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Feature

# BEDSIDE BIOCHEMISTRY: THE COST OF CONVENIENC

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## Summary

Bedside biochemistry: the carrying out of complex analytical procedures by relatively unskilled staff close to the patient, has become fashionable since the introduction of sophisticated compact analysers over the last five years. The need for this is related more to clinical convenience than clinical necessity; the quality of analysis is likely to be poorer;

and the true cost of analysis is likely to be much higher than analyses carried out in a centralised laboratory. Much of the demand for bedside biochemistry would disappear if there were proper collaboration and consultation between clinical and laboratory staff.

Keywords: Bedside biochemistry; quality of analyses; cost of analyses; speed of service.

"When we mean to *build*,  
We first survey the plot, then draw the model;  
And when we see the figure of the house,  
Then we must rate the cost of the erection;  
Which if we find outweighs ability,  
What do we then but draw anew the model  
In fewer offices, or at last desist  
To *build* at all?" (1)

"Is it not strange that *desire should* so many years outlive *performance?*" (1)

Bedside biochemistry is the carrying out of complex analytical procedures by relatively unskilled staff: in the clinic; in the ward or GP's surgery; or even in the patient's home. It is not a new phenomenon. Pathology started when many doctors in the nineteenth century set aside a room for a laboratory. In those days, the principal equipment was a microscope; and it was not until the 1920s that scientists were employed to carry out complex assays (2, 3). As pathology grew and became more specialised, it was realised that a better and more efficient service could be provided for clinical biochemistry by a

single large laboratory because of the consequent concentration of apparatus and expertise (4). For laboratory staff, the emphasis was on manual analytical skills.

Automatic analysers came into general use in the 1960s. A relatively unskilled analyst could then carry out more analyses with better precision and accuracy than by using the older manual techniques. However, a whole new range of skills was needed to operate the new machines, and this was reflected in an increased centralisation and amalgamation of clinical laboratories.

Up until the late 1970s, the clinical demand for tests grew, and both the size of laboratories and the complexity of their instrumentation increased. But over the last five years, since the introduction of the microprocessor, a wide range of technically advanced, cheap and portable analysers have been introduced. These new instruments are said to be within the technical competence of virtually any literate and sufficiently well motivated person (3), and

can therefore be operated at any level by the patient's bedside. The wheel has full circle and bedside biochemistry has been reborn.

The essential questions to be answered are: the advantages and disadvantages of the apparently new approach are discussed in these:

1. What is the real clinical need for both in terms of the rapidity of service and the quality of analysis?
2. What is the real financial cost of decentralising analyses?

There is surprisingly little data published to answer either of these questions; and it is difficult to escape the conclusion that the crux of the argument rests on a lack of dialogue between the clinician and the central laboratory.

## Rapidity of Service

In any laboratory, a small proportion of results is needed rapidly in order to initiate change of treatment. However there is an inverse correlation between the rapidity of the turn-round time of the routine service and the number of urgent requests in main laboratories. Most urgent requests have to do with the state of the patient; medication; with the timing of ward rounds; and in the laboratory, the volume of urgent requests has to do with last minute afterthoughts by inexperienced young doctors. In the laboratory, the volume of urgent requests makes it more difficult to deal with the patient-related emergencies quickly. From the laboratory viewpoint, most of the requests for rapid results seem to be related mainly to clinical convenience; and as there are frequent claims that a central laboratory cannot deal adequately with genuine clinical emergencies, it is often said that the laboratory is not approached for more rapid service can be provided where it is needed.

## Quality of Analysis

To a clinician, a result is in general either right or wrong—correct or totally mistaken. A laboratory worker describes results as accurate (i.e. free from bias); and precise (i.e. subject to a minimum of scatter around the accurate value). Superimposed upon this idea of a distribution of results is the "blunder rate": the proportion of totally incorrect results caused by misidentification of the patient; incorrect sample; or analytical or clerical error in the laboratory. In most laboratories this is about 3% of all results.

It is very difficult to ensure that the bias of two different machines is the same, particularly when machines of two different types are used. Thus, a flame photometer and an ion-selective electrode can produce a sodium result differing by 5 mmol/L on the same sample. This can make it difficult to interpret successive sodium results carried out on different machines.

