DRY CHEMISTRY PATHOLOGY TRIAL

PART 4

OVERVIEW

A REPORT BY THE

NON-LABORATORY PATHOLOGY TESTING WORKING PARTY

OF THE

NATIONAL HEALTH TECHNOLOGY ADVISORY PANEL

FEBRUARY 1989

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EXECUTIVE SUMMARY

- An overview is presented of the dry chemistry pathology trial, which evaluated the use of five clinical chemistry analysers in general practices and hospital ward side-rooms, following initial appraisal of analyser performance by a pathology laboratory.

- Common themes in the general practice and hospital ward side-room studies were the unsatisfactory levels of analytical performance achieved, lack of appreciation of the need to perform quality control procedures, the need for suitable training and education of non-laboratory operators of dry chemistry pathology equipment and the significant demands on the coordinating laboratories.

- Dry chemistry pathology testing carried out by general practices in the trial was additive, overall, to tests requested by the practices from pathology laboratories. Effects on patient outcome, as measured by clinical chemistry indicators, were inconclusive for three of four selected conditions. Further work is needed to define the overall costs and benefits of this technology in general practice.

- Details are given of the experiences of the coordinating laboratories, with particular emphasis on support provided by them for non-laboratory operators, quality control, responsibilities of manufacturers, and responsibilities of 'office laboratories'.

Recommendations

The Working Party recommends that:

- Preparation of educational programs for office pathology workers, such as those developed by the Royal Australian College of General Practitioners, be undertaken by relevant professional bodies.

- The National Pathology Accreditation Advisory Council (NPAAC), the National Association of Testing Authorities and equipment manufacturers give continued consideration to the provision and distribution of such educational material.

- Accreditation of services operating dry chemistry pathology analysers should be mandatory.

- In regard to future arrangements for accreditation of non-laboratory pathology services:

  - governments should take action to extend the coverage of existing pathology laboratory accreditation requirements to cover all operators of dry chemistry pathology equipment;

  - cost and effectiveness of accreditation programs for office pathology be kept under review by health authorities, and NPAAC;

  - the feasibility and suitability of applying accreditation to use of other pathology technologies in the non-laboratory situation be considered by NPAAC.

- Users and potential users of dry chemistry pathology critically consider the value and cost of this type of technology.

- A further study be undertaken to assess the usage of dry chemistry pathology and other relevant technology by accredited general practices and its effects on the health status of patients. Further, more extensive, study of the costs and effectiveness of dry chemistry pathology testing in hospital wards would also be desirable.

- Manufacturers and quality assurance program organisers make available suitable quality control material for non-laboratory pathology services which is in liquid form, appropriately packaged and compatible with dry chemistry pathology technology.

- The NPAAC consider means of overcoming current impediments to the use of pathology services as mentor laboratories to provide sources of advice and support for non-laboratory testing.

- Unions, government agencies, professional bodies and administrators consider and discuss effects of non-laboratory testing on employment conditions for laboratory staff.

- The assessment of the safety and efficacy of analytical systems for non-laboratory use be given consideration by relevant government organisations and professional bodies.

INTRODUCTION

This report presents an overview of the Dry Chemistry Pathology Trial, details of which have been given in previous publications (1,2,3). It also considers more generally the place of 'dry chemistry' pathology technology in decentralised pathology services(often referred to as 'office laboratories'). In dry chemistry pathology technology reagents for a test are contained within single or multiple dry layers on a strip or slide. Addition of the sample to the strip initiates a reaction and the intensity of the colour produced is measured by reflectance photometry. Such analytical systems are convenient for use outside the laboratory, as they are compact, require little or no sample preparation and all the reagents are provided in the strip.

BACKGROUND

The trial was established following a report on dry chemistry pathology tests prepared for Australian Health Ministers (4) which recommended that information on the performance and utilisation of such tests under non-laboratory conditions be obtained through a trial involving both hospital wards and general practices. At that time there had been relatively little use of dry chemistry pathology techniques in Australia. However, the report noted that the introduction of systems to the Australian market had begun, and had been reflected in changes to the Medicare Benefits Schedule as a result of availability of the Ames Seralyzer analyser.

The report also noted:

- the potential for the introduction of such technology outside pathology laboratories to lead to significant changes in provision of pathology services;
- the possibility of new analytical systems being acquired by individual practices, hospital boards and businesses not under the supervision of persons with appropriate laboratory training;
- concern that introduction of such systems within office laboratories could lead to services of lesser quality, with consequences for patient care;
- possible increases in cost to the health care system through proliferation of instrumentation, use of which might be additive to existing pathology services;
- lack of assessment of dry chemistry pathology systems under conditions of non-laboratory usage;
- the importance of appropriate quality control procedures and the possibility that these might be accorded a low priority;

. the need for appropriate training of personnel using the dry chemistry analysers. While to some extent advances in instrument design could take account of lack of laboratory experience, there might easily be difficulties arising from deficiencies in basic analytical technique, specimen handling or analyser malfunction.

ORGANISATIONAL CONSIDERATIONS

As noted in previous reports (1-3), five analytical systems designed for non-laboratory usage were used in the trial:

SERALYZER	-	Ames Division, Miles Laboratories
EKTACHEM DT60	-	Eastman Kodak Company
VISION	-	Abbott Laboratories
REFLOTRON	-	Boehringer Mannheim GmbH
HEMOCUE	-	Aktiebolaget Leo Diagnostics

These systems comprised the dry chemistry analysers available in Australia and a wet chemistry analyser (the Vision) also intended for non-laboratory applications. Although a number of laboratory assessments of the Seralyzer had been reported in the literature, there had been little independent assessment of the other analysers, some of which were only just emerging from the research and development phase.

