Non laboratory pathology testing

A report by the

National Health Technology Advisory Panel

November 1990

Australian Institute of Health

NON LABORATORY PATHOLOGY TESTING

A report by the

National Health Technology Advisory Panel

This report was prepared by the National Health Technology Advisory Panel (NHTAP) and finalised by the interim Australian Health Technology Advisory Committee. Any comments or information relevant to the subject matter of the report would be welcome. Correspondence should be directed to:

The Secretary
Australian Health Technology Advisory Committee
Australian Institute of Health
GPO Box 570
CANBERRA ACT 2601

Researchers:

Mr AR Lea and Dr DM Hailey

November 1990

NON LABORATORY PATHOLOGY TESTING

ISBN 0 642 15825 8

Australian Institute of Health

NATIONAL HEALTH TECHNOLOGY ADVISORY PANEL MEMBERS

The membership of the Panel during preparation of this report was

Dr John Deeble (Chairman)	Health Services Fellow, National Centre for Epidemiology and Population Health, Canberra.
Dr David Hailey	Head, Health Technology Unit, Australian Institute of Health, Canberra
Ms Dallas Ariotti	Assistant Secretary, Health Care Evaluation Branch, Commonwealth Department of Community Services and Health, Canberra
Dr Brendon Kearney	Administrator, Royal Adelaide Hospital, Adelaide
Dr Allan Passmore	Secretary-General, Australian Medical Association, Canberra
Dr Nicola Ward	Strategic Planning Executive, Cochlear Ltd, Sydney
Ms Sophie Hill	Coordinator, Health Issues Centre, Melbourne
Mr Richard Warwick	Research Officer, Hospital Employees Federation, Launceston
Dr John Morris	Chief Executive Officer, Peter McCallum Cancer Institute, Melbourne
Mrs Helen Owens	Economist, Australian Hospital Association, Melbourne
Dr Ian McDonald	Director, Cardiac Investigation Unit, St Vincent's Hospital, Melbourne
Dr David Dewhurst	Consultant Bioengineer, Portarlington, Victoria.

Secretariat

Dr D E Cowley

Mrs N Hirsch

CONTENTS

EXECUTIVE SUMMARY

- There has been continued development of analytical systems intended for provision of pathology tests outside the laboratory setting. Such systems include low capital cost analysers and also kits which do not require use of instrumentation.

- Use of non laboratory pathology testing (NLPT) has become popular in a number of countries, but in Australia less than one per cent of pathology tests for which Medicare reimbursement is claimed are performed outside the laboratory.

- Results from studies in Australia and other countries indicate that levels of analytical performance achieved with NLPT can be unacceptable, particularly if appropriate training and quality control measures are not put in place.

- Australian data suggest that general practitioner office pathology could result in a net increase in pathology services and increase costs to the health care system.

- Pathology laboratory accreditation schemes cover all NLPT laboratory settings, except home testing, in Victoria, and all services for which a Medicare benefit is payable in the rest of Australia. The Panel considers that all NLPT, with the exception of self testing, should be required to meet the accreditation standards developed by the National Pathology Accreditation Advisory Council(NPAAC). This would require State and Territory governments to introduce complementary accreditation provisions.

- Educational and quality control programs for non laboratory operators have been developed by the Royal Australian College of General Practitioners in association with the Royal College of Pathologists of Australasia and the Australian Association of Clinical Biochemists. The Panel sees a need for the expansion of suitable educational material for providers of pathology tests who have not had appropriate training.

- Application of accreditation provisions to performance of tests using kits may not be appropriate. Assurance of effective performance of such products may require increased attention to manufacturers' quality control linked to testing and assessment by appropriate agencies.

- The Panel considers that while NLPT has potential value in improving diagnostic services, its overall benefit in most situations remains unclear and may be marginal.

The Panel recommends that:

- Accreditation provisions be extended to cover all non-laboratory operators of pathology analysers and that health authorities give consideration to the means of achieving this objective.

- The NPAAC consider and report on the feasibility and usefulness of accreditation provisions covering the use of diagnostic kits by persons without appropriate training.

- Mechanisms be established to ensure that diagnostic kits are tested to determine whether the specifications and label claims are met. The Commonwealth Department of Community Services and Health might consider development of such an approach in association with relevant professional bodies.

- The NPAAC, the National Association of Testing Authorities, the Royal Australian College of General Practitioners, other relevant professional bodies and equipment manufacturers give continued consideration to the preparation and distribution of educational material for providers of pathology services who have not had appropriate training.

- Further work is undertaken to obtain measures of the costs and effectiveness of NLPT, and that this area of pathology testing is kept under critical review by professional bodies and health authorities.

INTRODUCTION

The National Health Technology Advisory Panel (NHTAP) participated in 1983/84 in the preparation of a report to Health Ministers on 'dry chemistry pathology tests', following a recommendation made by the Australian Health Ministers' Conference (1). That report considered the emergence of dry chemistry technologies used in clinical chemistry analysers intended for use outside the laboratory, but also touched on wider questions of non specialist pathology testing.

One of the recommendations of the report was that information on the performance and utilisation of dry chemistry tests under non laboratory conditions be obtained through a trial. Such a trial was established following provision of funding in the Federal Budget of 1984 and supported by a Technical Committee of the NHTAP. The results have given further indications as to the possible future of non laboratory pathology testing (NLPT) in this country (2-5).

The Panel also saw a need for a more broadly-based report to take account of not only dry chemistry and other 'doctor's office' biochemistry analysers, but also developments in decentralised testing in other divisions of pathology and the implications for home testing in Australia. The present report considers recent developments in both instrumentation and diagnostic kits which allow persons who have not been trained in a laboratory to perform pathology testing without a great deal of sample preparation.

TRENDS IN NON LABORATORY PATHOLOGY TESTING METHODOLOGY

There is a trend in the development of pathology instrumentation and kits towards reducing any operator manipulations or decision making requirements such as estimation of colour changes during a chemical reaction. The report to Health Ministers (1) indicated that the introduction of dry chemistry technology was part of a wider trend arising from increased availability of lower cost, easy to use systems which could be based on various types of technology. It was noted that the combination of new chemistries, improved packaging and availability of microprocessors had made possible the development of low capital cost pathology testing systems. A further significant factor is that the reagents for new equipment or kits can be manufactured reproducibly on a very large scale.

There have been two major approaches to provision of decentralised pathology testing. The first of these is the development of relatively cheap instruments that can perform commonly required tests.

The instrumental methods include microprocessor controlled systems utilising dry chemistry (carrier bound) technology and conventional wet chemistry technologies. Typically, the slide or cartridge containing the reagents for a pathology test is bar coded so that the microprocessor can recognise the test and establish relevant parameters for operation of the analyser. With some instruments it is necessary for the operator to pipette the sample. Some instruments only accept plasma specimens.

