The Auditor-General
Audit Report No.5 2007–08
Performance Audit

National Cervical Screening Program- Follow-up

Department of Health and Ageing

Australian National Audit Office

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Australian National Audit Office

Canberra ACT
16 August 2007

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in the Department of Health and Ageing in accordance with the authority contained in the *Auditor-General Act 1997*. I present the report of this audit and the accompanying brochure to the Parliament. The report is titled *National Cervical Screening Program Follow-up.*

Following its tabling in Parliament, the report will be placed on the Australian National Audit Office's Homepage—http://www.anao.gov.au.

Yours sincerely

Ian McPhee
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office. The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits and financial statement audits of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

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Contents

Abbreviations

ACSQHC	Australian Council for Safety and Quality in Health Care
AHMAC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
ANAO	Australian National Audit Office
APA	Approved Pathology Authority
APHDPC	Australian Population Health Development Principal Committee
APP	Approved Pathology Provider
BSA	BreastScreen Australia
CCSER	Cervical Cancer Screening Evaluation Report
CSC Review/ Report	Cancer Screening Committee Review
Corrs Review/ Report	Evaluation of the Australian Pathology Laboratory Accreditation Arrangements
DHAC	Department of Health and Aged Care
DoHA	Department of Health and Ageing
HIA	*Health Insurance Act 1973*
HIC	Health Insurance Commission
HPV	Human Papillomavirus
KPI	Key Performance Indicator
NAC	National Advisory Committee
NATA	National Association of Testing Authorities Australia

NCSP	National Cervical Screening Program
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
PHOFA	Public Health Outcome Funding Agreement
PRC	Professional Review Committees
PSSCS Review/ Report	Population Screening Section Committee Structures Review
QAP	Quality Assurance Program
QUPC	Quality Use of Pathology Committee
RCPA	Royal College of Pathologists of Australasia
RCPA QAP	RCPA Quality Assurance Programs Pty Ltd

Summary and Recommendations

Summary

Overview

1. In 2001, the Australian National Audit Office (ANAO) completed an audit of the Australian Government Department of Health and Aged Care's (now the Department of Health and Ageing—DoHA) administration of the National Cervical Screening Program (NCSP). The audit report included four recommendations.[1] Of these, three were directed to DoHA and one recommendation was jointly directed to DoHA and to the Health Insurance Commission (now Medicare Australia).

Background

2. Cervical cancer, like other cancers, is a disease where normal cells change, begin to multiply, and form a growth or tumour.[2] The Cancer Council of Australia has reported that the risk of Australian women developing cervical cancer before the age of 75 years is one in 183, with cervical cancer the eighteenth most common cause of cancer death in Australian women.[3]

3. The incidence of, and mortality from, cervical cancer in Australia has decreased significantly over the last two decades. A major factor contributing to improved cervical cancer health outcomes for Australian women has been the introduction of a coordinated population screening program that aims to detect pre-cancerous abnormalities and reduce the number of abnormalities that develop into cervical cancer.

4. Cervical screening has been available for Australian women since the 1960s, but it was largely opportunistic. Cervical screening became a more structured program in 1991. In 1995, the program became known as the National Cervical Screening Program. NCSP aims to reduce morbidity and deaths from cervical cancer, in a cost-effective manner through an organised approach to cervical screening.

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1 Australian National Audit Office Audit Report No.50, 2000–01, *The National Cervical Screening Program*, Canberra.

2 See Appendix 1 for further information on cervical cancer.

3 The Cancer Council of Australia, *Position Statement: Cervical Cancer Screening*, [Internet] Sydney, 2006, p.1, available from <http://www.cancer.org.au/documents/Cervical_cancer_screening_pos_statement_2006.pdf> [accessed 23 January 2007].

5. Under the auspices of NCSP, nearly three and a half million women in Australia, aged 20 and over, had Pap smears in 2004–05.[4]

Audit objective

6. The objective of this audit was to assess the progress made by DoHA and Medicare Australia (recommendation 3) in addressing the four recommendations from ANAO Audit Report No.50, 2000–01 designed to improve the administration and performance of NCSP.

Key findings

7. Table 1 summarises the ANAO's key findings against each of the recommendations from the earlier audit.

[4] Australian Institute of Health and Welfare, *Media Release*: *Early detection curbing cervical cancer rates* [Internet], Canberra, 2007, p.x. available from <http://www.aihw.gov.au/publications/index.cfm/title/10457> [accessed 25 June 2007].