As a first step, the analytical performance of each of the systems was to be evaluated under laboratory conditions prior to any usage by non-laboratory workers. After this initial phase, use of the analytical systems was to be assessed both in hospital ward side rooms and in general practices. In addition to assessing the analytical performance of the analysers under these conditions, there was interest also in obtaining measures of their utilisation, robustness and effect on patient management.

Because of the perceived need to provide the non-laboratory users with comprehensive back-up support to cover trouble shooting and assistance with quality assurance, both the hospital ward side room and general practice phases of the study were coordinated by pathology laboratories at the Institute of Medical and Veterinary Science, Adelaide; Dandenong and District Hospital, Victoria, and the Repatriation General Hospital, Concord, NSW. This in part addressed another recommendation of the report to Health Ministers that providers of non laboratory tests should register with institutions which would be able to act as referral laboratories for the non-specialist (4).

PRE-TRIAL INSTRUMENT EVALUATIONS

The performance of the five analysers was assessed by laboratory staff at the Institute of Medical and Veterinary Science, Adelaide. Particular attention was paid to the **imprecision** (the distribution of results when repeated analyses are performed on the same specimen) and **inaccuracy** (the deviation or bias of the result from the "true" value).

Analytical imprecision was considered acceptable when the coefficient of variation (CV) was no more than the calculated CV based on twice the median standard deviation obtained for the corresponding analyte by laboratories participating in the relevant Australian Quality Assurance Programme (AQAP).

Analytical inaccuracy was considered acceptable when, in comparison with an established analytical method, the correlation coefficient was greater than 0.950, the slope was between 0.90 and 1.10 and the intercept was less than the standard error of the residual error of regression Syx.

These criteria were seen as representing realistic levels of performance that should be easily achievable by operators of available dry chemistry pathology instrumentation.

Overall, the results of the laboratory assessment were reasonable and all analysers were considered suitable for use by the non-laboratory trained persons who would operate them in later phases of the trial. The criteria were not met in some tests and the lower levels of performance may have been associated with the relatively early stages of development of some analytical systems. In the hands of laboratory operators, departures from the trial criteria were generally negligible and considered to be of little consequence, particularly when put in the context of the median performance achieved by pathology laboratories in the AQAP.

Significant problems existed with a few analytes, notably sodium on the Ektachem DT60, and hospital ward and general practice operators in later phases of the trial were advised accordingly.

Some additional testing was carried out on the Vision and Reflotron analysers to obtain indications of their robustness. The results gave added support to the suitability of these analysers for non-laboratory operators.

HOSPITAL WARD SIDE ROOM STUDY

In the hospital ward side room study two of the analysers, the Ektachem DT60 and the HemoCue, were used by resident medical officers (RMO's) at the Lyell McEwen Health Service, Adelaide over a period of 13 weeks. There was low utilisation of the equipment by all but one of the RMO's concerned.

The reasons for low utilisation have been considered (2). Availability of laboratory services to the wards meant that there was limited incentive for medical staff to conduct their own testing. Removal of such services might have increased utilisation. However, the intention of the trial was to introduce the dry chemistry analysers in a setting which corresponded as far as possible to routine hospital operation. Pressure of other work on the RMO's was a further possible cause of low utilisation although the Working Party has some reason to believe, from anecdotal information, that this may not have been a dominant factor.

More significant reasons were disquiet by the RMO's at the prospect of taking responsibility for results and at having to carry out quality control testing. Use of a different group of medical practitioners to operate the equipment might have produced different results and more extensive data. On the other hand, use of RMO operators would seem to be a possibility in hospital wards particularly outside specialised areas and in remote locations.

The question of who should operate decentralised analytical systems within a hospital is one that will needs careful consideration . It might well have been better, in the context of the trial, for the operators to have included nursing staff. This was not feasible because of determinations at that time by relevant staff associations that operation of such equipment did not form part of nursing duties. Use by non-professionals is a further possibility, but in all cases there will be a need, as identified in pathology laboratory accreditation documentation, for adequate standards of training and performance with supervision by professional staff (5,6).

Some of the analytical performance achieved by the RMO's caused concern. The unacceptable analytical inaccuracy achieved for sodium was not unexpected given the results obtained in the pre-trial instrument evaluations. However, the RMO operators also achieved unacceptable inaccuracy for potassium and the random error achieved for this analyte appeared to be operator-related. There were also systematic errors with unacceptable inaccuracy for measurements of bilirubin and haemoglobin.

Levels of inaccuracy obtained for the other analytes tested, glucose and urea, were acceptable and imprecision was satisfactory in all cases, although levels of imprecision were, as anticipated, more than those obtained during the pre-trial instrument evaluations.

A survey of RMO users of the equipment gave some indication of attitudes to this sort of testing. Some responses revealed a degree of anxiety or lack of confidence in the equipment or the operators' ability to use it, although thorough training had been provided. Possibly some operators would have achieved greater confidence had they operated the equipment more extensively. Such attitudes may give an

indication to hospital administrators of the need for constant training and reassurance of non-laboratory staff undertaking pathology testing. An obvious difficulty is that in many wards there may be a significant turn-over of operators, so that training and achievement of quality assurance could both be challenging tasks.

In some instances the responses obtained from users were ambivalent. The majority of users who responded to a questionnaire considered that analysis of unknown specimens under supervision was helpful in maintaining skills required to use the Ektachem DT60. A majority also considered that performance of tests assisted patient management. However, such responses seemed inconsistent with the reluctance to undertake routine quality control and the low utilisation. It is unlikely that the operators would have been able to assess impact on patient management, given the limited use of the analysers. On the other hand, if they were convinced that the machines did assist in patient management, more use of the technology might have been expected.