The second approach involves the development of simple, specific kit procedures which require no capital outlay for instrumentation. Such kits are commonly based on antibody technology, usually monoclonal antibodies(MCA's), and have high specificity. Commonly, the result of a test with such kits is indicated by presence or absence of a colour change. While no instrumentation is required, the cost per test may be considerably higher than that for a slide or cartridge used in a 'desktop' instrument.

Monoclonal antibodies can be used to detect virtually any molecule with antigenic capacity. Typical applications of this technology have been in the detection of pregnancy, in occult blood test kits used to screen for colorectal cancer, in monitoring or detecting conditions such as throat or urinary tract infections and in the monitoring of therapeutic drug levels. Detection of sexually transmitted diseases has been an area of particular interest, and several companies have developed kits for this application.

NLPT has become popular in some countries, particularly the USA. Some details of overseas usage of these technologies are given in Appendix 1.

THE PROVISION OF PATHOLOGY TESTING IN AUSTRALIA

Pathology services in Australia over the last three decades have increasingly been provided by large centralised laboratories. The great bulk of laboratory services is performed in laboratories under the control of pathologists and senior scientists with emphasis on automated testing, especially in the areas of biochemistry and hematology. Approximately 70 percent of the specimens are analysed at public hospital laboratories (6). The trend towards complex, automated, centralised services has been associated with a reduction in cost per test, and a steady increase in numbers of tests and overall costs of pathology services. Development of information and courier systems have to some extent led to a distancing of pathology services from referring doctors and their patients.

Some pathology testing is performed in hospital wards, particularly through use of blood gas analysers, bilirubinometers and glucose meters. Large hospital laboratories have responded to a demand for continuous availability of results by creating sections that operate on a 24 hour shift basis.

At present, only about one percent of pathology tests for which Medicare reimbursement is claimed are being performed in general practices and other non-laboratory settings.

For the purposes of reimbursement under Medicare and accreditation, pathology tests performed by medical practitioners who are not pathologists fall into two groups. The first comprise simple 'side room' tests for which separate reimbursement is not claimed. These include various simple hematology procedures, microscopy and immunochemical methods.

The second group of tests are those for which reimbursement is claimed against items within the main body of the pathology services table of the Medicare Benefits Schedule. For such tests to be eligible to attract reimbursement they must be performed in 'office laboratories' which meet the pathology accreditation requirements shown in Appendix 2.

The possibility also exists for the diversification of NLPT outside the medical system with testing being performed by commercial screening groups, health clubs, gymnasiums and pharmacies. In particular, cholesterol screening services are thriving due to publicity in the media and vigorous marketing. An increase in home testing seems possible, although at present in this country only blood glucose tests are being conducted in any numbers in the home.

STUDIES OF THE RELIABILITY OF NON LABORATORY PATHOLOGY TESTING

In the Australian dry chemistry pathology trial the analytical performance of five types of instrument was assessed when used by resident medical officers in hospital wards (3) and by general practice staff (4). Accuracy and precision of the instruments had been shown to be acceptable when operated by laboratory staff (2). Both the precision (the distribution of results when repeated analyses are performed on the same specimen) and accuracy (the deviation or bias of the result from the 'true' value) were determined.

In the hospital ward study, precision achieved was acceptable for all tests, but accuracy was acceptable only for measurement of glucose and urea. In the general practice study, levels of analytical precision achieved were acceptable for 18 of 26 analytes while only 3 out of 19 tests were considered acceptable for analytical accuracy(4).

Similar findings have been reported by Nanji, Poon and Hinberg (7,8). Leese and Hutton(9) also found cause for concern at the variation in analytical performance achieved by untrained users. Sandberg et al (10) reported unacceptable accuracy for a number of analytes in an external quality control program of dry chemistry instruments used in primary health care. Bain et al (11) found that out of 552 paired samples (results produced by nurses and a laboratory) 37 percent differed from the true result by more than 15 percent.

Although many MCA-based kit products now include built-in controls to indicate whether the reagents are added in the correct order, false negative results have been observed for chorionic gonadotropin (12,13,14). Tests for fecal occult blood can give false positives in the presence of dietary hemoglobin or peroxidase activity from vegetables (15).

False negative results with MCA-based pregnancy kits resulting from the use of old urine or the presence of detergent in the urine container have been reported by Smith, Rustin and Bagshawe(16). False positives may also result from the ingestion of drugs such as phenothiazines, from heavy proteinuria or hematuria, or from raised human gonadotrophin concentrations associated with other conditions. A

false positive result may lead to a conception or delay in the diagnosis of a more serious condition, such as cervical cancer, where increased beta-HCG levels can occur (16).

Incorrect results from use of a kit will tend to reflect shortcomings in the product, but may be more probable and less readily recognised when the test is conducted outside a laboratory.

ACCREDITATION AND QUALITY ASSURANCE FOR NON-LABORATORY TESTS

On the basis of results and experience of the dry chemistry pathology trial, the Non Laboratory Testing Working Party of NHTAP recommended that all services operating office pathology analysers should be required to meet mandatory accreditation standards(5). It also recommended that the National Pathology Accreditation Advisory Council (NPAAC), relevant professional bodies, the National Association of Testing Authorities (NATA) and instrument suppliers prepare suitable educational material and programs for the non laboratory operator. The need for appropriate material for external quality assurance programs was also recognised. Continuing education programs, designed as reinforcement for persons without appropriate training, are necessary for these persons to maintain an acceptable level of performance.

The Royal Australian College of General Practitioners (RACGP) has developed an education program on office pathology in association with the Australian Association of Clinical Biochemists (AACB) and the Royal College of Pathologists of Australasia (RCPA). An external quality assurance scheme which covers biochemistry, hematology and microbiology has been produced by the RACGP and the AACB.

As part of the Australian accreditation program, NATA has conducted a number of inspections of 'doctors office' pathology facilities. Some practitioners have been advised to withdraw their applications for accreditation on the basis of preliminary visits. NATA has noted that common faults in such facilities 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. All these problems were noted in the NHTAP general practice study(4).

In the Australian trial there was a general lack of appreciation by non-laboratory operators of the need to perform quality control procedures(4). In the general practice study only 11 out of 28 practices performed 80 per cent or more of their tests within control. Burrin and Fyffe (17) conducted a survey of the pathology instruments held outside the hospital laboratories in the North West Thames Region, UK. In the 14 hospitals that responded, 220 glucose meters, 22 blood gas analysers, 13 bilirubin meters and six instruments for determining sodium and potassium levels were identified. In the majority of cases little control was exerted over the operation and quality control of the analysers by the hospital laboratories. Burrin and Fyffe found that less than 50 per cent of blood gas and bilirubin meters were operated with the appropriate quality control procedures while less than 25 per cent of glucose meter operators followed the quality control regimens.

The NPAAC resolved that any test for which a Medicare benefit is payable should not be exempted from the accreditation process. This recommendation exceeds the current Commonwealth arrangements as tests performed from the Division 9 section of the Medicare Benefits Schedule ('side room tests') would also be included. The inclusion of MCA-based kit methods in the accreditation system also presents some difficulty. The steps required to perform the tests are very simple, and many kits will give only qualitative results.