Table 1

Key findings

Recommendation	Status	Findings
Recommendation No. 1 The ANAO recommends that, in order to further improve the performance of the National Advisory Committee (NAC) and the National Cervical Screening Program, DHAC, in conjunction with the NAC, investigates: • whether efficiencies might be gained by amalgamating Working Groups of the National Cervical Screening NAC with Working Groups of the BreastScreen Australia NAC that have issues in common; and • whether current lines of communication between stakeholders, and the NAC and its Working Groups adequately meet the requirements of the NCSP and whether there are opportunities for strengthening communications.	**Implemented**	Since the earlier audit, DoHA has comprehensively restructured committee arrangements for NCSP. The department commissioned two reviews to examine communication arrangements and to inform its restructuring of NACs and working groups. The review process also incorporated a comprehensive consultation process with stakeholders. However, DoHA did not apply similar rigor to inform its decisions regarding subsequent committee restructures. The absence of a peak advisory body for screening issues and lengthy delays in the establishment of new committees were undesirable outcomes from the restructuring process.

Recommendation	Status	Findings
Recommendation No. 2 The ANAO recommends that DHAC, in collaboration with the NAC and Working Groups, develops protocols for the provision of secretariat services to the NAC and its Working Groups, to enhance accountability for the provision of services and provide members of these groups with realistic expectations of the services to be provided.	**Implemented**	The ANAO concluded that DoHA, in collaboration with committees/working groups and in accordance with departmental guidance, has established appropriate protocols for the provision of secretariat services for national screening committees established since the earlier audit. The ANAO also acknowledges the department's intention to introduce a process to: • review the guidelines on, at least, an annual basis, and update where required; and • monitor the adequacy of the secretariat services it provides under NCSP. The proposed monitoring process should allow the department to identify issues, such as the timeliness of agenda paper and meeting minute distribution, and take corrective action where service levels are outside of those specified in applicable operating guidelines.
Recommendation No. 3 The ANAO recommends that DHAC and the HIC explore with the pathology industry the inclusion, as a requirement for accreditation for gynaecological (cervical) cytology, a condition that data on a pathology laboratory's performance against quantitative standards is made available annually to the HIC. This would improve the Commonwealth's ability to satisfy itself that services for which it is paying are of the required quality.	Implemented	The ANAO acknowledges that DoHA, as the agency with policy responsibility, is working to introduce more regular reporting of pathology laboratory performance against established standards. The ANAO also recognises that the development and implementation of a scheme to identify laboratories of concern, through regular reporting against quantitative standards, is complex and necessitates input from technical experts and requires sufficient time to undertake effective consultation with stakeholders. The ANAO considers that actions taken by DoHA adequately respond to the issues identified in the 2001 audit report. While acknowledging the current absence of annual reporting of quality data to Medicare Australia, the ANAO noted: • the actions taken by the department and Medicare Australia to facilitate the provision of external quality assurance data to NATA through revised pathology laboratory principles and undertakings; and • the establishment of projects to develop quantitative standards against which laboratory performance can be assessed, and the subsequent piloting of developed standards.

Recommendation	Status	Findings
		Therefore, the ANAO considers that DoHA has sufficiently explored the issue of performance reporting with the pathology industry and, as a consequence, has adequately implemented this recommendation.5
Recommendation No. 4 The ANAO recommends that DHAC, in order to achieve well-defined stewardship of the pathology quality assurance process, should take steps to assign responsibility for oversight of the process.	Partially Implemented	Having regard to Recommendation 4, the Department accepted at the time of the original audit that there would be merit in seeking single stewardship to provide effective national oversight of quality assurance processes for pathology. However, it subsequently became evident that the approach envisioned at that time was not feasible. Having considered the recommendations in an external review (the Corrs Report) and consulted widely with the stakeholders, the Department has introduced measures to strengthen the pathology accreditation system and now believes that it has fully achieved an effective level of oversight. Accordingly, the Department considers that while the original recommendation was not implemented as first envisaged, it has in place a coherent system with clear and appropriate degrees of accountability for each participant and does not propose to take any further action on Recommendation 4. However, as part of its continuous improvement process, the Department will continue to work with all relevant stakeholders to further improve the pathology accreditation system and the overall quality of pathology services provided to the Australian community. Taking DoHA's response into account, the ANAO has concluded that the Department has partially implemented recommendation 4, noting that a decision was made by DoHA that the steps it has taken to date provide the Department with an effective level of oversight of the pathology quality assurance processes for cervical screening. In particular, the Department has taken steps to improve stewardship of the pathology quality assurance process by introducing measures designed to clarify degrees of accountability for individual participants that have a contractual relationship with the Commonwealth. Given the range of

[5] It should be noted that the ANAO has not formed an opinion on the adequacy or appropriateness of the key performance indicators developed and piloted under the KPI development and implementation projects.