Requests by RMO's for 'after hours' laboratory tests decreased during the period of the study. This reduction may have been associated with the presence of the dry chemistry analysers in the ward side rooms. There was a significant increase in ordering out of hours tests, compared to the pre-trial period, after ward testing was discontinued. The reason for this increase is uncertain.

While the hospital ward side room study provided useful experience of the application of dry chemistry pathology in this type of setting, many questions are unresolved. It is not clear from the results of the study that use of such equipment in the decentralised situation would necessarily be of overall benefit in a hospital. Any hospital considering development of such services would need to carefully consider training and accreditation requirements, in addition to the cost of decentralised services as compared with expenditure on laboratory services.

Central laboratory services may continue to provide an adequate basis for routine diagnostic tests in many hospitals. The matter is one which deserves further consideration. It would be of value if a major hospital could conduct a thorough utilisation and cost analysis of the use of decentralised services over several months to establish whether there is a potential for worthwhile advantage over using laboratory services, and if so how this might best be achieved.

GENERAL PRACTICE STUDY

This phase of the trial was designed to assess the usage, standards of performance and impact of dry chemistry pathology testing in general practice. Practices were recruited from areas in reasonable proximity to the coordinating pathology laboratories at Dandenong and Concord.

Detailed information on the trial and technology was provided to participating general practitioners (GP's) at seminars. Twenty eight practices participated in the study.

Utilisation of the dry chemistry analysers was consistent with the modest levels of usual pathology requests by the practices. The pattern of tests performed related to their availability on the analysers but gave an indication of the popularity of lipids, potassium, glucose and haemoglobin. The relatively limited use of the analysers raises doubts as to whether operation of the present generation of analysers will be financially viable for many general practices under current levels of reimbursement and government regulatory requirements.

Under the conditions of the study, the dry chemistry pathology tests were additive to normal pathology services requested, (although in five practices there was a decrease in total pathology tests while the analysers were available). Introduction of the technology therefore increased the amount of pathology testing for the period of the trial. The significance of this is uncertain. It is possible that with a longer period of use some laboratory test ordering would have declined as practices became more confident in the use of their equipment. On the other hand, in some practices there could have been a continued wish to seek reassurance on results of tests performed on the premises, or to monitor patients more closely.

Potentially, use of dry chemistry pathology tests by general practices could reduce the incidence of multiple biochemical analyses requested from pathology laboratories through practitioners more closely identifying the tests needed for individual patients. However, the results from the study did not support such a trend. Overall, pathology tests conducted within the practices did not appear to have an effect on the number of multiple tests ordered through pathology laboratories.

The report on the General Practice Study (3) noted that a new, easy to use diagnostic technology such as dry chemistry pathology may have the potential both to increase the number of relevant investigations and to substitute for older technologies. Any cost savings associated with use of dry chemistry pathology will depend upon the balance of these tendencies and on the cost of the diagnostic and therapeutic decisions generated by the new technology as compared with older methods. Such wider considerations of the effects of dry chemistry pathology testing will require further study.

Availability of dry chemistry pathology analysers in the practices was associated with an increased rate of detection of new cases of hypercholesterolaemia. Availability of the analysers was not shown have an effect on the detection rate of new cases of anaemia. Nor was any effect apparent on the outcomes of hypo/hyperkalaemia in diuretic users or of diabetes mellitus, as judged by biochemical parameters.

The analytical performance achieved by general practice operators caused some concern. Imprecision achieved was acceptable for 18 of 26 tests as judged by the trial criteria. Unacceptable imprecision was obtained for potassium on the Ektachem DT60, triglycerides on the Reflotron and for six of eight analytes on the Seralyzer. Levels of inaccuracy achieved were disappointing, with only three of nineteen tests on the Ektachem DT60, Vision, Seralyzer and HemoCue meeting the specified criteria.

For the assessment of inaccuracy, patients' samples were tested at both the practice and at the coordinating laboratory (split sample analysis). For most of the analytes, an unacceptably high proportion of the differences between the results from the practice and the coordinating laboratory fell outside the Allowable Limits of Performance of the AQAP*. For only 4 of 17 tests did more than 90% of the differences fall within these Limits. Results obtained from analysis of external quality control material supported the results of the split sample analysis and also confirmed the trend, seen in other parts of the trial, that analytical performance tended to worsen when the number of operator - dependent steps in the testing procedure increased.

In the analysis of the inaccuracy (split sample) data, no data points were rejected as the object of the study was to assess the performance actually obtained by operators in the general practices. However, the presence of outliers had relatively little influence on the overall compliance with trial criteria. On rejecting outliers, defined as data points at greater than 4 x Syx from the regression line, only two more tests met the criteria for acceptable inaccuracy. Table 1 shows the tabulated data for those tests.

No difference could be detected between the analytical performance achieved by the four different types of operator in the study - general practitioners, nurses, receptionists and scientists. Similar findings were reported in the study reported by Nanji *et al* (7).

In general, poorer analytical performance was achieved by general practice staff where more elaborate steps were needed to obtain a result, particularly with pipetting, dilution or timing procedures. These results are consistent with those reported by Nanji, Poon and Hinberg (8) who studied the use of the same group of multi-test instruments by nurses, physicians and medical students in an outpatient clinic setting. In that study, the proportion of results differing by more than 10% from those obtained by trained technologists depended on the relative complexity of procedures and was lowest for the Vision and highest for the Seralyzer. Systems such as the Seralyzer which are more complex to operate can give acceptable results in a non-laboratory situation (9) but are more demanding on the less experienced operator.