Present accreditation arrangements might require inspection of a doctor's office which was using kits by a team of three persons, with a half day inspection fee. This would seem excessive. The level of scrutiny of the quality control and documentation required of such a team would usually be trivial if only kit-based pathology tests were being undertaken. However, there is a need for assurance that these products produce reliable results in an NLPT situation. Possible approaches would be to have a much smaller inspection unit or to have some form of regulatory testing to ensure that the relevant products are observed to work reliably when marketed.

The importation of diagnostic kits is covered under the Therapeutic Marketing Goods Act 1966 and in principle these products could be examined for compliance with the manufacturers' specifications. This could imply an expansion of the testing resources of the Commonwealth Department of Community Services and Health to cover such diagnostic kits. An alternative might be for the Commonwealth to obtain the assistance of professional bodies, such as the RCPA, AACB, Australian Institute of Medical Laboratory Scientists (AIMLS) and the Australian Society for Microbiology (ASM) in performing this testing. Such testing could not of course cover all production batches and would not guard against use of incorrect storage conditions or use of the kits beyond their expiry dates.

RECENT DEVELOPMENTS IN NON LABORATORY PATHOLOGY TESTING

Since the introduction of this technology in Australia this type of testing has been adopted by general practitioners, pharmacists, dentists, community health services, naturopaths, chiropractors, occupational health facilities, and commercial screening groups.

Table 1 shows the numbers of instruments that are currently being used by non trained personnel and the number of these 'office laboratories' which are accredited under Commonwealth legislation.

TABLE 1
NUMBERS OF OFFICE PATHOLOGY ANALYSERS BEING USED IN NON LABORATORY SETTINGS IN AUSTRALIA.

	Clinical chemistry	Hematology	Accredited premises
GPs	398	1	214
Others	453	300*	-

* Includes hemoglobinometers.
Source: Commonwealth Department of Community Services and Health

The Panel understands that the accredited premises are enrolled in appropriate quality assurance programs, and that acceptable results have been obtained in these by a number of office laboratories. It appears that participation in accreditation and quality assurance arrangements may be helping NLPT operators to attain acceptable standards, but data from the programs run by the RCPA, AACB and RACGP are not made generally available. It would be desirable for a detailed presentation and analysis of results from the quality assurance programs to be published at some stage.

Approximately 180 general practitioners are operating pathology analysers instruments and charging the patients for tests directly. As the practitioners' premises are not accredited, these patients are not eligible for rebate from Medicare for these services. Except in Victoria, such practices are not required to meet accreditation standards. It is possible that these general practitioners are participating in quality control programs, and producing acceptable results, but it is also possible that inspection would reveal limited understanding of pathology testing and poor technique.

The other groups which are performing testing would also need to rely on the instrument suppliers for a quality control service. Some naturopaths and chiropractors are using microscopes fitted with video cameras, and on the basis of results from dark field illumination on unstained blood films are prescribing mineral supplements (Maynard, personal communication). The testing being performed at community health centres is mostly of a screening nature.

POTENTIAL BENEFITS AND DIFFICULTIES

Several authors have seen the increased use of office laboratories as inevitable, as technologies capable of performing relatively complex assays come within the technical and economic reach of even small pathology services. Widely quoted potential benefits of non laboratory testing include a closer relationship between doctor and patient, elimination of laboratory overheads, prompt feed back of results, greater patient convenience, decreased costs and advantages for testing in remote sites. The common presumption is that application of near-patient testing will achieve benefits in terms of quality of life and influence on patient management and outcome.

It has been noted that evidence to support the existence of such benefits still appears very limited, and must to an extent be qualified by concerns as to the level of competency of providers of near-patient testing services(18). Proof of effectiveness has been slow to emerge, and most reports of benefit from near-patient testing rely on relatively soft data. Near patient testing in some hospital acute care settings has proved helpful in patient management. Suitably supported self testing of glucose levels by diabetics is widely considered to be beneficial.

White et al(19) reported a randomised prospective study of home prothrombin time monitoring compared with clinic testing following initiation of warfarin therapy. They concluded that patients

undertaking home monitoring can achieve superior anticoagulation control to those with standard hospital and anticoagulation clinic care.

Some studies have been unable to demonstrate benefit. Newman, Lagua and Engelbrecht(20) found no differences over a three year period between the glycohemoglobin levels of diabetics who self monitored and those who did not measure their glucose levels. They concluded that the self-monitoring of blood glucose alone did not influence the degree of glycemia in those patients. In the dry chemistry pathology trial(4) objective changes in disease measures for diabetics, persons with anemia and those taking diuretics were not observed.

The question of a closer relationship between the patient and medical practitioner was not specifically addressed in the Australian study. However, two groups of general practice patients surveyed were strongly supportive of office pathology and rated specialist pathology laboratory services less highly when the analysers were available to their GP's. Such a preference for office pathology may be attributable to the convenience of not having to go to a collection centre or wait for the results of tests. There may also be downstream economic benefits to the patients, resulting for example from savings on absences from work and transportation costs.

The perceptions of the general practitioners participating in the Australian study were less positive. Most (68 per cent) considered that desktop pathology made only a minor contribution to patient management, and only 37 per cent thought that the dry chemistry analysers fitted easily into the operation of their practices. A common comment was that the use of the analysers interrupted the flow of patients through the practice.

Immediacy of results may not always be seen as important. Members of a group practice that dropped out of the dry chemistry pathology trial did not wish to see the pathology results immediately, and preferred to be able to contemplate the implications of the results prior to any further contact with the patient.

The prospect of eliminating laboratory overheads through use of office pathology is perhaps more a case of exchanging one set of costs for another. Non-laboratory operators may need to hire technical staff in order to achieve the required analytical performance. Potentially the largest saving to the health care system over laboratory services would arise from the reduction in the need for blood collecting nursing staff and courier services.

There will be advantages for office or ward side room testing in remote areas. However, caution may need to be exercised as the equipment may not be utilised sufficiently to justify its expense.

Non laboratory pathology will be attractive for physicians in critical cases where an urgent test is required. Justification for the acquisition of non laboratory equipment may in part be based on such considerations. The Panel accepts that these cases will occur but

suggests that the probable incidence should be critically assessed by those considering undertaking their own pathology testing.

The impact of this technology on specialist pathology services is hard to assess, as it may be influenced by the way in which laboratories respond to new developments in diagnostic technology. Monoclonal antibody based kits and recombinant DNA methodology may well break down the current division of specialties within pathology laboratories and allow specialist pathologists more time to concentrate on the more difficult aspects of pathological diagnosis.

The hospital study of the dry chemistry pathology trial(3) showed very low utilisation of analysers within wards. Ward side testing may well have little impact on requested testing from pathology laboratories in most hospitals. On the basis of data on Australian pathology services cited by Hynes et al(6), this would imply that approximately 70 per cent of the pathology testing performed in Australia would be virtually unaffected by near-patient testing. It is possible that ward testing would increase the workload of laboratories, if they were made responsible for maintenance and quality control of the ward-based apparatus.

