

Diagnostic equipment outside the laboratory

J M BURRIN, J A FYFFE*

*From the Department of Medicine, Hammersmith Hospital, London, and the *Department of Biochemistry, Queen Elizabeth II Hospital, Welwyn Garden City*

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 extra-laboratory 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*

Does your hospital/district have instruments performing biochemistry analyses outside the laboratory?	Yes/No
Do you have:	Yes/No
glucose stick meters	Yes/No
other stick meters	Yes/No
blood gas analysers (including fetal pH)	Yes/No
instruments for sodium/potassium	Yes/No
bilirubin meters	Yes/No
others?	Yes/No
If yes to any of the above, please complete part 2 of the questionnaire for each type of instrument.	

Accepted for publication 21 April 1988

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

Type of instrument:

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?

Results

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.

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

Hospital	Meter type	(n =)	Location	Responsibility	Users	Laboratory training	Other training	Maintenance	Bought by:	Laboratory advice	Running costs	Internal quality control	Laboratory quality involved	External quality control	Workload change
1	Reflo-check	26	Wards	Sisters	Nurses	Yes	No	Laboratory	Donated	Yes	Pharmacy	Yes	Yes	Yes	No
2	Reflux Glucometer	20+	ITU Wards OPD	Nurses	Nurses	No	No	Nurses	Research	No	ITU?	No	No	No	No
3	Various	75+	Wards	Nurses	Nurses	Yes	Yes	Laboratory?		No	Pharmacy Laboratory	Yes	Yes	Yes	?Yes
4	Glucometer Hypocount Reflo-check	Various	Wards	Nurses	Nurses	No	?	Nurses	?	No	?	No	No	No	?
5	Various	Various	Wards	?	?	No	?	?	?	No	?	No	No	No	?
6	Glucometer	4-6	ITU SCBU	?	?	No	?	?	?	No	?	No	No	No	?
7	?	8	Wards	Sisters	Nurses Drs	No	No	Nurses	?	No	Pharmacy	No	No	No	No
8	Yes	?	?	?	?	?	?	?	?	?	?	?	?	?	?
9	No														
10	Reflo-check Hypocount	2													
11	?	45	Wards	Sisters	Nurses	No	No	?	?	No	?	No	No	No	Yes
12	Various	4-8	OPD	Sisters	Nurses	No	Manu- facturer	Nurses	Donated	No	Pharm- acy Pharm- acy	Yes	Yes	No	?
13	Various	30-40	Home OPD	Patients ?Lab	Patients Nurses	No Yes	Nurses	?		No	Pharm- acy	?	No	No	?
14	Various	7+	Wards	?Lab Drs./Hosp.	Nurses Nurses	Yes No	?	Lab Hospital Engineer	Dist- ri- c Diabetic consultant	No No	Pharm- acy	No No	?	No	Yes
14	Glucometer	12+	OPD	Engineer	Patients	No	Manu- facturer	Engineer		No		No	No	No	No

Diagnostic equipment outside the laboratory

Table 4 Replies to part 2 of questionnaire (blood gas analysers)

Hospital	Machine type	(n =)	Location	Responsibility	Users	Laboratory training	Other training	Maintenance	Bought by:	Laboratory advice	Running costs	Internal quality control	Laboratory quality control involved	External quality control	Workload changed
1	None														
2	IL 413	1	ITU	Anaesth	Anaesth	No	No	Service contract	ITU	No	Anaesth	Yes	No	No	No
3	C 168 C 178	1 1	SCBU	Works dept Cardiol Techs	Drs Drs	No No	No ?	Works Cardiol	Paed NWT	No Yes	Paed Cardiol	Yes Yes	Yes No	Yes No	Yes Yes
4	C 178	1	SCBU	Nurses	Drs	No	?	Techs Nurses	Matern- Laboratory	Yes	Matern- ity unit	Yes	Yes	No	?
5	? ?	3 3	ITU SCBU	Anaes/Lab Paed	Drs	Yes No		Laboratory	Donated	Yes No	Anaes Paed	Yes	Yes	No	Yes
6	?	2	HDU ITU SCBU	Anaes/Lab ?	Paed Anaes	Yes No	Manu- facturer ?	Theatre Tech Lab	NWT region	No	ITU SCBU	Yes Yes	No Yes	No No	Yes Yes
7	None														
8	C 178	3	ITU SCBU Childs hosp	Laboratory Drs	Drs Laboratory	Yes	No	Laboratory	1 × NWT 1 × donated 1 × ?	Yes	1 × ITU 2 × Lab	Yes	Yes	No	Yes
9	?	1	ITU	Anaes	Anaes	No	Anaes	Laboratory	NWT region	Yes	Anaes	Yes	Yes	No	No
10	?	1	Neonatal ITU	Paed	Paed	No	?	Paed	Paed	No	Paed	No	No	No	Yes
11	IL 302	1	Postop	Laboratory	Drs Tech	No	Med Phys Tech No	Laboratory	Hospital	No	Anaes	Yes	Yes	No	Yes
12	ABL 2	2	SCBU Paed	Paed	Drs	No		Elec Tech	Hospital	?	SCBU	Yes	Yes	No	?
13	IL 1302 ABL 1 ABL 30 IL 613	1 1 1 1	ITU Theatre SCBU Chest	? ? Paed Physiol	? ? Drs Drs	? ? Yes No	? ? No Tech	? ? Laboratory Tech	? ? Paed Ex-Lab	? ? Yes Yes	? ? Paed Chest	? ? Yes Yes	? ? Yes No	? ? No No	? ? Yes No
14	IL 1312	1	ICU	Anaes	Drs	No	Anaes	Laboratory	Anaes	Yes	District	Yes	Yes(?)	No	Yes