*The Allowable Limit of Performance is the allowable variation around a target value for a particular analyte and is used to assess the acceptability of results obtained on quality control material by laboratories participating in the AQAP.

TABLE 1

DETAILS OF TESTS WHERE EXCLUSION OF OUTLIERS RESULTED IN ACCEPTABLE ACCURACY

CHOLESTEROL

Ektachem DT60

	n	Slope	Intercept (mmol/L)	Syx (mmol/L)	r
Outliers Out	126	0.920	+0.06	0.28	0.948
Outliers In	128	0.874	+0.30	0.43	0.886

URATE

Ektachem DT60

Outliers Out	43	1.009	+0.002	0.018	0.980
Outliers In	45	1.019	-0.009	0.033	0.925

Attitudes of participating GP's were obtained from a questionnaire answered by 81% of those participating in the study. More that 90% of those who responded rated the training and support provided as at least adequate, and few reported difficulties in use of the analyser or in performing the quality control analyses. Fifty percent reported some problems relating to the reliability of the instrument, most of which were minor.

While 94% of the GP's considered the technology had contributed to patient management, 68% saw the contribution as being minor. Only 37% stated that dry chemistry pathology had fitted easily into the operation of their practices.

Most positive comments focused on the potential of dry chemistry pathology to contribute to general practice and patient care. Most negative comments concerned the time consuming nature of test performance and the interruptions introduced into the practice routine. There were also doubts about the financial viability of such testing. Overall, 57% of participating practitioners were positive or very positive about dry chemistry pathology.

In one practice the nursing staff performing the tests became extremely enthusiastic about the analyser and with their continued enthusiasm the medical practitioners became more

interested in purchasing the equipment after the study was finished.

A survey of patients who were diabetics or diuretic users and who had had a specimen analysed in a practice indicated that 95% rated their experience of use of dry chemistry pathology analysers in general practice as good or very good. These patients regarded normal pathology services less favourably during periods when their general practitioner had access to an analyser.

Performance of tests by general practices was carried out without reimbursement through Medicare. However, all analysers and consumables other than electricity were provided to them at no cost and substantial support was provided by the coordinating laboratories. Financial disincentives to using the analysers were therefore minimised. However, it would be of interest for a follow-up study to be undertaken in general practices operating as accredited laboratories, with services reimbursed through Medicare. Such accredited practices would be regarded as Category 5 laboratories in the classification developed by the National Pathology Accreditation Advisory Council (NPAAC) and adopted in pathology accreditation legislation. In a Category 5 laboratory services are performed only on the patients of the medical practitioner who is the laboratory supervisor.

EXPERIENCE OF THE COORDINATING LABORATORIES

Training and Educational Considerations

During the trial it became obvious that GP's, RMO's, nurses and receptionists required additional training in:

- pipetting and dilution skills
- the need for internal and external quality control
- documentation of quality control analysis
- differences between limits for quality control specimens and analyte reference ranges
- documentation of specimen results
- general cleanliness, disposal of sharps and waste
- specimen collection, including fingerstick specimens
- principles by which the instruments work
- basic trouble shooting, and
- maintenance of analysers.

The experiences of coordinating laboratories in the general practice study suggest that it would take some time for a practice to become self supporting in its management of office pathology testing. Two factors are identified as playing a key role: education and practice organisation.

Most study practice staff, including the GP's, were ignorant of laboratory procedures and techniques. This was not unexpected as specific clinical laboratory training is not necessarily available to medical and paramedical staff in the general practice situation. The office pathology analysers used in the study are relatively simple to operate.

It does not require much time to learn the basic steps required to produce a test result. What takes longer to learn, but is an essential part of operating such equipment, is a knowledge and application of laboratory principles and techniques. Sufficient attention has not been give to the broader educational requirements of those seeking to perform office pathology. The Working Party notes that the Royal Australian College of General Practitioners (RACGP) has recently addressed these issues in educational programs.

Quality Control Procedures

The requirement of the study protocols for quality control testing was regarded as reasonable and certainly not excessive. On entry to the study, all operators had been instructed in the need for testing of quality control specimens, but it became clear that the significance and relevance of quality control testing was not well understood by some.

Operators without laboratory training had little awareness of the sources of random error or bias in an analytical procedure. These persons, therefore, had no appreciation of the need for the performance of internal and external quality control analyses. In the hospital ward side room study 10 out of 19 RMO's would have used the analysers or used them more frequently if it had not been necessary to perform the quality control analyses (2).

Each participating general practice was instructed in the protocol requirements for quality control testing and the coordinating laboratories supplied and delivered the quality control material ready for use. However, even with this level of support only one of the participating practices achieved total compliance with the quality control procedures established for the study and only 11 of 28 practices performed 80% or more of tests in control.

Quality control/assurance caused major problems because many of the practices had difficulty understanding the difference between reference ranges and control values, how frequently the quality control should be run and how to perform dilutions. Duplicates were performed frequently by splitting the sample and sending a portion to the coordinating

laboratory to be analysed in a conventional manner. This helped considerably to improve the confidence of the practitioners in the results they were obtaining. With three practices there was a major problem in convincing operators to use the quality control material as a routine once they had mastered the technique.

One practice, when reminded of the requirement for quality control testing, began to perform all patient tests in duplicate and to call the duplicate sample the quality control sample. Another operator, at a different practice, believed that by testing the quality control material for one analyte all analytes would be 'in control'. Other operators apparently performed testing on the control material but did not record the results on the Clinic Work Sheet until reminded to do so.

