Bedside Clinical Biochemistry — How Far and How Fast?

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Concern has been expressed that instruments for 'bedside' clinical biochemistry may displace laboratory staff. The circumstances in which such instruments may become attractive are reviewed. Only when there is a need for urgency which precludes transport to a laboratory, or when patients are seen outside the hospital environment, do these instruments seem to offer significant advantages. For most work the cost of 'bedside' tests will remain much greater than the benefits.

INTRODUCTION

The development of instruments or systems for biochemical analyses designed for use in a ward or clinic, rather than a laboratory, and capable in many cases of giving reliable results when used by an operator not trained in laboratory methods, poses some problems for clinical biochemists. However, technical developments in general have posed novel problems for clinical biochemists in the past, the solution to these problems not always being that expected by their more enthusiastic or pessimistic exponents.

This article is somewhat hypothetical in that the very nature of the topic does not allow a review of *facts*, established (or tested and not disproved) by experiment. In this case, the passage of time will be the test as to the validity of the arguments contained herein. Even though it is necessary to look into the future, there are certain principles of rational enquiry which can be applied to this as much as any other problem. Given the technical feasibility of 'bedside' instruments, the main questions are of economics. Some might say that economics should be kept out of clinical areas, but, in the end, resources are always limited and health professionals are reduced to seeking the maximum health care for each dollar which the community can make available.

COST AND EFFECTIVENESS

The demands which medicine makes on laboratory services are varied and the balance between cost and clinical benefit will differ according to circumstances. At least four areas can be identified:

(i) Extremely urgent work

In critical care areas information may be needed within a few minutes if it is to be useful in the management of a crisis. The range of tests likely to be required is small, probably only blood gases and potassium, but the time requirement of five minutes or less means that a central laboratory serving the entire hospital cannot cope. Transport is the limiting factor, together with the time needed to centrifuge the specimen to obtain plasma. The five-minute requirement can only be met by systems in the critical care area which can measure blood gases and plasma potassium on whole blood samples.

The cost of such a system is mainly in the depreciation of equipment. If it is assumed that three areas in an average large hospital may need such equipment, with no back-up, and that the two machines (a blood gas analyzer and an ion-selective electrode system for potassium) cost $25,000 and have a useful life of five years, then the capital cost is $(3 \times 25{,}000)/(5 \times 365) = \$41$ per day. This is a very crude approach to capital costs but it gives an idea of the amounts involved. If we assume a further $10 for calibration and quality control materials and an hour of someone's time at $20 to perform appropriate maintenance and checking procedures, the total daily cost is about $70. This is small compared to the other costs of intensive care but not entirely negligible. Operator costs are a separate consideration and, in this context, it is generally assumed that the medical or nursing staff can inject the sample into the machine and read the result. However, the times when the results are needed most urgently will also be the times when medical or nursing staff are fully occupied with other duties relating to critically ill patients.

I think that 'bedside' instruments will take over in this situation due to the difficulty of providing an instant service by alternative means. We should make sure however, that the assumed clinical benefit to patients in terms of lives saved is actually true. Are more lives saved or the number of complications decreased by high technology instruments than by, say, an extra nursing staff member or by something else which may cost about the same? Clinical biochemists, even those with medical qualifications, cannot be expected to judge between these alternatives, but they should make sure that questions of this type are posed.

(ii) Out-of-hours work

The next requirement to be considered relates to the wider range of tests, the results of which may be needed within half an hour to an hour. These cannot wait for the routine procedures and the usual answer has been to set up a special section within the laboratory. To equip a number of wards, maybe up to a dozen, with systems capable of offering a repertoire of six to ten tests seems entirely uneconomic at present. At a cost of about $40,000 each (and the Dupont and Kodak systems cost much more than this), ten would cost $400,000 or about

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$220 a day. Reagent costs would be over $1 a test. If few tests are required on each specimen, depreciation makes this system impractical; if many tests are needed, reagent costs are too great and full-time staff would have to be available for instrument operation. A centralized laboratory for urgent work with one such machine, not necessarily located in the same place as the main laboratory, offers economies of scale and is probably the best solution at present. Transport delays still present a problem and so it would be desirable to place this urgent laboratory near the ward generating most work. The need for urgent haematology tests should also be considered in this context.

