

**AUSTRALIAN MEDICAL ASSOCIATION  
COUNCIL OF GENERAL PRACTICE**

**NEAR PATIENT TESTING IN GENERAL PRACTICE**

***Status and Strategy***

November 2001

## **Background**

1992 Amendments to the Health Insurance Act that restricted access to on-site (near patient testing) pathology, disadvantaged general practitioners and their patients. The legislation imposed significant requirements related to registration, assessment and quality control on general practitioners who undertook to perform pathology outside those on the MBS. The legislation, therefore, effectively restricted the capacity for general practitioners to undertake Near Patient Testing (NPT) beyond those provided for under the MBS<sup>1</sup> by making the costs prohibitive. These high costs have severely limited near patient testing and thus ignored the potential and substantial benefits to be derived.

This restrictive legislation also means that general practice cannot take advantage of the benefits to be derived from significant technological advances that have led to a wide range of inexpensive, simple-to-use, equipment and pathology tests. In the interests of improved health care through access to immediate diagnostic, monitoring and preventative care information during primary care consultations, this technology must be made available for use by general practitioners.

## **Issues**

The manner in which the Government is addressing the issue of NPT is confusing and is characterised by what appears to be a “silo” approach in the Department of Health and Aged Care (DHAC) to activities that should by their nature be intimately linked. Three activities in particular, that will provide significant direction on the future of NPT, have been undertaken by DHAC in apparent isolation from one another. They are:

- the Review of the Role and Value of Near Patient Testing in General Practice;
- the Review of Commonwealth Legislation related to Pathology, and;
- a Royal Australian College of General Practitioners (RACGP) Quality Use of Pathology Research and Development Program.

All are discussed in further detail below.

## **Review of Commonwealth Legislation Regarding Pathology**

In accordance with the Pathology Quality and Outlays Agreement, a Steering Committee was established in 2000 to conduct a broad review of the regulatory framework for pathology, specifically Part IIA of the Health Insurance Act 1973. The purpose of the review was to examine the appropriateness and relevance of the legislation in light of current and future needs of industry, Government and its regulatory approaches and broader health objectives. It was also intended to fulfil the Government’s commitment as part of the national competition policy review and , where appropriate, reform legislation that restricts competition and may be costly to business.

The Steering Committee members are:

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<sup>1</sup> These are known as the Group P9 tests of the MBS and are classified as simply basic pathology tests. They include: semen examination for presence of spermatozoa; haemoglobin, ESR, leucocyte count, examination of blood film, haematocrit and erythrocyte count; microscopy of urine and catalase test; pregnancy test by one or more immunochemical methods; microscopy for wet film other than urine; microscopy of Gram-stained film; chemical tests for occult blood in faeces; microscopy for fungi in skin, hair, or nails; and Mantoux test.

- David Borthwick (Department of Health and Aged Care)
- Christina Cobbold (Department of Health and Aged Care)
- Joh Jepson (Department of Treasury).

The Steering Committee received 59 submissions from a range of stakeholders including private individuals and community based organisations.

In July 2000 the AMA provided a brief written submission to the Review Steering Committee. The AMA subsequently sought an opportunity to provide further direct input into the review on behalf of general practitioners. On 26 September the RACGP and AMA jointly met with the Review Steering Committee. AMA Council of General Practice Chair, Dr David Rivett, reported that the meeting was very positive. The Steering Committee had indicated a good understanding and some support for the issues raised. The following recommendations, agreed between the AMA and RACGP, were put to the Review Steering Group members:

