type of instrument:</th>
<th>Number of instruments in the hospital/district: Where are the instruments sited (ITU, theatre etc)? Who is responsible for each of these instruments? Who uses the instruments? What training has been given by laboratory staff? What other training has been given? By whom? Who maintains the instruments? Who purchased the instruments? Was the laboratory asked for advice on these purchases? Who pays for the running costs of the instruments? Is internal quality assurance run on the instruments? If yes, by whom? Is the biochemistry laboratory involved in the procedure? If no, describe the procedure used: Is the instrument in any external quality assurance scheme? If yes, which? (Wellcome, NQAS, lab) Has the work of the laboratory changed since the introduction of these instruments?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td></td>
</tr>
</tbody>
</table>

Fourteen laboratories out of the 22 circulated returned questionnaires, and their replies for glucose meters, blood gas analysers, and bilirubin meters are detailed in tables 3–5, respectively.

Table 3  Replies to part 2 of the North West Thames Region questionnaire (glucose meters)

<table>
<thead>
<tr>
<th>Hospital type</th>
<th>Meter type</th>
<th>Location</th>
<th>Responsibility</th>
<th>Users</th>
<th>Laboratory training</th>
<th>Other training</th>
<th>Maintenance</th>
<th>Bought by:</th>
<th>Laboratory advice</th>
<th>Running costs</th>
<th>Internal quality control</th>
<th>Laboratory quality control</th>
<th>External quality control</th>
<th>Workload change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reflox-check</td>
<td>26</td>
<td>Wards</td>
<td>Sisters</td>
<td>Nurses</td>
<td>Yes</td>
<td>No</td>
<td>Laboratory</td>
<td>Donated</td>
<td>Yes</td>
<td>Pharmacy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Reflox-lux Glucose-meter</td>
<td>20+</td>
<td>ITU</td>
<td>Wards</td>
<td>Nurses</td>
<td>Nurses</td>
<td>No</td>
<td>No</td>
<td>Nurses</td>
<td>Research</td>
<td>No</td>
<td>ITU?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>Various Glucose-meter Hypo-counter</td>
<td>75+</td>
<td>Wards</td>
<td>Nurses</td>
<td>Nurses</td>
<td>Yes</td>
<td>Yes</td>
<td>Laboratory?</td>
<td>No</td>
<td>Pharmacy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>?Yes</td>
</tr>
<tr>
<td>4</td>
<td>Various Glucose-meter Hypo-counter Reflox-check</td>
<td>26</td>
<td>Wards</td>
<td>Nurses</td>
<td>Nurses</td>
<td>No</td>
<td>?</td>
<td>Nurses</td>
<td>?</td>
<td>No</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>Various Glucose-meter 4-6</td>
<td>75+</td>
<td>ITU</td>
<td>SCBU</td>
<td>Wards</td>
<td>Nurses</td>
<td>Drs</td>
<td>No</td>
<td>No</td>
<td>Nurses</td>
<td>?</td>
<td>No</td>
<td>Pharmacy</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>?</td>
<td>45</td>
<td>Wards</td>
<td>Sisters</td>
<td>Nurses</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>?</td>
<td>?</td>
<td>No</td>
<td>?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>?</td>
<td>4-8</td>
<td>OPD</td>
<td>Sisters</td>
<td>Nurses</td>
<td>No</td>
<td>Manufacturing</td>
<td>Nurses</td>
<td>Donated</td>
<td>No</td>
<td>Pharmacy</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>11</td>
<td>?</td>
<td>7+</td>
<td>OPD</td>
<td>Lab</td>
<td>Nurses</td>
<td>Yes</td>
<td>?</td>
<td>Lab</td>
<td>Distinct</td>
<td>No</td>
<td>Pharmacy</td>
<td>Yes</td>
<td>?</td>
<td>No</td>
</tr>
<tr>
<td>12</td>
<td>?</td>
<td>12+</td>
<td>OPD</td>
<td>Engineers</td>
<td>Patients</td>
<td>No</td>
<td>Manufacturing</td>
<td>Hospital</td>
<td>Engineer</td>
<td>Diabetic</td>
<td>No</td>
<td>Consultant</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

GLUCOSE METERS

There are over 220 glucose meters in use in the North West Thames region (table 3). These are of various types and usually located in wards or outpatient departments where they are mainly used by, and are the responsibility of, the nursing staff. Only three laboratories have been involved in training the users and these same laboratories are responsible for maintenance of the instruments. Pharmacy departments are responsible for the running costs of the instruments in most instances. Internal quality control procedures are used in only four hospitals with the laboratory being involved in three. External quality assessment procedures were used in two hospitals. These laboratories thought that their workload had been changed by the presence of the extra-laboratory instruments.