Urgent work requirements outside normal working hours are at present provided by either a shift system of some kind or a call-back system. Shift or overtime penalties can make labour costs $20-$30 an hour, depending on the grade of staff employed. In most hospitals call-back is even more expensive. In New South Wales a minimum four hour payment (two hours at time and one-half plus two hours at double time), equivalent to seven hours normal pay, is prescribed by the industrial awards and so a single test can generate labour costs of $70 or more. In hospitals with a low out-of-hours workload, which cannot justify 24-hour laboratory staffing, a 'foolproof' system which could be operated by someone already on site would be very attractive. In hospitals with a greater workload, a similar system could replace shift work staff and make the others more efficient.

(iii) Routine work

In the area of routine laboratory tests with a same-day turnaround for the ten or twenty most commonly requested tests, there seems no immediate justification for bedside testing. There is no clinical reason for instant results and automated machines (whether multichannel or selective) offer economies of scale. A Technicon SMAC^{TM} can provide 20 results for $5 or less and, even if only a quarter of these results are used, this is still cheaper than any current alternative.

Even if cheap systems with low reagent costs are developed, they may have only a limited effect. Glucose analyzers, such as the YSI^{TM}, can be trolley-mounted and wheeled around the wards, but a trial of such a system at Royal Prince Alfred Hospital showed that the staff time consumed was greater than that needed to collect the specimens and take them to the laboratory for analysis. In this instance there was the added problem that the specimens needed to be taken at a set time, two hours after a meal, and this could not be achieved by analysis in the ward.

(iv) Out-patient and non-hospital practice

Analyses in the surgery, rooms or clinic offer more than ward analysis on hospital in-patients. In this situation the patient is present for a short time only and, in some cases (but by no means all), it would be useful to know the test result before his/her departure. There is the added benefit of convenience to the patient in not having to attend a second place, the laboratory or collecting rooms, and possibly in not having to return for a further consultation when the laboratory results are available. The extra cost of on-the-spot testing could be balanced by savings for which the patient or the community would be prepared to pay. However, in many cases a second visit must occur anyway, independently of the laboratory test results.

The management of both acute and chronic diseases could benefit from fast results, and in the latter case specialized instruments for the measurement of glucose, therapeutic drugs or thyroid hormones, could be attractive to medical specialists. Since doctors in some specialities make considerable use of biochemical tests, they are likely to be the first to introduce such instruments. The economics of buying a machine for $10,000 to $20,000 appear quite favourable if it is needed for an average of even ten patients a day for a fee which might average $20.

If these instruments are to be used by medical practitioners or their receptionists, in their own surgeries or rooms, absolute reliability will be essential. Even minor faults which could be rectified in a few minutes by a laboratory technician are likely to result in a service call to the supplier.

IMPLICATIONS FOR THE HEALTH INSURANCE SYSTEM

Our present Australian system, at least as far as diagnostic tests are concerned, separates the person who decides a test is needed from the person who benefits financially from providing it, as shown in Figure 1. Recent history suggests that if this separation disappears, a small number of people will take advantage of clinic instruments to increase their incomes. After a lag phase, health insurance organisations and governments would be compelled to act on this abuse, imposing further controls on the medical system.

A wider implication and one more difficult to control, is that large laboratories can currently perform common tests for considerably less than the scheduled fee, thus providing some restraint on fee increases. Also, much of the surplus generated in the larger laboratories from fees being set to allow the survival of smaller laboratories, is retained in some way within the public hospital system. The price of ward instrument systems and reagents is likely to be set initially at whatever the market will bear, their greater costs being justified on the grounds of presumed clinical benefit. The overall net cost of providing diagnostic tests could thus rise with the benefit going to overseas manufacturers of instruments and their obligatory reagents.