- Legislation should be changed to allow near patient testing (NPT) in general practice;
- Funding for pathology services in general practice, including NPT, should continue to come from the Pathology Pool;
- A classification system for NPT devices should be developed and GPs need to be represented on the body that takes on this role;
- The classification system should allow for NPT devices with reliable in-built quality controls, such as the “Cholestech” machines in the USA for measuring blood lipids and glucose, to have “waived test” status and not require expensive quality assurance programs. This could be achieved by moving such tests to the P9 Group in the MBS;
- The RACGP is willing to run a Quality Assurance Program for GPs wishing to provide NPT services. CME on the underlying principles and quality use of test is supported;
- The validation of NPT devices should be against conventional pathology testing;
- Issues such as the efficacy and clinical effectiveness of pathology services need to be addressed across the board for all pathology services. They are not unique to NPT services and should not be used to exclude NPT from the MBS.
- NPT and pathology ordering in general practice should be conducted in accordance with appropriate guidelines or best practice.

The General Practice Department has kept in constant contact with DHAC on progress of the Review that was to have been completed and disseminated for consultation in July 2001. However, informal advice received from DHAC in August 2001 that the draft review would not be available until early 2002 was confirmed in a letter from DHAC on 9 October.

The AMA’s ongoing monitoring of progress of the review has elicited some broad information on its contents. The draft report will look at the history of the legislation, the issues and objectives it originally sought to address, how the legislation has worked and the experience of stakeholders. It will then provide an assessment of the relevance of the legislation given the significant changes that have occurred since it was first promulgated, particularly structural changes and advances in technology, and provide options on how to manage these issues through changes to the legislation. The

report will be not prescriptive. It is proposed that options will be put on the table for consultation. An integral part of the paper will look at “competition”. In fact the Australian Competition and Consumer Commission has the review of pathology legislation on its agenda – a fact which the area of the Department responsible for undertaking the Review of the Role and Value of NPT in General Practice seemed to be unaware.

AMA is concerned as to how the Department’s Review of the Role and Value of NPT in General Practice, now completed, will contribute to, or be considered in the recommendations of, the review of pathology legislation, yet to be completed. This question has never been satisfactorily answered by DHAC.

### **Review of the Role and Value of Near Patient Testing in General Practice**

The aim of this Review was to examine the role and value of NPT in general practice in Australia and provide a series of recommendations to the DHAC’s Expert Pathology Committee on how it might move forward on NPT in Australia. The methods used in this review included, literature review, questionnaire surveys to Australian and international industries involved in NPT, qualitative studies (focus groups and interviews) and cost analysis. This Review was completed in early 2001 but was not released by the Department until later in the year.

It would be true to say that the premise on which the recommendations were based can found in the following quote from the review:

*“The question “should NPT be introduced in general practice?” is obsolete. The current relevant question is “how?””*

The following recommendations from the Review are designed to assist consideration of how to introduce effective, efficient and cost effective near patient testing in general practice:

- A classification of tests for accreditation purposes is mandatory;
- A NPT practice accreditation process is essential;
- Current registration and accreditation costs be reviewed;
- Participation in external quality assurance programs for each NPT must be mandatory;
- Technical and practical performance indicators of NPT devices based on structured and appropriate assessments are essential;
- Funding for health services evaluative research on NPT is essential, and should be supported by sectors with an interest in its use including industry, government and relevant professional organisations;
- Evaluation of diagnostic accuracy, efficacy, clinical effectiveness and cost effectiveness is essential;
- Evaluation of the impact of NPT on the patient and on health care delivery is highly desirable;
- A mechanism for developing national guidelines on the use of NPT is essential;
- Continuing medical education on the underlying principles and quality of use of tests is essential;

- A system that promotes collaboration between pathologists and general practitioners is desirable;
- Reimbursement of NPT in general practice should be funded at a level that fosters appropriate selection and quality use of pathology tests;
- Reimbursement should be used to provide equity in access to care, particularly in rural and remote areas and for indigenous people.

In providing its recommendations the authors of the review developed a framework which followed what they viewed as a logical sequence. “First, there must be regulations and structures providing the parameters within which NPT can evolve. Second, the equipment must achieve technical standards that are satisfactory for the purposes of use in the clinical and practice context of NPT in general practice. Third, research and in particular health services evaluative research, must support and provide the evidence necessary for all levels of decisions. Fourth, a particular NPT should bring substantial clinical benefits to patients. Only if the previous issues are resolved in favour of NPT will it be worthwhile for Government and the other stakeholders to consider the educational organisational, financial and societal requirements.”