Recommendation	Status	Findings
		participants involved in the quality assurance processes for cervical screening and the important role of quality assurance in providing comfort that appropriate standards for pathology laboratories are being set, applied and monitored, the ANAO considers that, as indicated by the Department, this is an arrangement that DoHA should monitor to ensure that its level of oversight continues to be effective.

Overall conclusion

8. The ANAO concluded that DoHA has made progress against the recommendations of Audit Report No.50, 2000–01 directed to improvements in the administration of NCSP, with three recommendations implemented[6] and for one recommendation (recommendation 4), partially implemented.

9. Notwithstanding, the ANAO considers that DoHA's implementation of the recommendations from the earlier audit would have benefited from a more structured approach to planning and greater consideration of the risks to timely implementation. The ANAO also noted weaknesses in DoHA's monitoring of implementation activities, which impacted upon the department's ability to make informed decisions regarding the actions required to successfully implement the recommendations.

10. The ANAO makes no further recommendations in this report.

[6] This includes the joint recommendation with Medicare Australia.

Agency responses

DoHA's response

11. DoHA's full response to the follow-up audit can be found at Appendix 2. DoHA provided the following overall comment on the follow-up audit:

> The Department notes the ANAO conclusion that Recommendation 4 from Audit Report No. 50 of 2000–2001 has been partially implemented.
>
> At the time of the original audit, the Department accepted that there would be merit in seeking single stewardship to provide effective national oversight of quality assurance processes for pathology. However, it subsequently became evident that the approach envisioned at that time was not feasible. Having considered the recommendations in an external review (the Corrs Report) and consulted widely with the stakeholders, the Department has introduced measures to strengthen the pathology accreditation system and now believes that it has fully achieved an effective level of oversight. Accordingly, the Department considers that while the original recommendation was not implemented as first envisaged, it has in place a coherent system with clear and appropriate degrees of accountability for each participant and does not propose to take any further action on Recommendation 4. However, as part of its continuous improvement process, the Department will continue to work with all relevant stakeholders to further improve the pathology accreditation system and the overall quality of pathology services provided to the Australian community.

Medicare Australia's response

12. Medicare Australia advised the ANAO that the following was its full response to the follow-up audit:

> Medicare Australia agrees with the ANAO that recommendation 3 has been implemented and supports the findings identified by ANAO in relation to that recommendation.

Audit Findings and Conclusions

1. Introduction

This chapter provides an overview of cervical cancer and its prevalence in Australia, and explains the aim of the National Cervical Screening Program. It also sets out the context for the audit and outlines the audit objective, scope and methodology.

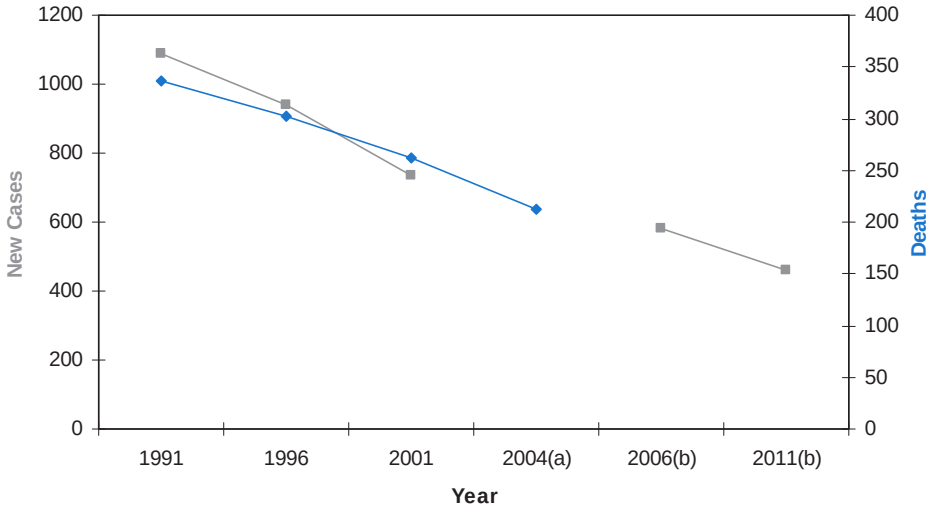
Cervical cancer

1.1 Cervical cancer, like other cancers, is a disease where normal cells change, begin to multiply, and form a growth or tumour.[7] The Cancer Council of Australia has reported that the risk of Australian women developing cervical cancer before the age of 75 years is one in 183, with cervical cancer the eighteenth most common cause of cancer death in Australian women.[8]