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

Hospital	Meter type	(n =)	Location	Responsibility	Users	Laboratory training	Other training	Maintenance	Bought by:	Laboratory advice	Running costs	Internal quality control	Laboratory quality control involved	External quality control	Workload changed
1	None														
2	American Optical	1	SCBU	Works Dept	Paed	No	No	Works Dept	Paed	No	Paed	No	No	No	Yes
3	American Optical	1	SCBU	Nurses	Nurses Drs	No	Nurses	Nurses	District	No	SCBU	No	No	No	Yes
4	?	1	SCBU	Nurses	Nurses	No	?	Nurses	Maternity unit	Yes	Maternity unit	?	Occasional comparison only ?	No	No
5	?	1	SCBU	Paed	Paed	No	?Drs	Paed	Paed	No	Paed	Yes	?	No	Yes
6	?	1	SCBU	SCBU Nursing officer	Paed	No	?	Laboratory	Consultant paed	No	SCBU	Yes	Yes	No	Yes
7	None														
8	?	3	2 × SCBU 1 × Child- rens' Hosp	Laboratory	Drs Laboratory	Yes	No	Laboratory	Laboratory	Yes	Laboratory	Yes	Yes	No	Yes
9	?	1	SCBU	Midwives	Nurses	No	Senior Nurse	SCBU	Hosp	Yes	Hosp	No	No	No	Yes
10	?	1	Neonatal ITU	Paed	Paed	No	?	Paed	Paed	No	Paed	Occasional	No	No	Yes
11	None American optical	1	SCBU	Paed	Drs	No	?	Elec Tech No	SCBU	?	SCBU	No	No	No	?
13	American optical	1	SCBU	Paed	Drs Nurses	No	No	No	Paed	?	Paed	?	No	No	Yes
14	?	1	SCBU	Paed Engineer	Drs Nurses	No	No	Hosp engineer	Paed	Yes	SCBU	Yes	Yes	No	Yes

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 reported¹⁻⁴ 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

- 1 Drucker RF, Williams DRR, Price CP. Quality assessment of blood glucose monitors in use outside hospital laboratories. *J Clin Pathol* 1983;**36**:948-53.
- 2 Burrin JM, Williams DRR, Price CP. Performance of a quality assessment scheme for blood glucose meters in general practice. *Ann Clin Biochem* 1985;**22**:148-51.
- 3 Fyffe J. Stick testing! A cause for concern. *Br J Hosp Med* 1986;**35**:196.
- 4 Burnett D, Henfrey RD, Woods TF, Fyffe J. Regional quality assessment of pH and blood gas analysers. *Ann Clin Biochem* 1986;**23**:26-36.
- 5 AACB Scientific and Technical Committee. Proposed guidelines for the performance of clinical biochemistry tests outside the environment of the laboratory. *Med J Aust* 1985;**143**:299-300.
- 6 Welsh Scientific Advisory Committee. *The use of diagnostic equipment and procedures outside the diagnostic laboratory*. WSAC, 1984. D/1/84
- 7 Anderson JR, Linsell WD, Mitchell FL. Guidelines on the performance of chemical pathology assays outside the laboratory. *Br Med J* 1981;**282**:743.
- 8 American Diabetes Association. Consensus Statement on self-monitoring of blood glucose. *Diabetes Care* 1987;**10**:95-9.

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