In informal discussions the Department advised that the proposed NPT workshop for December 2001 was aimed at developing implementation of the recommendations of the Review of the Role and Value of NPT in General Practice. AMA’s understanding that any outcomes of this workshop must be predicated on the outcomes of the legislation review (not due until early 2002) was confirmed. Again this points to an lack of broad strategy. It would be more effective to await the outcome of the legislative review, identify the agreed parameters for NPT established by the legislation and base any implementation plan, further research or clinical trials on the legislative parameters.

It is clear that the Review of the Role and Value of NPT in General Practice provides the policy directions that would largely be supported by the AMA. Further, it undertakes a critical analysis of specific tests that might be considered and bases assessment of these specific tests on a range of criteria. It is important to note, however, that the authors indicate that some of their findings on specific test are inconclusive and much more work needs to be done on which tests are suitable for NPT.

The Review is significant in that it has undertaken a good deal of the ground work necessary to move on to the method of assessment of different tests and leaves no doubt as to the necessity to make some real changes. In terms of the directions the Review is proposing it also offers the opportunity for significant roles for the AMA and the RACGP. These could be developed jointly in the context of the work that will be necessary to determine which NPTs might be made accessible to GPs, the criteria on which such determinations might be based and an implementation and monitoring plan. The implementation plan would incorporate development of a necessary Quality Assurance Program, to which RACGP have already provided a commitment, and CME.

As the authors of the review indicate the scope of their brief did not allow for a detailed implementation plan to be developed for the recommendations. Clearly the

cornerstone of any such plan will depend upon the outcomes of The Review of Commonwealth Legislation Regarding Pathology and any subsequent appropriate amendment to the Health Insurance Act. Any AMA lobbying strategy on NPT should thus be focussed on ensuring that the recommendations of the Review of the Role and Value of NPT in General Practice are reflected in any recommendations on legislative change to the Health Insurance Act.

### **RACGP- Quality Use of Pathology Research and Development Program**

DHAC has pursued and funded progress on the above program separate from the issue of NPT. This program is aimed at addressing the Quality Use of Pathology in General Practice. DHAC requested the RACGP and the Royal College of Pathologists of Australasia (RCPA) to explore issues that may be contributing to the growth in pathology test ordering which has been experienced over the last few years. As a consequence of dialogue with the RCPA a proposal was developed and submitted to the Department by RACGP to convene a Steering Committee for the development of a research and development proposal addressing the appropriate use of pathology in general practice in Australia. At a workshop convened in late August/early September participants developed and agreed on six proposals to be submitted to DHAC for consideration as part of the research and development program. The agreed proposals were:

- To investigate how the changing face of general practice during the last decade may have impacted on GP pathology ordering volume (as separate to pathology appropriate ordering);
- To determine GP current rationale and logics for pathology ordering in clinical practice (why GPs do what they do);
- To investigate use and effectiveness of pathology tests alert systems (flagging inaction on abnormal test results either by the pathology lab or within the general practice setting) and of actioning systems to improve the appropriate clinical use of pathology tests;
- To determine and explore mechanisms of collaboration and two-way communication of useful information between GPs and pathologists;
- How has changing technology associated with pathology practice impacted on the usefulness of item numbers? It was agreed that workshop attendees collectively alerting the appropriate authorities to review the list of current item numbers with a view to eliminating those that are obsolete would deal with this proposal;
- To develop and trial an audit methodology for pathology requesting in general practice. It was agreed that submission of this proposal would be a lower priority and based on availability of resources.