In the majority of cases, tests were out of control because of failure to perform the test on the quality control material rather than because a quality control result was outside specified limits. Performance of quality control tests could in some practices have caused interruptions to patient flow, giving a further reason for non-compliance.

It is important in any laboratory setting and in particular in settings where infrequent testing is performed, that the quality of the result obtained is monitored. Educational programs for those performing office pathology testing must emphasise the reason and requirement for quality control procedures, including the testing of quality control material, because of both their importance and their expense.

Support Provided by Laboratories

A high level of support was required from the coordinating laboratories to maintain the performance achieved in the general practice study. Laboratory staff were trained so that they knew the dry chemistry pathology equipment well. The availability of such expertise was communicated to general practice staff. At each co-ordinating laboratory, a Scientific Officer was used on a full-time basis in the support of the practices for the duration of the study. The support provided included:-

- installation of the analyser(s) and centrifuge, if required
- training of operators (in conjunction with the supplier)
- performance of analyser calibrations, as required
- performance of all analyser maintenance procedures, as required
- ordering and supply of reagents and consumables

- performance of all trouble shooting
- liaison with suppliers for service support
- supply and preparation of appropriate internal and external quality control material, ensuring that material was within expiry date when used
- removal of sharps and contaminated waste containers
- provision of data recording sheets and checking on recording of data
- checking on performance of quality control samples
- arranging, at the request of GP's, for patients' samples to be analysed at the coordinating laboratory in cases where the result obtained in the practice appeared doubtful (in addition to the 'split sample' analyses).

The points that had to be considered when introducing the technology were: the practice organisation; the staff using the equipment; and the space and time available to do the testing. In some of the practices there were problems with regard to siting the analyser and centrifuge and in ensuring that dedicated refrigeration was available. The experience of the co-ordinating laboratories covered different types of surgeries from multi practices to single practice. The laboratories kept diaries and many of the day to day problems were noted and followed through.

In addition to the support given by the Scientific Officer, support from the coordinating laboratory was provided when advice was sought by some GP's about comparative reference ranges, method differences and the processing of external quality control samples.

The report to Health Ministers (4) had suggested that ideally office laboratories could make arrangements with local hospitals, government laboratories or private pathologists for equipment and methods of operation to be kept under review by qualified laboratory staff. It was appreciated that such arrangements would require goodwill on the part of the established laboratories and that there could be some logistical difficulties.

From the experience of the coordinating laboratories, provision of support to general practices at the level offered in the trial would not be financially feasible under current arrangements. In addition to the salary of the Scientific Officer, transport was required as many of the trouble shooting problems required on-the-spot attention.

The coordinating laboratories met the costs of reanalysis of patients' samples.

Even if appropriate education has been provided to a practice and the operators are aware of laboratory procedures and carry them out appropriately, situations will arise where the assistance of a central laboratory is needed. Continued visits and monitoring from the coordinating laboratory would be desirable and a source of ready advice concerning quality assurance and the basic matters such as pipetting which are needed in any laboratory are essential in any physician office laboratory arrangement .

In the United States the mentor or co-ordinating laboratory concept has become developed, but it is not clear how this could be easily followed in Australia for non hospital-based office laboratories. The potential for conflict of interest is clear, particularly when the central laboratory may itself be a specialist private pathology practice. There may be less potential for conflict if a public hospital laboratory provides support but this may be neither geographically nor financially possible. A further difficulty is that coordinating laboratories might find themselves in breach of current Commonwealth regulations should they develop a relationship with other pathology practitioners.

Support by Manufacturers

Adequate support for the office pathology laboratory from the company supplying the analyser is essential. In some instances during the trial, difficulties were experienced by the coordinating laboratories with instrument manufacturers' customer support. The back-up by the manufacturers' representatives was generally good. However, telephone consultation and advice by two of the companies at one of the centres was not adequate.

The office pathology situation is a new one for instrument suppliers. Customer support staff have been used to dealing with persons trained in laboratory procedures. With office pathology a different level of support, which is more intensive and more time consuming (at least initially) will be required. Some companies have already responded to this requirement by recruiting additional staff and by devising special procedural manuals, quality control charts and result sheets.

The quality control material used in the trial was that recommended by each analyser manufacturer. Some of the material required reconstitution and some had relatively short stability. Both of these factors could discourage use of quality control material or lead to errors in analysis. To minimise the time required for preparation of material, liquid material of relatively long stability is best, but it must be cautioned that not all such material presently available is suitable for "dry chemistry" technology. Manufacturers of quality control material and organisers of quality assurance programs should consider the expanding market and make available liquid material compatible with dry chemistry technology, packaged in sizes suitable for low

volume use and in appropriate containers such as dropper-type dispensers.

Responsibilities of Office Laboratories - Safety and Liability Considerations

The nature of the trial protocol required a high level of laboratory support for the general practice and hospital ward operators. In the more usual situation, under non-trial conditions, it would be expected that the operators themselves would assume many of the functions performed by the study Scientific Officer.

It would be reasonable to expect installation and training to be provided by customer support staff of the company supplying the analyser and basic trouble shooting undertaken by the operators themselves, with resort to service support when necessary by direct communication with the company. In addition, the practices would be responsible for the ordering and appropriate storage of supplies, the choice and preparation of internal quality control material as well as enrolment and participation in an external quality assurance program. Basic cleanliness of the laboratory area would be expected, with appropriate arrangements for disposal of sharps and contaminated waste. Preparation of laboratory manuals, performance and recording of maintenance and service procedures as well as appropriate recording of test results would also be required.