TESTING OUTSIDE MEDICAL FACILITIES

Home Testing

The advances in diagnostic technology are now at a stage where home testing or monitoring represents an alternative, at least in some medical conditions, to the more conventional forms of diagnostic testing and health care. Developments such as sleep apnea monitors for infants suspected of being susceptible to Sudden Infant Death Syndrome(21), blood pressure monitors, glucose meters and diagnostic kits for occult blood testing provide examples. These developments, like home dialysis, are part of a trend towards deinstitutionalising health services.

Because of the potential to decentralise testing towards the home and away from institutions, evaluation is needed to determine how reliable the results produced by this method of testing are in the hands of users without appropriate training. The product quality control and information leaflets associated with kits also require consideration. The use to which results from home testing are put requires study. It has been shown that some diabetics who were performing their own serum glucose levels were rounding extreme results towards normal range values in their record books(22). Although this finding does not discredit the technology, it does raise questions on the overall worth of such testing. The interpretation of abnormal results is an area where the home user would need considerable support and counselling as to the meaning of the results and possible future action.

Hoskins and Turtle have noted that there is a large list of possible errors in home blood glucose monitoring with large potential for incorrect clinical decisions. These include insufficient sample, poor timing, inadequate clean up techniques and poorly maintained

machines. Reliability of home glucose machines is very dependent on the technique of the user. Use of visual reading strips as an alternative to glucose meters may cause problems as those most likely to use them are 'often least equipped intellectually or visually to interpret the colour change and correctly record the blood glucose range'(22).

Indications are that home blood glucose monitoring requires support by a doctor and a pathology laboratory if reliable results are to be achieved and correctly applied. Hoskins and Turtle recommend supplementation of home monitoring by three monthly estimates of glycohemoglobin levels with consultation between patient and doctor to resolve the reasons for any discrepancies between the two methods(22).

Referral of visual reading strips, where these are of a type with adequate stability, to a clinic or doctor for reading is a possible means of patient support. Kirk et al(23) have drawn attention to the importance of quality control in home blood glucose monitoring and the need to critically review results and monitoring techniques, with particular reference to home monitoring by children with reagent strips.

Doshi(12) investigated the accuracy of in-home pregnancy testing in early pregnancy using three brands of kits. Accuracy ranged from 45.7 to 89.1 per cent (95 per cent confidence level), substantially lower than manufacturers' claims. Sensitivity was calculated at 56 per cent and specificity at 83 per cent. Doshi comments that the low sensitivity obtained is disconcerting as prenatal care may be delayed and discontinuation of teratogenic substances postponed. Specificity limitations could lead, on the results in this study, to false positive results in 1 out of 10 specimens.

Smith, Rustin and Bagshawe (16) cite two cases where false positive results required follow up investigation as the human chorionic gonadotrophin levels were elevated for other reasons. The potential danger in such cases is that, if these tests were performed in the home or other non-medical settings, the appropriate follow-up action may not be taken. The degree to which false positive and false negative results occur is masked by the women seeking the confidentiality that home testing would confer. Manufacturers were urged to stress the possible sources of error in product literature and to include control specimens in each test kit.

Collins et al(24) conducted a study on the use of three commercial home test kits for occult blood and tested the incidence of positive results in subjects who were taking regular doses of ibuprofen. A number of false positive results were observed during the periods when the drug was taken. The most widely used commercial kit detected only 25 per cent to 35 per cent of polyps and 70 to 90 per cent of cancers. The predictive value for the test when applied to asymptomatic patients was 40 per cent for polyps and 12 per cent for cancers. False positive tests may be followed up by procedures that could cost up to $US1000 in addition to being both invasive and painful for the patient.

Such findings indicate the need for some type of counselling service. The supposed first contact for those who have obtained high or positive results is said to be the general practitioner or specialist(16). This may be the case when the patients are undergoing maintenance therapy. However, where an individual chooses home testing for reasons of privacy, cost and/or dislike of institutionalised medicine, the first contact may be the pharmacy from which the product was purchased. Pharmacists selling these products should therefore be prepared to advise the clients of possible interferences to the test and counsel them on appropriate action following a positive result.

Manufacturers may also need to provide detailed advice on possible interferences and suggested courses of action if positive results are obtained. Another possibility is that community health centres might provide the necessary counselling for concerned persons.

A concern must remain that some users of pathology tests who obtain abnormal results may not choose to consult anybody, and that possible physiological or psychological damage could result. Such action by the 'home tester' may have serious consequences both to third party insurers and society. Should home kits for sexually transmitted diseases and other communicable diseases be marketed in this country, certain legal and ethical questions would need to be resolved, for example whether individuals would be required to contact the appropriate bodies responsible for notifiable diseases.

Screening Services

Desk top instruments and MCA-based kits can be used for general screening of the population for certain conditions. Although screening may have the potential to detect disease within the community at an earlier stage in its development, there are problems to be considered.

Non laboratory personnel may produce results which are less precise and accurate than those achieved by persons with laboratory training. Screening services are not reimbursable under Medicare and so are excluded from the requirements of the Commonwealth accreditation provisions. Such services would only be required to meet accreditation requirements in Victoria. Screening services could use quality assurance programs provided by the instrument suppliers, but these do not provide the same check as accreditation on the development of poor technical habits or understanding of the test procedures.

Greenland et al(25) found that the cholesterol concentrations in finger-stick derived plasma were consistently higher than cholesterol levels obtained from venous serum. The average positive bias detected was 3.6 per cent. Greenland et al state that if a bias of this magnitude is left unadjusted, substantial numbers of people will be labelled at risk unnecessarily. Bachorik et al(26) found an even greater difference where capillary blood cholesterol measurements were found to be seven per cent higher than the venous measurements. Simmers(27) found that results achieved by a dry chemistry method were up to 10 per cent lower than the laboratory results. He suggested that such discrepancies could lead to wrongful risk assessment. These

biases would give errors which were well within the total error of the method, but point to the need to interpret blood cholesterol levels with caution.

The costs following a true positive in a screening test may include items such as consultations, repeat testing, pharmaceuticals and surgery. This in the best case may facilitate the control of the disease or risk factor at an early stage. These costs may of course escalate when screening tests have poor predictive value. Similar cost items are associated with false positive results, and anxiety, inconvenience and possible interventions are needlessly incurred.

As is the case with those persons who obtain positive results with home testing, people with positive results following screening would need counselling as to what constitutes appropriate action. Again, it is often assumed that the recommended first action would be to consult a general practitioner. However, the success of the screening test would depend upon the counsellor's ability to motivate the person concerned.

The overall worth of such screening is still a matter for some debate. For example, blood cholesterol levels indicate only a risk factor rather than a disease. Following the screening process persons with elevated results may choose not to take any further action. Of those who decide to take action on the elevated results, a considerable proportion may be instructed 'not to worry' by the practitioners (28).