The analytical imprecision is not of great importance for some analyses since the range of normal variation is very wide, e.g. urea. For other analyses, e.g. sodium it is of great importance. If the imprecision of sodium analysis changes from CV 1% (typical of a large centralised laboratory) to CV 2% (typical of a peripheral laboratory) staffed by inexperienced analysts) the error range doubles; and a change in sodium concentration of 12 mmol/L between consecutive measurements can be caused solely by laboratory imprecision.

Modern sophisticated analytical machinery is often easy to operate. Whether it is "foolproof", i.e. it can be operated by anyone with no worsening of quality, is debatable. In a recent survey of ion-selective electrodes for sodium and potassium measurement, no instrument was found to fulfill all the criteria required for operation within a paediatric intensive care unit (5). Although some claims have been made that the performance of modern machinery at the bedside is no worse than that of a centralised laboratory (6), the general experience in hospitals in which a common quality control scheme is used is that the performance of peripheral instruments is worse than that of centralised instruments. The reason for this is twofold. First, even though the machine may be easy to operate, the staff running it must have an awareness of when things go wrong. This awareness only comes with analytical experience. Second, particularly for modern instruments, it is vital that a rigorous service and maintenance schedule be carried out. In the absence of dedicated staff, this tends to be neglected.

The worsening of performance by peripheral instruments means that less reliance can be placed on any result: so either an increased likelihood of making wrong clinical decisions is accepted; or more analyses have to be done on each patient to attain the same confidence in result.

## Financial Cost

The financial cost of decentralising a service by introducing additional bedside instruments can be broken down in the following way.

### 1. Capital cost of instrument

The centralised laboratory must maintain its

capacity for analyses because of the possibility of breakdown of the peripheral instrument. The capital cost of the peripheral instrument is therefore a direct incremental cost.

### 2. Running cost

#### Maintenance

Good performance can only be expected from modern machinery if a strict service and maintenance protocol is rigidly followed. A typical service cost is between 5 and 10% per annum of the capital cost of the instrument and this can be more expensive if a rapid response to breakdown is required.

#### b. Additional reagent costs

If the workload in the centralised laboratory decreased as peripheral instruments came into operation, the additional reagent cost would be small. The experience in some centralised laboratories is that the workload in the centralised laboratory increases, because of the need to check both the performance of the peripheral instrument and individual "problem" results.

#### c. Control materials

It is vital to maintain a check on the performance of an instrument, particularly when it is likely to be used by inexperienced staff. Commercial control materials are expensive.

#### d. Spares

An adequate supply of spare parts must be maintained to enable rapid recovery from breakdown. Particularly for devices such as ion-selective electrodes; these can be expensive.

#### e. Staff costs

Since the workload in a centralised laboratory is not significantly affected by the operation of peripheral instruments, all staff costs involved in operating and, more important, checking and maintaining the performance of a peripheral machine, are additive.

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## Chemical Pathology on the Ward

Those who provide routine analytical services in laboratories are worried that the purchase of instruments for doing such work on the ward or in side-rooms may not be always in the best interests of the patient.

The assays in question include blood gases and acid base balance, serum sodium and potassium, and paracetamol (acetaminophen). This equipment, by providing the clinician with rapid results, could lead to earlier diagnosis or prompt adjustment of treatment. However, use by staff untrained in laboratory practice—notably, in quality control and in the criticism and assessment of the results—may introduce hazards for the patient.

The presidents of the Royal College of Pathologists (Prof. J.R. Anderson), the Association of Clinical Pathologists (Dr W.D.

## Guidelines on the Performance of Bedside Biochemistry

Clinical biochemical testing has not yet reached the point where either instruments or analyses are foolproof. Most laboratory heads are concerned at the proliferation of instruments at the bedside: first, because of the major financial implications; and second, because of the difficulties in ensuring that an adequate analytical service is maintained.

For these reasons, in the UK the presidents of the Royal College of Pathologists, the Association of Clinical Pathologists and the Association of Clinical Biochemists issued in 1981 a joint statement (reprinted at the end of this article). This is essential reading for all who want to buy and use analytical machinery outside the centralised laboratory. To some extent the most important guideline is the last:

".. there should be full collaboration between medical and clinical staff outside the routine laboratory and the staff of the main routine laboratory .."