As a result of the requirements of the study protocol, the involvement of practice operators in such duties was not onerous and hence it was of concern that the limited number of procedural requirements were not met in some cases. The failure of most practices to perform tests 'in control' has already been discussed. Recording of patients' and quality control results was not performed consistently by a number of practices. Some practices did not maintain the laboratory area in a hygienic state nor were some of the analysers and appropriate equipment kept clean, which led to equipment failure in some cases.

All the general practices involved in the trial were busy ones and a number of GP's expressed doubt about the additional time taken to perform office pathology testing. Some commented that without the support of the Scientific Officer, they would have withdrawn from the study. In this situation, it is likely that apparently 'unimportant' procedures, such as result recording, maintenance of cleanliness and tidiness, performance of tests on quality control specimens, and analyser maintenance could receive a lower priority than the performance of the test on the patient's sample. Individual practices contemplating introducing office pathology should consider how such testing could be integrated into practice routine without compromising appropriate operational procedures.

Work in an office laboratory has its own risks. Safety must therefore be a concern for physicians, nurses and other staff. Such items as hand-washing, working with cut hands, and food, drink, cosmetics and cigarettes in the testing area are all matters to be addressed. Hepatitis vaccination, avoidance of needle sticks, pipetting techniques and the use of centrifuges require documentation and education. Routine cleaning and disposal of laboratory reagents and other materials are all important.

The director or designated laboratory supervisor assumes liability when a test is performed by an office worker. Such employees need to have appropriate job descriptions and must work within the scope of their employment. The office laboratory supervisor must ensure that the equipment is calibrated, records are kept, controls and quality assurance specimens are run, and that specimens are properly handled.

With regard to errors, office laboratories must be able to show that they have taken reasonable care to identify the problems through daily quality control testing and if an error is made, be able to show that patient care was not knowingly compromised. If patient data are released and later found to be incorrect, the patient should be contacted and told of the error and appropriate retesting should be done. Proper patient contact and discussion is important.

Practices which are considering the purchase of dry chemistry pathology equipment should be aware of safety requirements. These would be closely considered during the accreditation procedure.

DEVELOPMENTS WHILE THE TRIAL WAS IN PROGRESS

Technical Developments

Relatively few new instruments for this type of market emerged while the trial was in progress. Overseas, substantial distribution of the HemoCue, Reflotron, Ektachem DT60 and Vision have occurred in the non laboratory sector, while the Seralyzer, which was introduced earlier than the other analysers, has continued to be widely used by such operators.

The range of analytes available to the multi-test analysers used in the study have continued to develop since the trial began. More analytes are now being offered and there have been various improvements to the quality of certain tests.

Newer machines are starting to reach the market but in part industry may be waiting to assess the requirements of operators based on the experience gained with the earlier generation equipment. An instrument intended to replace the Seralyzer has been developed by Ames. Bio-Chem Laboratory Systems Inc has produced the ATAC series of wet chemistry systems, at least one of which is being operated in general practice in Australia, (B. Hardie, personnel communication).

There has also been considerable developmental work and introduction of new products in the area of diagnostic kits, many based on monoclonal antibody technology. The Working Party suggests that appropriate critical assessment of newer analytical systems should be carried out before any widespread use by non-laboratory operators. Ng et al have drawn attention to the need for pipetting skills in using the Du Pont Analyst System (11).

Introduction of Pathology Laboratory Accreditation

Since the proclamation of the Commonwealth Health Legislation Amendment Act 1986, all pathology services for which a Medicare Benefit is paid must be provided by an accredited pathology laboratory. In addition, pathology services must take out Approved Pathology Practitioner (APP) and Approved Pathology Authority (APA) undertakings for such benefits to be payable.

The current arrangements require the laboratory to apply to the Commonwealth for accreditation and pay the prescribed fee. This application is evaluated by the Commonwealth Department of Community Services and Health and provisional accreditation granted if the laboratory has also applied to a designated inspection agency.

The National Association of Testing Authorities (NATA) has approval to inspect all categories of laboratories in all States. The RACGP is approved to inspect Category 5 facilities in Victoria. Details of the costs of accreditation for Category 5 laboratories and of APP and APA undertakings are given in Table 2.

NATA has conducted a number of both preliminary visits and full inspections of doctors' office facilities. Some practitioners have been advised to withdraw their applications on the basis of preliminary visits. NATA has noted that common faults in Category 5 laboratories include lack of supervision of staff and the failure to understand preparation of patient and specimen, test procedures, quality control, external quality assurance, record keeping, laboratory housekeeping and safety (11). All these faults were noted in the general practice study by the co-ordinating laboratories.

A result of the introduction of these arrangements has been a drop in the number of persons holding APP status from 3350 (July. 1986) to 1456 (February, 1989). Many persons who were previously APP's would have potentially been associated with office pathology testing. Some practitioners, who for economic reasons let their APP status lapse, may have continued to test their patients and claimed under Division 9 of the Medicare Benefits Schedule, which covers basic side room tests and is exempt from accreditation requirements.

TABLE 2

COSTS OF CURRENT COMMONWEALTH PATHOLOGY ARRANGEMENTS FOR CATEGORY 5 FACILITIES

Requirements	Cost	Period
APP Undertaking	$100	Annual
APA Undertaking	$100	Annual
*Accreditation Fee (Commonwealth)	$200	Annual

INSPECTION COSTS

NATA Inspection Costs	"Remote"	"Local"
Year 1 all inclusive fee (if inspected in year 1)	$1135	$1030
Subsequent Years prior to registration (Admin Fee)	$475	$430
Following Registration	$527.50 p.a.	$480 p.a.
RACGP Inspection costs		
Existing Applications	$425)	) per inspection
New Applications	$500)	

EXTERNAL QUALITY ASSURANCE PROGRAMS

Chemical Pathology	$320
Haematology	$160
Microbiology and Serology Dipstick Chemistry and Pregnancy Test	$50
Serum IM and RA	$70
Urine Culture and Microscopy Rapid Streptoccal Test	$100

*The Commonwealth accreditation fee drops to $50 p.a. once an acceptable State accreditation scheme is operating.