Questions remain on the value of measurement of glucose levels as a method of screening for diabetes mellitus. Limited knowledge exists as to the natural history of diabetes mellitus and the effectiveness of therapy for asymptomatic patients with impaired glucose tolerance or mild diabetes. In particular, the influence of such therapy on the incidence of vascular and neurologic complications for asymptomatic patients led Mulley(29) to state that serum glucose screening is not recommended. He concluded that 'screening tests can help or hurt the healthy subject. Most laboratory tests should be reserved for patients presenting with signs or symptoms or at risk for a particular disease. The disease in question must be treatable and there should be some advantage to treating during the asymptomatic detectable period'(29).

Testing in other centres

Pregnancy testing services are currently available in pharmacies and as the range of tests available increases pharmacists may wish to extend their testing services. Some corporate bodies are purchasing office pathology equipment for testing staff(30) as part of their occupational health programs. Sporting associations may wish to test athletes; such testing is currently being performed by the laboratory at the Australian Institute of Sport by trained personnel. Health clubs may also wish to offer these services to their patrons.

Such testing would generally be performed outside accreditation guidelines. It would be desirable for such tests to meet the same standards for quality as other pathology services.

COST IMPLICATIONS OF GENERAL PRACTICE OFFICE TESTING

The overall profitability of a pathology service within general practice with tests rebatable under Medicare is governed by costs associated with the instrumentation, kits and other consumables together with regulatory costs. Details are given in Appendix 3. The analysis shows that for a practice to recover costs when operating a biochemistry analyser a test rate of approximately five tests per day would be required. This would represent a testing rate about three times higher than that observed in the dry chemistry pathology trial (4). Choice of a cheaper instrument would reduce the number of tests required to run at a profit. For a general practice operating outside the Medicare accreditation arrangements, fixed costs could be reduced by up to $6,220 per year which would make the break even point approximately four tests per day.

If a practitioner decided not to purchase an analyser and to use only kit methods, while still remaining within the Medicare arrangements, the fixed costs associated with the pathology testing would be $1200 per year. The profitability of such testing would be predominantly determined by the cost of kits and the numbers of tests. Should such a practitioner elect to conduct kit-based testing outside Medicare then profitability would be determined by the amount the patient was charged and the costs of the kits.

Should use of NLPT increase in Australia, it seems likely that much of its impact would fall outside the hospital setting. For the costs of pathology tests to decrease as a result of non-laboratory testing, significant substitution for tests performed in laboratories would need to occur. This was not observed for general practices in the Australian study (4) where overall the pathology tests performed by the practices were additive to tests ordered from laboratories. It is possible that similar effects may occur with the routine use of NLPT in general practice and other settings, but data to support this point are not available. Health Insurance Commission data indicate that GPs who performed their own pathology tests either performed or ordered more tests per patient than other GPs. As an illustration of potential cost implications, should use of NLPT result in a one per cent net increase in pathology services funded through Medicare, the additional cost would be of the order of $4M a year.

CONCLUSIONS AND RECOMMENDATIONS

The Panel recognises that analysers intended for non laboratory use, and test kits, give reliable results when used by trained analytical staff. However, the Panel is concerned at the level of performance achieved in tests carried out by operators without appropriate training. Also of concern is the trend for pathology testing to move away from the medical influence altogether, which may not only result in poor analytical performance, but also inaccurate interpretation of the results.

The diversification of testing creates a need for educational material and counselling services, particularly for those persons performing

testing at home. Bodies such as the National Pathology Accreditation Advisory Council, the Therapeutic Devices Evaluation Committee and the relevant professional bodies should give consideration to preparing such material. The Panel supports the efforts of the Royal Australian College of General Practitioners and Australian Association of Clinical Biochemists in creating educational programs for office pathology work.

The dry chemistry pathology trial identified the need for technical support groups to be established for general practices which provide pathology services. Such advisory services will become increasingly important when testing by employers, screening services and home testing become more frequent. While an informal process of analytical method evaluation goes on within the pathology laboratory community, such continuous professional appraisal is not in place for methods to be used by the non-laboratory operator. The Panel considers that some form of regulatory control over the marketing of these products would be desirable. The Panel realises that full regulatory testing and control would be very resource demanding and suggests that relevant professional bodies should be involved in any assessment procedure.

The Panel notes the limitations in coverage of the Commonwealth pathology laboratory accreditation provisions and sees a need for the compulsory accreditation of services operating office laboratory analysers in all settings. This would require State and Territory governments to introduce complementary accreditation provisions to cover the operation of all office pathology analysers, with the exception of those used for self-testing. However, accreditation of services which are providing only tests based on kits may not be realistic and this issue should be examined by the appropriate body.

The Panel considers that while NLPT has potential value in improving diagnostic services, its overall benefit in most situations remains unclear and may be marginal. NLPT may be additive overall to other pathology services, and could increase costs to the health care system. There is a need for critical appraisal of the costs and benefits of this technology.

On the basis of the information available, the Panel recommends that:

- Accreditation provisions be extended to cover all non-laboratory based operators of pathology analysers and that health authorities should give consideration to the means of achieving this objective.

- The National Pathology Accreditation Advisory Council(NPAAC) consider and report on the feasibility and usefulness of accreditation provisions covering the use of diagnostic kits by persons without appropriate training.

- Mechanisms be established to ensure that diagnostic kits are tested to determine whether the label claims are met. The Commonwealth Department of Community Services and Health

might consider development of such an approach in association with relevant professional bodies.

- The NPAAC, the National Association of Testing Authorities, the Royal Australian College of General Practitioners, other relevant professional bodies and equipment manufacturers should give continued consideration to the preparation and distribution of educational material for providers of pathology services who have not had appropriate training.

  Further work is undertaken to obtain measures of the costs and effectiveness of NLPT, and that this area of pathology testing is kept under critical review by professional bodies and health authorities.

APPENDIX 1 - NON LABORATORY PATHOLOGY TESTING IN OTHER COUNTRIES

Table 2 gives an estimate of the world market for diagnostic pathology in 1987 US dollars. Table 3 summarises information provided to the Panel by manufacturers on placement and use of desk top instruments in eight countries (excluding the USA). The instruments were located predominantly in laboratories (both hospital and private) with only 11 per cent being used by general practitioners. A higher incidence of general practitioner testing has developed in Japan but this was not sufficient to bias the data. The figure of 12 per cent placement in hospital wards is biased by the high usage in Japanese hospitals and was no higher than 6 per cent in any of the other countries. Another interesting facet is the significant use of this technology by veterinarians (this was not observed in the USA data). This high incidence of use by veterinarians was heavily biased by the Canadian figures where veterinary use almost paralleled the use within hospitals.

It was also reported that:

- In six of the eight countries studied, glucose was the most common test performed. In the other two, glucose was ranked third and fourth respectively.
- Blood urea nitrogen (BUN) was the next most popular test performed, ranking first in three countries, equal second and third in the remainder.
- Creatinine was ranked as the third most popular test, being equal top in two countries and second in the remainder.
- Total bilirubin, creatinine kinase and uric acid were the next most popular tests.
- cholesterol, triglycerides and hemoglobin had a low usage.