### **Discussion**

The Department appears to have an overriding concern about NPT that relates to a perception that NPT will increase screening levels and thus costs. Elements of its work to date, including the objective of the RACGP research and Development Program and the comments on the MSAC decision on Cholestech, discussed further below, highlight this.

Informal discussion with the Department has confirmed that it does not view the RACGP research and development program as being linked to issues of NPT. The nature of some of the proposals being developed and the Government's overriding objective for the program, which stems from perceptions of increased pathology ordering by GPs, does establish, however, a clear link to NPT

The implications of NPT for GP pathology ordering is a factor that will be taken into account by Government in progressing NPT.

This is confirmed by the recent report that an application by industry for Cholestech LDX, which would give GPs the ability to test patients in their surgeries, to be listed under Medicare for NPT in general practice, was rejected by the Medicare Services Advisory Committee (MSAC). Its recommendation was subsequently endorsed by the Minister in September 2001.

The direct link of the Cholestech decision with the research being undertaken by the RACGP and in turn its links with NPT strategies are clear. The Review of the Role and Value of NPT in General Practice concluded that while the studies they looked at generally indicated that the consequences of cholesterol NPT availability would be an increase in screening the advantages and disadvantages of screening in different patient groups is still unclear. The report in Australian Doctor reported MSAC's view that while they acknowledged there was potential value in near patient cholesterol testing using the Cholestech LDX device, they wanted more information on how the device would affect the number of tests done, lipid management, patient compliance and the number of GP consultations.

During informal discussions with the Department they advised that the MSAC decision on Cholestech confirmed the findings of the Review of the Role and Value of NPT in General Practice that cholesterol testing in general practice settings was not cost effective. This is an incorrect assessment of the findings of the Review. It is of serious concern, however, that the Department appears to be using the Review to develop or support recommendations and/or make decisions on specific NPT tests. In the AMA's view, this is a rather selective approach. While the Review represented significant groundwork it does not represent a basis for decision making on access to specific NPTs to general practice. As indicated earlier the authors emphasised that the work they had undertaken on specific tests was not conclusive and more work was needed. The Review provided no recommendations in relation to specific tests being made available for NPT.

What is clear is that the MSAC have made a decision in the absence of any established criteria for consideration of NPTs in general practice. When questioned on this issue the Department advised that the decision on Cholestech was the first decision on NPT made by MSAC. The Department has, however, been unable to provide any information on the criteria that MSAC might have used to come to their decision and it would be safe to assume that specific criteria do not exist.

The AMA would argue that decisions on NPT must be undertaken in the context of agreed and established criteria for assessment. For example, patient convenience is not a factor that appears to be relevant in Government assessments on the value of NPT. AMA would argue that opportunity costs, such as patient convenience,

contributes along with others, such as potential cost effectiveness of reduced primary care consultations/referrals, to producing a broad picture of the value of specific NPTs.

As a further example, issues such as combining “academic detailing” strategies may be considered to address increased testing where this is a real concern.<sup>2</sup> Trials of “academic detailing” on PSA testing in general practice in Australia are currently underway.

The AMA would argue, therefore, that what appears to be an overriding factor in Government thinking on NPT, the concern of increased testing, is not necessarily an insurmountable barrier where other benefits can be derived.

The issue of NPT must be a central component to the efficient and effective achievement of other government policy initiatives. Once again, however, there is evidence of a significant gap in communication across policy areas of DHAC. While policy makers are dragging their heels on NPT other parts of the portfolio are pursuing initiatives that are not only consistent with implementation of NPT in general practice, but where NPT would make a strong and positive contribution to achievement of policy objectives. They include:

**Population Health.** The Joint Advisory Group (JAG) on General Practice and Population Health produced a consultation paper in April 2000 in which they state the Minister for Health and Aged Care accepted recommendations of the General Practice Strategy Review Report (1998) that the public health role of GPs be enhanced. The JAG indicated that this was consistent with the Government’s commitment to investing in and supporting preventative and primary health care initiatives. The consultative paper developed a range of principles underpinning the GP role in Population Health most of which would supported by and be consistent with introduction of NPT in general practice. These principles include GP roles in:

- identifying those who are at risk of developing a disease or disability;
- early detection of disease, especially when early detection and early treatment is known to lead to better outcomes (screening);
- managing patients with diseases.