BLOOD GAS ANALYSERS

There are 22 blood gas analysers in use outside laboratories in the North West Thames region (table 4). Most of these are located in intensive care units or special care baby units and they are mainly used by anaesthetic staff or medical personnel. Little laboratory training has been given for any of these
### Table 4 Replies to part 2 of questionnaire (blood gas analysers)

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Machine Type</th>
<th>Location</th>
<th>Responsibility</th>
<th>Users</th>
<th>Laboratory training</th>
<th>Other training</th>
<th>Maintenance</th>
<th>Bought by</th>
<th>Laboratory advice</th>
<th>Laboratory Running costs</th>
<th>Internal quality control</th>
<th>Laboratory quality control</th>
<th>Workload changed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 None</td>
<td>IL 413</td>
<td>ITU</td>
<td>Anaesth</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Service contract</td>
<td>ITU</td>
<td>No</td>
<td>Anaesth</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>2 C-168</td>
<td>SCBU</td>
<td>Works dept Drs</td>
<td>Paed</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>Works Cardiol</td>
<td>Paed</td>
<td>No</td>
<td>Paed</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3 C-178</td>
<td>Cardiology</td>
<td>Cardiol Nurses</td>
<td>Drs</td>
<td>No</td>
<td>?</td>
<td>?</td>
<td>Cardiol Techs</td>
<td>Matern-</td>
<td>Yes</td>
<td>Maternity unit</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>4 C-178</td>
<td>SCBU Nurses</td>
<td>Nurses</td>
<td>Drs</td>
<td>No</td>
<td>?</td>
<td>?</td>
<td>Technology unit</td>
<td>District</td>
<td>Yes</td>
<td>Aneas/Paed</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>5 ITU</td>
<td>?</td>
<td>?</td>
<td>ITU Aneas/Lab</td>
<td>Yes</td>
<td>?</td>
<td>?</td>
<td>Laboratory</td>
<td>District</td>
<td>Yes</td>
<td>Aneas/Paed</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6 ?</td>
<td>ITU</td>
<td>?</td>
<td>ITU Paed/Anaes</td>
<td>No</td>
<td>?</td>
<td>?</td>
<td>Theatre Fut Lab</td>
<td>Lab NWT</td>
<td>No</td>
<td>ITU</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>7 None</td>
<td>C-178</td>
<td>ITU</td>
<td>Laboratory</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>1 x ITU</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>8 ?</td>
<td>SCBU SCBU</td>
<td>SCBU</td>
<td>Laboratory</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>1 x ITU</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>9 ?</td>
<td>ITU</td>
<td>?</td>
<td>ITU Aneas</td>
<td>No</td>
<td>?</td>
<td>?</td>
<td>Laboratory</td>
<td>Yes</td>
<td>1 x ITU</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>11 IL 302</td>
<td>Postop</td>
<td>LaboratoryDrs</td>
<td>Tech</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>No</td>
<td>Aneas</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>12 ABL 2</td>
<td>SCBU</td>
<td>SCBU</td>
<td>Paed</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Electro Tech</td>
<td>Hospital</td>
<td>?</td>
<td>SCBU</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>14 IL 1312</td>
<td>ICU</td>
<td>SCBU</td>
<td>SCBU Nursing officer</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>Laboratory</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