TABLE 2
ESTIMATES OF PATHOLOGY DIAGNOSTIC MARKET
($US, BILLIONS)

Year	Total	US Laboratory Laboratory	Other countries	Decentralised
1980	3.05	1.50	1.54	0.01
1985	5.7	2.5	2.5	0.07
1990	9.5	3.7	3.0	2.8

Source: Syntex Medical Diagnostics

TABLE 3
INSTRUMENT PLACEMENT (EXCLUDING THE USA)

Placement	Per cent of total
Hospital laboratories	42
Hospital wards	12
Health centres	1.5
Private laboratories	14
General practitioners	11
Veterinarians	11
Private clinics	2
Companies	1
Universities/Government	4.5
Other	1.0

Source: Manufacturers' data

Table 4 shows the placement of the desk top instruments within the USA where predominantly the instruments are being used by physicians or general practitioners. Hospital ward usage is very low, while extra care centres, HMO's and clinics account for the rest of the placements. There are therefore marked differences between the USA and other countries.

Information was also obtained as to the type of operator of NLPT physicians' offices (Table 5). These data indicate that the general practitioner performed only 5 per cent of the testing with 40 per cent of the work or more being carried out by medical technologists employed in the practices. A further 40 per cent of all testing was carried out by nursing staff. Manufacturer 1 reported that the number of operators averaged 2.5 per practice.

Table 6 shows the size of practice purchasing NLPT equipment with the solo practitioners placing in excess of 55 per cent of the instruments and the two - four physician practice responsible for the remainder.

The data presented in Table 7 show the preference for the different analytes offered. The data for Manufacturer 1 are presented in per cent of sales while the data presented for Manufacturer 2 are ranked such that the top score attainable is 25. Hemoglobin, glucose, potassium and cholesterol were the most popular tests performed. Additional information provided by Manufacturer 3 shows a marked preference for glucose, urea and cholesterol. As each instrument does not offer exactly the same analytes, preferences cannot be directly compared.

The test preference obtained from the Australian Dry Chemistry Pathology Trial (Table 8) is included for comparison purposes. The preference shown by the Australian practitioners resembled those of American physicians' office laboratories rather than the preferences shown by practices in other countries.

TABLE 4
PLACEMENT OF NLPT BIOCHEMISTRY INSTRUMENTS IN THE USA

	Manufacturer		
	1	2	3
Physicians office	82%	81%	79%
Clinics			
Ultra care centres/HMO	8%		9%
Hospitals	4%		
Commercial laboratory	3%		6%
Other	5%		5%

TABLE 5
PRIMARY JOB RESPONSIBILITY OF USERS OF NLPT IN THE USA

Job Classification	**Manufacturer 1**	**Manufacturer 2**
Nurse	39%	40.6%
Medical Technologist/ Technician	22%	55.1%
General Practitioner	14%	4.3%
Other		
Secretary/Receptionist	12%	
Medical Assistant	14%	
X-Ray Technician	5%	

Total for Manufacturer 1 is more than 100% as more than one operator used the equipment in many practices.

Source: Manufacturers' data

TABLE 6
SIZE OF PRACTICE USING NLPT ANALYSERS, USA

Numbers of physicians	Manufacturer 1	Manufacturer 2
1	55%	59%
2	21%	
2-4		34%
3-5	16%	
5+		6%

TABLE 7
TEST PREFERENCE, PER CENT US NLPT USAGE

Chemistry	Manufacturer 1	Manufacturer 2
Hemoglobin		25
Glucose	25	24.7
Potassium	20	18.7
Cholesterol	12	11
BUN	11	10
Triglycerides	10	10.7
Sodium	10	-
Uric acid	8	8.2
Total bilirubin	2	4.7
Chloride	1.5	-
Total protein	0.5	-
Amylase		-
CPK		4
LDH		5.2

Source: Manufacturers' data

TABLE 8
NUMBERS OF TESTS PERFORMED BY PRACTICES
IN THE AUSTRALIAN DRY CHEMISTRY PATHOLOGY TRIAL

Analyte	Number of Tests	Per cent of Total
Cholesterol	421	23
Glucose	403	22
Triglycerides	307	17
Potassium	237	13
Hemoglobin	194	11
Urea	76	4
Urate	71	4
Creatinine	69	4
Sodium	24	1
AST	10	<1
Creatine kinase	10	<1
Bilirubin	8	<1
Alkaline phosphatase	5	<1
Theophylline	5	<1
Lactate dehydrogenase	4	<1
Phenytoin	2	<1

AST = Aspartate aminotransferase.

Source: Reference 4

Stoeckle (30) states that the number of physicians' office laboratories in the USA rose from 48,000 out of 462,000 medical practitioners in 1985 to 98,400 in 1988. The estimated number of pathology tests performed in 1986 was 8.6 billion with 25 per cent (2.15 billion) of these being performed in physicans' office laboratories. Stoeckle also states that the spending on doctors' office equipment was estimated at $1.2 billion US in 1987. However, this figure may also include outlays on ECG, x-ray, stress testing and other equipment. Estimates for increased earnings of office laboratories are thought to be between $5,000 to $10,000 a year. He estimates that approximately half the laboratory tests performed in the USA are performed within hospital laboratories, with one quarter of the testing being performed by commercial laboratories and the remaining quarter being conducted within the doctor's office.

These trends observed in the USA may not be immediately transferable to Australia owing to the difference in the reimbursement systems in the two countries. In the USA, when the practitioner orders a test from a private laboratory, the doctor obtains a fee for sampling and interpretation, and the laboratory charges for the performance of the test. The laboratory was claiming the combined fee from the third party insurer and splitting the fee with the general practitioner. Fee splitting or other financial arrangements between referring practitioner and the testing laboratory are precluded under the current arrangements for pathology testing in Australia. New legislation in the USA compels all physicians' office laboratories performing 5000 or more tests per year to be subject to some quality control.

APPENDIX 2 - AUSTRALIAN PATHOLOGY ACCREDITATION AND REGISTRATION REQUIREMENTS

Commonwealth Arrangements

The current Medicare arrangements were initiated by the Health Legislation Amendment Act (1986) which required all pathology services for which Medicare Benefits were payable to meet the following three criteria:

(1) The owner of the laboratory obtain Approved Pathology Authority status. This required the owner to apply, pay the appropriate fee, provided details of corporate structure and be accepted by the Health Insurance Commission.

(2) The medical practitioner must apply for and obtain Approved Pathology Practitioner status by demonstrating that they are of acceptable character and by paying the relevant fees.

(3) Laboratories and other providers of pathology services must seek accreditation. Accreditation is intended to complement State schemes as these come into force. To date both NSW and Victoria have introduced legislation, but this is in force only in Victoria. Under the provisions of the Commonwealth scheme the laboratories have to apply to the Commonwealth Department of Community Services and Health with the approved fee; the information supplied is evaluated and provisional accreditation may be granted if the laboratory service has also applied to an approved inspection agency.