The benefits to be derived from NPT in general practice can clearly be linked to the aims of the Government’s population health strategy.

**Diabetes Initiatives** - The most recent study of diabetes prevalence (The Australian Diabetes and Lifestyle Study [AusDiab]) found that there are 940,000 people with diabetes, only half of whom are diagnosed. The stated aim of the Government’s budget linked diabetes initiative is to encourage better management of all patients with diabetes regardless of age. The HbA1c test enables monitoring of diabetes treatment as it provides an estimate of the degree of blood sugar control over the

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<sup>2</sup> Describes an educationally-oriented face-to-face visit from a well credentialled, commercially independent, and soundly-trained visitor to a doctor in his or her own practice setting. A September 1997 Chochrane review of the effects on professional practice and health care outcomes from “educational outreach” concluded that educational outreach (academic detailing) visits, particularly when combined with a social marketing approach appear to be promising in terms of modifying professional behaviour, particularly prescribing.

previous three months. The diabetes control and complications trial showed that tight control of HbA1c led to few complications in patients with IDDM (Diabetes Control and Complications Trial Research Group 1993)<sup>3</sup>. NPT in general practice which provides GPs with the capacity to undertake HbA1c testing would be consistent with and enhance the objectives of the Government's diabetes policy and strategy. It would also be consistent with principles of the GP role in population health.

The above two examples simply attempt to highlight the need for Government to critically examine the contribution NPT in general practice could make to achievement of objectives in other broad primary health care policies and strategies. Government largely sees NPT in isolation and then as a cost problem. Introducing NPT into general practice as a component of broader primary health care policies offers the opportunity to incorporate implementation strategies that are designed to mitigate or minimise any potentially undesirable cost effects. Such an approach represents a rationale and logical approach to NPT. It provides the opportunity for the Australian health care system to realise the significant benefits to be gained from NPT in general practice.

### **AMA Strategy**

In the interests of progressing the issue of NPT the AMA will pursue a lobbying strategy that incorporates the following directions and/or principles:

- highlights the impatience of the profession about the unwarranted delays around the review of the legislation;
- seeks appropriate amendment of the legislation to progress NPT access in general practice;
- expresses an expectation that the review of the legislation will have positively considered the Review of the Value and Role of NPT in General Practice and its recommendations;
- expresses an expectation that the profession will be consulted on the outcomes of both reviews and agreement from the profession will be sought on what recommendations will be implemented;
- seeks a Government commitment to immediately, and in consultation with the profession, develop an implementation plan for introduction of NPT based on the agreed recommendations from these reviews. Such an implementation plan must:
  - incorporate an ongoing monitoring role on NPT, particularly in relation to technological advances that would allow ongoing implementation of NPT on the basis of set criteria, including clinical management, cost effectiveness, improved patient outcomes;
  - establish clear criteria for the assessment of NPT for the purposes of decision making in forums such as MSAC, and;
    - that ongoing monitoring processes contribute to updating of these assessment criteria when necessary recognising that technological advances and other factors that critically impact on the availability of NPT are not necessarily static;

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<sup>3</sup> "Review of the Role and Value of Near Patient Testing in General Practice", Associate Professor R Guibert et al, page 57

- seeks a Government commitment to immediately commence negotiations with AMA and GP Groups through the General Practice Representative Group. Such negotiations to focus on MBS issues related to NPT and a strategy for the future, including equalisation of the MBS between pathologists and GPs undertaking the same tests for patients.

This strategy should be pursued with the new Minister for Health, in GP Group forums and during participation in a DHAC workshop on NPT scheduled for early December.