Pathology accreditation arrangements have imposed both financial and technical restraints on use of dry chemistry analysers. It is possible that numbers of such services may increase as sufficient practices acquire greater competence and training, and obtain adequate workload to justify capital, consumable and regulatory expenditure.

The experiences with the dry chemistry pathology trial, and those reported by NATA, indicate the need for accreditation of operators of the present generation of dry chemistry pathology systems. There are, however, three areas where present accreditation measures are either inadequate or could be inappropriate.

The first of these is the limited coverage of the Commonwealth scheme, which applies only to those services for which Medicare Benefits are claimed. Wider coverage will not be achieved until State Governments introduce complementary accreditation requirements. Such action is pending in Victoria but appears to be some distance away in other States. Because the present accreditation requirements do not apply to all pathology services there is at present no control of dry chemistry tests that are offered in a number of settings - for example in health clubs or in shopping centres. The Working Party has drawn attention to this lack of control and consequent concerns in view of the recent increase in the numbers of non-regulated operators offering cholesterol testing and other services to the general public (12). There is at present no way of knowing whether such services meet adequate standards, whether the results produced are beneficial or detrimental to patient health or if questions of safety and potential liability have been considered by the operators.

The second possible area of concern is the cost of accreditation - a matter of some controversy. An accreditation system linked to inspection of pathology services is seen as essential by various authorities and professional bodies and the Working Party would share that view. However, such a scheme inevitably has costs associated with expenses of assessors and processing of data. Such costs (detailed in Table 2) provide a disincentive for the smaller operator with a low potential workload. On the other hand, accreditation of services is applied very widely to small facilities in non-medical areas of laboratory testing. The Working Party also considers that if office laboratories do not carry out sufficient tests to readily cover the costs of dry chemistry analysers there must be some question as to whether they can readily reach and maintain adequate levels of competence.

There will be challenges for the accreditation process in dealing with the problems of multiple, relatively unsupervised users of dry chemistry pathology equipment. High staff turnover may be a reality in some practices and clinics. Opportunities for inspection visits will be limited and the training responsibilities of supervisors will be

demanding. The Working Party suggests that continued appraisal of the costs and benefits of accreditation of office laboratories is required.

The third possible area of concern is that accreditation may not be readily applicable or necessarily appropriate to future office pathology testing which involves use of other technologies such as monoclonal antibody-based kits. This is likely to be an emerging area of some complexity which deserves detailed consideration by accreditation authorities, NPAAC and the National Health Technology Advisory Panel.

FURTHER MATTERS ARISING FROM THE REPORT TO HEALTH MINISTERS

It is of some interest to consider other aspects raised in the original report on dry chemistry pathology tests (4).

That report's recommendation on quality control procedures has now been met through the introduction of accreditation, subject to the limitations noted above. These requirements also cover the recommendation that provision of hard copy reports be mandatory for all providers of pathology tests, including those carried out using ward and office-based analytical systems.

The report also discussed reimbursement for dry chemistry pathology testing and suggested that the items then in the Medical Benefits Schedule be reviewed. This is an area which has been subject to detailed appraisal by the Commonwealth Government over the last few years and discussion on this complex area is still proceeding.

The question of provision of educational material for non-specialist operators of pathology testing equipment has been addressed by the NPAAC and the RACGP. In addition, NATA has continued to develop documentation associated with inspection of facilities. The question of referral or reference laboratories for the non-specialist remains unresolved. The desirability of such expert support is at present more than offset by uncertainties as to cost, possible conflict of interest and perceived potential competition between the non-specialist and the laboratory. Reference laboratories in the hospital setting are, however, eminently feasible and in many cases hospitals are already providing support for ward testing through their laboratories.

The issues raised in the report to Health Ministers on suitable assessment of analytical systems continues to require discussion and formulation of a workable plan for Australia. The report suggested that there was a need for national technical reference laboratories. Suitable assessment of analytical systems for non-laboratory use prior to their widespread introduction in Australia may well be desirable, but it is difficult to see how this could readily be achieved at present by government organisations.

Involvement of professional bodies might provide a useful means of conducting such work.

The report made the point that the dry chemistry pathology analysers had to be viewed as part of a wider trend arising from availability of lower capital cost, easy to use systems based on various types of technology and applicable to other areas of pathology. While decentralised testing has so far been dominated by biochemistry analysers, the Working Party suggests that this is likely to change with the progressive introduction of easy-to-use systems aimed at other divisions of pathology including microbiology, haematology and immunology. The overall place of such additional tools for the non-laboratory pathology provider will require further detailed consideration in the context of Australian health care system.

EFFECTS OF DECENTRALISED TESTING ON PATHOLOGY LABORATORY STAFF

During the hospital ward side room study there was strong disquiet on the part of some coordinating laboratory staff at decentralised testing equipment being operated by non-laboratory personnel. This was seen as having the potential to remove workload from the regular pathology facility with downstream consequences for employment and 'out of hours' duties of laboratory scientists and technicians.