The Commonwealth has appointed the National Association of Testing Authorities (NATA) as an agency to conduct inspections of all categories of laboratory in all States in Australia while the Victorian Faculty of the Royal Australian College of General Practitioners (RACGP) is approved to inspect doctors' office laboratories (Category 5) in Victoria only.

The categories of laboratory covered by the Commonwealth scheme are as follows:

Category 1

Laboratories where tests in all divisions of pathology are performed and the person in charge is a pathologist.

Category 2

Laboratories in which a range of tests within only one division of pathology is performed. Each such service shall be under the direct full-time supervision of a pathologist qualified in that division of pathology or a scientist with prescribed qualifications and who has had, in the opinion of the Minister satisfactory and extensive experience in the work of that division of pathology.

Category 3

Laboratories in which the range of tests undertaken and the standard of the pathology service shall be under the direction and control of a pathologist from a Category 1 service, or a Category 2 service approved for that purpose by the Minister.

Category 4

Laboratories of "recognised hospitals" within the meaning of the Health Insurance Act 1973, other than services in Category 1, 2 or 3. These services shall meet the requirements of a Category 1, 2 or 3 service within two years after the commencement of the accreditation provisions.

Category 5

Laboratories in which pathology tests approved by the Minister are performed by or under the supervision of a registered medical practitioner for patients of the medical practitioner or practitioners of whose practice the service is a part.

Category 6

Laboratories in which is performed a limited range of pathology tests approved by the Minister, where those tests are of a specialised nature and are performed under the supervision of a person having special qualifications or skills, acceptable to the Minister, in the field of those tests.

Category 7

Laboratories located in isolated areas in which pathology tests approved by the Minister are performed.

Category 8

Laboratories that do not comply with the above criteria that are approved by the Minister.

APPENDIX 3 - COST FACTORS FOR GENERAL PRACTICE PATHOLOGY TESTING

Medicare Benefits for some of the items of relevance to NLPT are shown in Table 9; all the benefits quoted are at the 'other pathology' (OP) rate. For those technologies falling under Items 1559-1592 the highest reagent cost is approximately $3.00 per estimation (not including controls). For items 1713-1717 a new kit based on monoclonal antibodies which needs no instrumentation and at a projected cost of $20.00 would appear less attractive to prospective users. These serum drug methodologies have also been developed or are in the process of development by the desk top instrument manufacturers. The consumables would be at a lower cost for these chemistries.

The overall profitability of a pathology service within general practice is influenced by the costs of Commonwealth regulation and associated programs. Such costs might range from $1200 to 2500 for a practice. Details are given in Table 11 Appendix 1. Table 12 lists estimated reagent and consumables costs for the most commonly performed disciplines of office pathology. Table 13 gives regulatory and operating costs on an annual basis and includes the cost of leasing an instrument at a rate of interest of 17.0 per cent per annum.

TABLE 9
CURRENT MEDICARE REIMBURSEMENT FOR TESTS THAT MIGHT BE PROVIDED BY OFFICE PATHOLOGY SERVICES

Item No.	Type of test	Reimbursement $
1559} 1561} 1563} 1565}	Basic biochemistry tests on serum and urine	From $9.90 (single test) to $19.90 (6 or more tests)
1570} 1572}		
1164	Blood counts including hemoglobin one or two procedures	5.55
1576	Qualitative urine tests for hemoglobin, bilirubin porphyrins	9.45
1580 1582	Immunological test for hemoglobin	12.00 27.40
1713 1715 1717	Drug assays in biological fluids	19.90 27.40 35.65
2134	Chlamydia identification	9.45
2136	Herpes identification	9.45
2182	Other antibodies to microbials	13.35

TABLE 10
COSTS OF CURRENT 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
Hematology	$160
Microbiology and serology Dipstick chemistry and pregnancy test $50	
Serum IM and RA $70	
Urine culture and microscopy rapid streptococcal test	$100

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

TABLE 11
ESTIMATED ANNUAL OPERATING COSTS ASSOCIATED
WITH OFFICE PATHOLOGY TESTING

COSTS/100 TESTS	Bio-chemistry	Hem-atology	Micro-biology	Pregnancy
Reagents (Path)	$200	$ 50	$100	$350
Reagents Q.A.	$ 48	$ 40	$ 20	$ 15
Reagents Q.C.	$ 40	$ 60	$ 20	$ 15
Consumables	$ 20	$ 20	$ 50	-
Specimen collection Consumables	$ 30	$ 20	$ 50	-
Confirmatory Referrals	$ 40	$ 40	$ 50	-
TOTAL	$378	$230	$265	$395

Source: Royal Australian College of General Practitioners

TABLE 12
COSTS ASSOCIATED WITH NON LABORATORY TESTING
FOR CLINICAL CHEMISTRY

Regulatory Costs

Commonwealth Government	$ 400
Accreditation inspection fees - 3 year annualised fee	$ 663
External quality assurance	$ 320
Equipment leases	$5000
Education updates	$ 150
Service contracts	$ 750
TOTAL (first year)	**$7283**

TABLE 13
POSSIBLE ANNUAL MEDICARE BENEFIT
CLINICAL CHEMISTRY ANALYSER FOR TESTS

Tests/Day	All Single Tests	1/3 x 2 Tests Reagents	
1	$2376	$2002	$907
2	$4752	$4003	$1814
3	$7128	$6005	$2721
4	$9504	$8006	$3628
5	$11880	$10008	$4335
10	$23760	$20016	$9070

TABLE 14
BASIC PROFIT LOSS CALCULATIONS OF
NON LABORATORY TESTING

No. of Tests Per Day	Gross Earnings	Costs	Profit/Loss
1	$2376	$ 8190	-$5814
2	$4752	$ 9097	-$4345
3	$7128	$10004	-$2876
4	$9504	$10911	-$1407
5	$11800	$11618	+$ 182
10	$23760	$16353	+$7407

Table 13 indicates the annual earnings by GP's for various numbers of tests and controls run on a daily basis. No attempt has been made to allow for such issues as taxation advantages obtained from claiming leasing costs and associated laboratory costs. Also, this analysis does not cover all the costs of establishing an office testing facility, such as those for centrifuge, refrigerator, pipettors, storage space, waste disposal system and services installation.

Table 14 gives the projected profit and loss calculated for office clinical biochemistry varying the number of tests performed on a daily basis. This calculation of earnings was obtained by assuming that all tests were performed as single tests on each patient. This most likely would not be the case so that the gross earnings shown in Table 14 could be considered as maximal, provided the general practitioners charged the Schedule fee. These calculations indicate that for the general practitioners to recoup their costs approximately 5 tests per day would need to be performed.

If a practitioner decided not to purchase an analyser and to use only the kit methods, the leasing costs and service contract commitments would not apply. This would mean for a general practitioner performing some microbiology, dipstick chemistry pregnancy tests and urine cultures, the fixed costs would be of the order of $1200 p.a. The costs of the kits would then influence whether the tests were profitable or not. If the costs of conducting pregnancy tests ($3.95 per test), as taken from Table 8, are used then at a testing rate of 20 per month the practitioner would be recovering costs.