### Table 5 Replies to part 2 of questionnaire (bilirubin meters)

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Machine Type</th>
<th>Location</th>
<th>Responsibility</th>
<th>Users</th>
<th>Laboratory training</th>
<th>Other training</th>
<th>Maintenance</th>
<th>Bought by</th>
<th>Laboratory advice</th>
<th>Laboratory Running costs</th>
<th>Internal quality control</th>
<th>Laboratory quality control</th>
<th>Workload changed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 None</td>
<td>American 1</td>
<td>Optical</td>
<td>Midwives</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>SCBU</td>
<td>Hosp</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>2 American 1</td>
<td>Optical</td>
<td>American</td>
<td>NeonatalPaed</td>
<td>Paed</td>
<td>No</td>
<td>No</td>
<td>Paed</td>
<td>Paed</td>
<td>Occasional</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>3 American 1</td>
<td>optical</td>
<td>American</td>
<td>SCBU Paed</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>SCBU</td>
<td>?</td>
<td>SCBU</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>4 ?</td>
<td>SCBU Nurses</td>
<td>Nurses</td>
<td>Drs</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>Paed</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>5 ?</td>
<td>SCBU Paed</td>
<td>Paed</td>
<td>Laboratory</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>Laboratory</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>6 ?</td>
<td>SCBU Paed</td>
<td>Paed</td>
<td>Laboratory</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>Laboratory</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>7 None</td>
<td>SCBU</td>
<td>SCBU</td>
<td>Paed Engineer</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Hosp</td>
<td>Paed</td>
<td>SCBU</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>8 ?</td>
<td>SCBU</td>
<td>SCBU</td>
<td>Nurses</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Hospital</td>
<td>Paed</td>
<td>SCBU</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>9 ?</td>
<td>SCBU</td>
<td>Midwives</td>
<td>Nurses</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Hospital</td>
<td>Paed</td>
<td>SCBU</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>10 ?</td>
<td>NeonatalPaed</td>
<td>Paed</td>
<td>ITU</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Paed</td>
<td>Paed</td>
<td>Occasional</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>11 None</td>
<td>American 1</td>
<td>Optical</td>
<td>SCBU Paed</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>SCBU</td>
<td>?</td>
<td>SCBU</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>12 American 1</td>
<td>optical</td>
<td>American</td>
<td>SCBU Paed</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>Paed</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>13 American 1</td>
<td>optical</td>
<td>American</td>
<td>SCBU Paed</td>
<td>No</td>
<td>No</td>
<td>?</td>
<td>Paed</td>
<td>No</td>
<td>Laboratory</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>14 ?</td>
<td>SCBU</td>
<td>SCBU</td>
<td>Nurses</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Hospital</td>
<td>Paed</td>
<td>SCBU</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
instruments despite the laboratory being responsible for the maintenance of 12 of them and also the running costs in two instances. Twenty one analysers are quality controlled internally, 15 by the laboratory. None of the instruments was entered into any external quality assessment scheme. In most hospitals their purchase had changed the workload.

**Bilirubin meters**

All of the hospitals except three have bilirubin meters in use outside the laboratory (table 3). Most of these instruments are located in special care baby units where they are used by members of the paediatric department and medical or nursing staff. In only one instance had the laboratory been involved in training and retained responsibility for the meter and its maintenance. In most cases the running costs were borne by the paediatric department. Six of the 13 meters were quality controlled internally and the laboratory was usually involved in this. In most cases the presence of these instruments had changed the workload of the laboratory.

**Other instruments**

There is one Reflotron (Boehringer, Mannheim, West Germany) in use in the region outside the laboratory. The laboratory was involved in the purchase of this instrument and is responsible for the maintenance, training, running costs and internal quality control procedures. The laboratory’s workload for urea, glucose, and haemoglobin estimate had been changed since the purchase of this instrument.

Four hospitals in the region have six instruments for the measurement of sodium and potassium. In most cases the instruments are maintained and internally quality controlled by the laboratory, although only one laboratory had been involved in training the users who were mainly medical staff of the anaesthetic department. None of the instruments, however, was externally quality assessed despite the change in the laboratories’ workload.

A few other types of instruments such as osmometers were in use outside laboratories. Although these instruments tended to be internally quality controlled, none has entered into external quality assessment schemes, and in most cases the laboratory was not involved in their maintenance, training, purchase or running costs.

**Discussion**

Clinical biochemistry laboratories can no longer ignore the problem of analytical equipment in use outside the laboratory. The replies to our questionnaire have indicated the large numbers of instruments in use and the wide range of analyses concerned. It is alarming to note that laboratories were prepared to maintain equipment over which they had no responsibility for purchase, use, or training.

The quality assurance of these instruments gives even greater cause for concern. Although internal quality control procedures are stated to be performed on some of the equipment, laboratories are involved in only a minority of these procedures. Often the quality assessment samples are analysed by laboratory staff when doing routine maintenance rather than as true quality assessment samples run by users of the instrument. Entry into external quality assessment schemes was non-existent, with the exception of glucose meters in two laboratories. It is tempting to speculate that the poor performance of extra-laboratory equipment reported is related to this.

In many instances laboratories felt that their workload had been changed by the introduction of extra-laboratory equipment. The cost effectiveness of transferring analyses from the laboratory, however, is an area which requires more detailed investigation.

We feel that the data obtained in the North West Thames region from this questionnaire are representative of the other health regions in the United Kingdom. The results show the enormous scale of the problem, which requires the urgent attention of all clinical biochemists.

We gratefully acknowledge the time and effort spent by the staff of the biochemistry laboratories in the North West Thames region in completing the questionnaires. This paper was prepared on behalf of the North West Thames Biochemistry Quality Assurance Working Party.

**References**


Requests for reprints: Dr JM Burrin, Department of Medicine, Hammersmith Hospital, Du Cane Road, London W12 0HS, England.