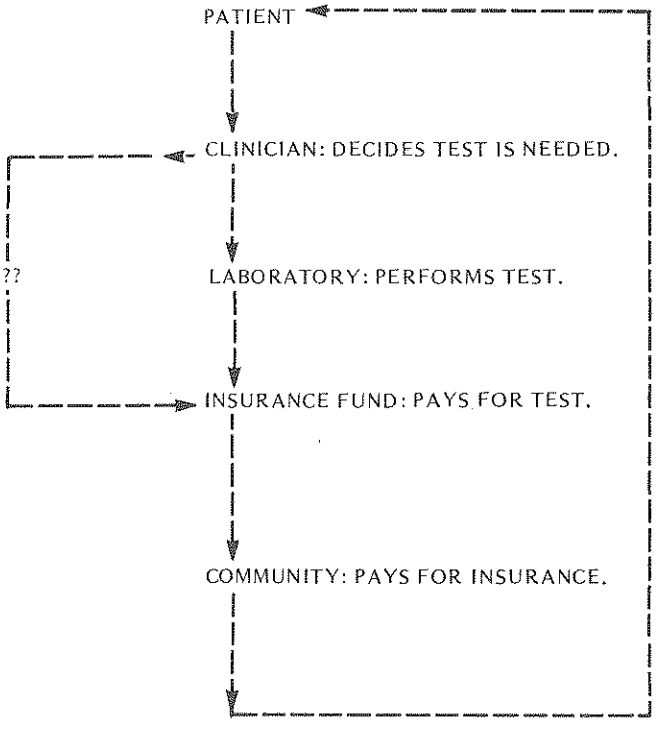

Figure 1. Health payments loop.

THE WORK OF CLINICAL BIOCHEMISTS

If the promised technology does eventuate in a reliable and affordable form, with widespread use in the urgent work and non-inpatient areas in particular, what will be the consequences for clinical biochemists and their work? A number of areas can be identified; for example, quality control, maintenance, instrument evaluation and selection and record maintenance. Each of these are essential in the context of decentralized analyses and must be added on top of a continuing workload of laboratory tests.

(i) Quality Control

Maintenance of precision and avoidance of between-instrument differences demands circulation of quality assessment materials and action when problems are found. Remedial action is likely to require diplomacy and a willingness to educate users in a subject in which they may be quite uninterested. Outside the hospital environment, regional schemes such as those developed in South Australia or Victoria for laboratories, will be required for these non-laboratory users.

(ii) Maintenance

Preventative maintenance and repairs are unlikely to be done adequately by people whose medical or nursing duties take up most of their time. Either the suppliers of the instrument or some independent professional will need to take responsibility for the continuing ability of such instruments to function correctly. The danger for clinical biochemists taking the responsibility, is that they may only be called on to fix someone else's mistakes. This responsibility without authority for both maintenance and quality control, should be avoided.

(iii) Instrument Selection

Evaluations are already carried out on a national or international scale by many groups. The *minimum* responsibility of the Australian Association of Clinical Biochemists is to bring these evaluations to the attention of those contemplating the purchase of 'bedside' instruments and to recommend standardization of purchases within a hospital with due regard for price, reliability and service backup.

(iv) Records

In some cases the instrument may produce a report in a form suitable for permanent storage in the patient's medical history. In most cases it will not, and in this case a hand-written result or an oddly-shaped piece of paper will be produced and promptly lost. Particularly for urgent work on hospital patients, the results should be entered to a computer system for generation of a cumulative report and, unless there is a terminal in every ward, the best solution is to return the results to the laboratory for entry. This will also ensure accurate billing, which is an important consideration and likely to appeal to health administrators.

CONCLUSIONS

There is room for differences of opinion on the speed with which 'bedside' clinical biochemistry instruments will come into use. Unless a change as dramatic as the microcomputer revolution occurs, which would have to involve mass production and its economies of scale in an expanding market, the market penetration will be limited to urgent work and to general practitioners and specialist offices. Electrode or solid-state sensor technology may ultimately provide the means by which mass production can occur, but many functions which can only be done in a laboratory will remain. If the situation for clinical biochemistry is compared to radiology, it can be seen that centralized departments have remained despite mobile X-ray machines.

One result of non-laboratory analyses will be to make the effective management of biochemistry services both more difficult and more important. It may ultimately be a further influence towards centralization of clinical biochemistry, with small laboratories being replaced by machines requiring little skill and with the less urgent tests grouped in departments offering a range of specialized services, such as those now found in major teaching hospitals.

BIBLIOGRAPHY

MITCHELL, F.M., New technology and its possible effects on our specialty. *Clin. Biochem. Newsletter* Number 56, 9 (1980).

ANDERSON, J.R., LINSELL, W.D., and MITCHELL, F.M., Guidelines on the performance of chemical pathology assays outside the laboratory. *Brit. Med. J.* 282, 743 (1981).

FRASER, C.G., and GEARY, T.D., Guidelines for the performance of clinical laboratory tests outside laboratories. *Clin. Biochem. Revs.* 2, 24-25 (1981).