Data from the dry chemistry pathology trial (4) gave an average test rate of approximately one test per day which represented about 60 per cent of the biochemistry ordered by participating practices. Assuming that the practitioners concerned having made an investment in an analyser would perform the most of their biochemistry tests there would be an increase to 4.5 biochemistry tests per day. Therefore, general practices participating in the trial would be required to increase their biochemistry testing by at least three times to recover costs.

An ECRI technology assessment (31) found that in the USA, once an office laboratory was established, the general practitioners used more pathology tests, and reported that more than 50 per cent of office laboratories showed a 30 per cent increase in workload on purchase of an automated clinical chemistry analyser. The ECRI report indicates the incidence of this type of pathology service will continue to increase at least 15 per cent per year in the USA and attributes this steady increase in some part to the ready acceptance of this technology by the newly graduated general practitioners.

REFERENCES

(1) Hailey DM, Maynard J, Opit LJ, Reed CS, Thomas DW. Dry chemistry pathology tests. Clin Biochemist Newsletter 1984;74:28-34.

(2) Dry Chemistry Pathology Trial, Part 1:Pre-Trial Instrument Evaluations. National Health Technology Advisory Panel, Australian Institute of Health, Canberra, September 1987.

(3) Dry Chemistry Pathology Trial, Part 2:Hospital Ward Side Room Study, National Health Technology Advisory Panel, Australian Institute of Health, Canberra, June 1988.

(4) Dry Chemistry Pathology Trial, Part 3:General Practice Study. National Health Technology Advisory Panel, Australian Institute of Health, Canberra, December 1988.

(5) Dry Chemistry Pathology Trial, Part 4:Overview. National Health Technology Advisory Panel, Australian Institute of Health, Canberra, February 1989.

(6) Hynes AF, Lea AR, Hailey DM. Pathology laboratory accreditation in Australia. Aust J Med Lab Sci 1989;10:12-16.

(7) Nanji AA, Poon R, Hinberg I. Comparison of hospital staff performance when using desktop analysers for 'near patient' testing. J Clin Pathol 1988;41:223-225.

(8) Nanji AA, Poon R, Hinberg I. Quality of laboratory results obtained by non-technical personnel in a decentralised setting. Amer J Clin Pathol 1988;89:797-801.

(9) Leese B, Hutton J. Discussion Paper 60: Changing medical practice: a study of Reflotron use in general practice. Centre for Health Economics, Health Economics Consortium. University of York, September 1989.

(10) Sandberg S, Christensen NG, Thue G, Lund PK. Performance of dry chemistry instruments in primary health care. Amer J Clin Pathol 1988;89:797-801.

(11) Bain OF, Brown KD, Sacher RA, MacPherson RA. A hospital-wide blind control program for bedside glucose meters Arch Pathol Lab Med 1989;113:1370-5.

(12) Doshi ML. Accuracy of consumer performed in home tests for early pregnancy detection. Am J Public Health 1986;76:512-514.

(13) Johnson W. FDA's comments on in-home pregnancy tests. Am J Public Health 1986;76:588.

(14) Clark JD. More on in-home pregnancy tests. Am J Public Health 1987;77-371.

(15) Gossel TA. Home testing products for self monitoring. Am J Public Health, 1988;45:1119-1126.

(16) Smith DB, Rustin GJS, Bagshawe KD. Don't ignore a positive pregnancy test. Brit Med J 1988;297:1119-1120.

(17) Burrin JM, Fyffé JA. Diagnostic equipment outside the laboratory. J Clin Pathol 1986;41:925-928.

(18) Hailey DM, Lea AR. Developments in near patient testing. Med Lab Sci. (in press)

(19) White RH, McCurdy SA, Von Marensdorff H et al. Home prothrombin time monitoring after the initiation of warfarin therapy. A randomised prospective study. Prim Care 1989;127:823-45.

(20) Newman WP, Lagua D, Englebrecht D. Impact of glucose self-monitoring on glycohemoglobin values in the veteran population. Arch Intern Med 1990;150:107-110.

(21) Hida W, Miki H, Kibuchi Y. et al. Home sleep monitor for detecting apnea episodes by nasal flow and tracheal sound recordings. Tohobu J Ex Med 1988;156:137-142.

(22) Hoskins PL, Turtle JR. Pitfalls in the management of Diabetes. Australian Family Physician 1986;1127-1128.

(23) Kirk CB, Burke H, Savage DCL, Hughes AO. Accuracy of home blood glucose monitoring by children. Brit Med J 1986;293:17.

(24) Collins CL, DeTullio PL, Berardi RR, et al. Comparison of home occult blood tests and interaction of tests with buprofen. Clin Pharm 1989;8:501-504.

(25) Greenland P, Bowley NL Meiklejohn B et al. Blood cholesterol concentration:fingerstick plasma vs venous serum sampling Clin Chem 1990;36:628-630.

(26) Bachorik PS, Rock R, Cloey T et al. Cholesterol screening:comparative evaluation of on-site and laboratory-based measurements. Clin Chem 1990;36:255-260.

(27) Simmers DG. Total blood cholesterol in a volunteer population. NZ Med J 1990;103:337-9.

(28) Greenland P, Levenkron JC, Radley MG et al. Feasibility of large scale cholesterol screening. Experience with a portable capillary-blood testing device. Am J Public Health 1987;77:73-75.

(29) Mulley AG. Screening the healthy subject. Clin Lab Med 1986;6:241-252.

(30) Stoeckle JD. Primary care and diagnostic testing outside the hospital. Int J Technology Assessment in Health Care, 1989;5:21-30.

(31) ECRI Technology Assessment. The growth of physician office laboratories. Will it continue? What does it mean for hospitals? J Health Care Tech, 1986;3:95-115.

ACKNOWLEDGEMENTS

The Panel grateful to the following for comments and advice:

Dr J Maynard,	Dandenong and District Hospital.
Dr J Summons,	Royal Australian College of General Practitioners
Mr S Angledal,	Medipac Pty Ltd, NSW
Ms J Martin,	Australian Institute of Medical Laboratory Scientists
Mr L Watkinson	Australian Association of Clinical Biochemists
Dr WF Hunter	Hampson, Schweitzer, Baker and Roberts, Pathologists
Mr D Kindon	Australian Association of Pathology Practices Inc.
Mr K Ho	Abbotts Diagnostic Division, Sydney
Ms L Peers	Boehringer Mannheim Australia, Pty Ltd., Sydney
Mr P Fraser	Health Insurance Commission, Canberra
Mr R Chapman	
Mr J Jenner	Commonwealth Department of Community Services and Health
Mr DB Smyth	Syva Australia, Sydney
Mr G Nicol	Office Pathology, Royal Australian College of General Practitioners
Ms B Scott	Pathology Services Accreditation Board, Victoria