With this collaboration most of the demand for bedside biochemistry would disappear. U

### References

1. Shakespeare, W. "Henry IV. Part 2"
2. Sanders, P.G. Evolution of Clinical Biochemistry in Relation to Clinical Practice. PhD Thesis, University of Cambridge, 1980.
3. Marks, V. Clinical biochemistry nearer the patient. *Br Med J* 1983; 286: 1166-1167
4. Musser, A.W. CRC Critical Review in Clinical Laboratory Science 1975: 6: 47-66
5. Mann, S.W., and Green, Anne Sodium and potassium measurement in the clinical area: assessment of an ion-selective analyser in a paediatric intensive care unit. In *Impact 1984*, Assoc. Clinical Biochemists National Meeting, Buxton 1984. Abstract.
6. Minty, B.D. and Barrett, A.M. Accuracy of an automated blood-gas analyser operated by untrained staff. *Br J Anaesth* 1978; 50: 1031-1039

Linsell), and the Association of Clinical Biochemists (Dr. F.M. Mitchell) have issued a joint statement recommending procedures aimed at reducing discrepancies in the performance of tests and ensuring reliability and quality of assays used in patient care. "Obviously," the statement says, "every endeavour should be made to avoid duplication of expensive equipment and services by providing effective laboratory cover at all times." However, where, in exceptional circumstances, assays have to be done away from the main routine service laboratory, the following conditions should be met:

### Guidelines on the performance of chemical pathology assays outside the laboratory

- (1) *Liaison*—There should be full consultation and agreement with the head of the routine laboratory department before any equipment is purchased or obtained and close liaison should be maintained during its use.
- (2) *Choice of equipment*—DHSS evaluations of equipment should be considered, as should local practice or equipment for similar assays carried out in the routine laboratory. Selection, demonstration, and preliminary trials of equipment should be carried out in collaboration with the staff of the routine laboratory.

(3) Health and safety-The facilities provided and the equipment and techniques used should comply with the Health and Safety at Work Act and with the Code of Practice for the Prevention of Infection in Clinical Laboratories and Post-mortem Rooms. There should be supervision by an appropriate safety officer. Advice should be obtained on the proper siting of the equipment.

(4) Training-No one should use analytical equipment without appropriate instruction or training in the operation of the equipment and in the concept of quality control. From time to time it may be necessary to retrain users. A formal list of trained users of equipment in side rooms and in small laboratories outside the main routine laboratory should be maintained and all those using the equipment should be aware of the medicolegal implications. Training in the use of the instrument and monitoring of subsequent performance should be supervised by a member of the staff of the routine laboratory. Records should be kept for each assay and its operator. Reports should be correctly prepared and filed in the patients' notes. They should be on a form recognisably different from the ordinary laboratory form. The system of units used should be agreed with the head of the routine laboratory.

(5) Quality control-Internal quality control

should be performed at regular intervals and records kept and displayed as in the laboratory itself. An external quality assessment scheme should be used when practicable-for example, for potassium, sodium, etc. The routine laboratory quality control officer should be responsible to the head of the department for checking the records and initiating remedial action, etc, when necessary. A similar policy should apply to patient-operated apparatus so far as possible. The performance and the manner of performance should be checked at appropriate intervals, as agreed between the clinician and the staff of the routine service laboratory.

(6) Maintenance-The main routine laboratory should normally be responsible for (a) periodic checking of simple day-to-day maintenance tasks carried out by the users; (b) the more complex maintenance, weekly or monthly (procedures involving dismantling of the equipment, cleaning or replacing parts); (c) Dealing with simple breakdowns; (d) service calls to the manufacturer. Patient-operated apparatus should be the responsibility of the relevant clinic. Laboratory support should be available for periodic checks on this type of equipment. Obviously routine service laboratory support is possible only if adequate information through consultation, as outlined in the above paragraphs, is available to the routine laboratory.

(7) Staffing-It may well be necessary to provide additional suitably qualified staff based on the routine service laboratory to meet these requirements. If possible the main operator of such equipment should be a member of the staff of the routine laboratory, which ensures continuity of methods of operation, maintains the serenity from a pool of staff of the routine laboratory and provides a career structure for the operator.

(8) General-It is essential that there should be full collaboration between medical and clinical staff outside the routine laboratory, the staff of the main routine laboratory, particularly in the supervision and training personnel and the maintenance of equipment. 0

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