While these concerns were resolved within the context of a brief trial this reaction from some laboratory professionals points to the need for there to be adequate consultation by hospital administrators with laboratory and other staff prior to the introduction of any decentralised testing. In contrast, in the general practice study, co-ordinating laboratory staff took an active interest in the testing by practices, communicated well with the practice staff and showed understanding of their problems. Any critical perceptions of a threat to job security of laboratory staff did not continue as the study progressed.

In a sense, the advent of dry chemistry desktop analysers is only an additional step in the progressive de-skilling of some aspects of the duties of professional staff in pathology laboratories. It may be that to some extent pathology laboratories will in the future focus on more specialised testing and that some routine tests will be carried out closer to the patient by non-specialists, although possibly under supervision by laboratory staff.

There would, however, seem to be limitations as to how many additional specialised tests will be required of the pathology industry. The list of potential analytes is virtually open-ended but the numbers that may be routinely used in achieving substantial gains in patient management may be rather limited. The Working Party sees the effects of office pathology testing on laboratory staff as a sensitive area which will require careful consideration and discussion

between unions, health authorities, professional bodies and administrators.

CONCLUSIONS

The dry chemistry pathology trial has helped to assess the potential of this type of technology in the provision of routine diagnostic services in Australia. The various analysers used in this work are well designed analytical instruments capable of giving excellent results in the hands of laboratory-trained operators. From the results obtained in the trial it was apparent that such levels of performance may not be readily achieved by the less experienced operator, particularly when any significant manipulative stages are involved in obtaining a result.

The trial provided some indication of patterns of usage of dry chemistry pathology equipment by operators in general practices and hospital ward side rooms. These data are regarded as useful, but further work is required to describe the utilisation of this technology in Australia. More importantly, there is a need for critical appraisal of the costs and benefits of dry chemistry pathology in the non-laboratory situation, taking account of usage rates and operating costs, but also effects on other services, patient management and health indicators.

The place of non-laboratory pathology testing in Australia, using dry chemistry and other types of technology, remains uncertain. From the perspective of the general practitioner and other office laboratory operators, there are significant costs associated with requirements for accreditation, registration and quality control programs, in addition to capital and operating expenditure.

It is possible that many office laboratories would perform relatively small numbers of tests. Low utilisation would increase costs to the practice and potentially decrease quality of service through decreasing levels of operator competence. Assurance of operator competence would be especially difficult in situations where there was high turnover of staff. These difficulties, and the ready availability of high quality pathology services in most centres of population may encourage general practices to continue to request tests from laboratories, rather than performing these themselves.

On the other hand, the potential remains for office pathology testing to provide benefits through improvements in patient management and increased convenience through not having to refer specimens to another centre. There also continue to be substantial attractions in the use of dry chemistry pathology in remote areas, where access to laboratory pathology services is difficult.

On the basis of the experience from the trial the Working Party makes the following recommendations and suggestions:

- While further developments are occurring in equipment and kits intended for non-laboratory pathology testing, effective use of such technology will require suitable education and back-up for operators. Without the discipline imposed by regular performance of quality control checks and other measures, it is most unlikely that persons without laboratory experience would be able to consistently achieve levels of analytical performance necessary to provide a useful service to their patients.

- The efforts by the Royal Australian College of General Practitioners to develop educational programs for office pathology work are supported. The National Pathology Accreditation Advisory Council (NPAAC) and the National Association of Testing Authorities should give continued consideration to the provision of such material to non-laboratory operators.

- Without the checks imposed by accreditation much usage of dry chemistry testing could incur an additional cost to the health care system and possible risk to patients without any discernible compensating benefit. With regard to future accreditation of office pathology services, it is recommended that :

  - accreditation of services operating dry chemistry pathology analysers should be mandatory;

  - governments should take necessary steps to provide complementary accreditation provisions to those of the Commonwealth, to cover all operators of dry chemistry analysers, except for the self-testing situation;

  - the costs, coverage and effectiveness of accreditation programs for office pathology laboratories be kept under close review by health authorities, the NPAAC and appropriate professional bodies; and,

  - the feasibility and suitability of applying accreditation provisions to use of other pathology technologies in the non-laboratory situation be considered by the NPAAC.

- In addition to taking suitable steps through the accreditation process to ensure quality of performance, users and potential users of dry chemistry pathology should consider critically the true value and costs of this type of diagnostic technology. The place of decentralised testing needs thorough evaluation on a case by case basis, taking into account the requirements of the areas concerned and the costs and availability of

diagnostic services by pathology laboratories. The broader perspective of non-laboratory testing will need to be kept under review by appropriate agencies.

- Results on the effects of the technology on patient outcome, as measured by clinical chemistry indicators, were inconclusive for three of four selected conditions. This topic deserves further attention. A follow-up study of dry chemistry pathology by accredited general practices, including appraisal of effects on the health status of patients would be desirable. The Working Party would also support a more extensive study of the costs and effectiveness of dry chemistry pathology usage in hospital wards.

- Manufacturers and organisers of quality assurance programs should make available quality control material for use by office pathology operators which is in liquid form, suitably packaged and easily accessible, and compatible with dry chemistry technology.

- The development of a network of 'mentor laboratories' to support non-laboratory pathology testing would present major financial, organisational and regulatory difficulties. It is suggested that the NPAAC might wish to consider means of overcoming such impediments to provision of expert technical advice and support.

- Non-laboratory testing has the potential to affect the workload and employment conditions of staff in laboratories. This sensitive area will require careful consideration and discussion between the interested parties concerned, including unions, government agencies, professional bodies and administrators.

- The assessment of analytical systems for non-laboratory use prior to their widespread introduction in Australia is a matter which continues to require consideration by relevant government organisations and professional bodies.

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