1.2 Notwithstanding, the incidence of, and mortality from, cervical cancer in Australia has decreased significantly over the last two decades (see Figure 1.1).

Figure 1.1

Cervical cancer incidence and mortality



(a) Incidence data for 2004 was not available.
(b) Projected new cases of cervical cancer.

Source: ANAO from AIHW data.

[7] See Appendix 2 for further information on cervical cancer.

[8] The Cancer Council of Australia, *Position Statement: Cervical Cancer Screening*, [Internet] Sydney, 2006, p. 1, available from <http://www.cancer.org.au/documents/Cervical_cancer_screening_pos_statement_2006.pdf> [accessed 23 January 2007].

1.3 The Australian Institute of Health and Welfare (AIHW) has reported that the number of new cases of cervical cancer decreased from 1091 in 1991 to 689 in 2002, with the age-standardised rate almost halving, from 17.2 per 100 000 women aged 20–69 to 9.1 per 100 000. In addition, the number of deaths in this period fell from 329 in 1991 to 227 in 2002. This trend continued in 2004, with the latest AIHW mortality data showing a reduction in deaths to 212 and in the age-standardised rate to 1.8 deaths per 100 000 women.[9]

1.4 A major factor contributing to improved cervical cancer health outcomes for Australian women[10] has been the introduction of a coordinated population screening program that aims to detect pre-cancerous abnormalities and reduce the number of abnormalities that develop into cervical cancer.

National Cervical Screening Program

1.5 Cervical screening by Papanicolaou smear, commonly known as the 'Pap smear' is the most common way to detect pre-cancerous changes. If detected early these changes can be prevented from becoming cancerous, as cervical cancer can take more than ten years to develop. Through population screening, the Pap smear has the potential to reduce up to 90 per cent of cervical cancer and is currently the best protection against the disease. It is estimated that cervical screening saves over 1200 Australian women from developing cervical cancer each year.[11]

1.6 Cervical screening has been available for Australian women since the 1960s, but it was largely opportunistic. Cervical screening became a more structured program in 1991. In 1995, the program became known as National Cervical Screening Program. Under the auspices of NCSP, nearly three and a half million women in Australia, aged 20 and over, had Pap smears in 2004–05.[12]

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9 Australian Institute of Health and Welfare, *Cervical Screening in Australia 2004–2005*, Canberra, 2007, p.x, available from < http://www.aihw.gov.au/publications/index.cfm/title/10457> [accessed 25 June 2007].

10 The incidence of cervical cancer amongst Indigenous women is an area of ongoing concern. Cancer Council data indicate that Indigenous women have a mortality rate attributable to cervical cancer of 7.9 per 100 000 women. In contrast, the rate for the general population is 1.8 per 100 000.

11 The Cancer Council of Australia, op. cit., p. 1.

12 Australian Institute of Health and Welfare, *Media Release*: *Early detection curbing cervical cancer rates* [Internet], Canberra, 2007, p.x. available from <http://www.aihw.gov.au/publications/index.cfm/title/10457> [accessed 25 June 2007].

1.7 The aim of NCSP is to reduce morbidity and deaths from cervical cancer, in a cost-effective manner through an organised approach to cervical screening.

1.8 NCSP seeks to integrate all elements of the cervical screening process. In particular, it aims to:

- demonstrate an increase in the percentage of eligible women who have ever been screened;
- establish more reliable and accessible services for taking, interpreting and reporting Pap smears;
- improve management of screen detected abnormalities; and
- monitor and evaluate these preventive efforts.[13]

Departmental role

1.9 DoHA's role in cervical cancer screening is to provide leadership and support to NCSP, and the committees and working groups established under the program, by:

- providing policy development and project services;
- coordinating NCSP activities with the activities of other programs administered by the department and with the States and Territories;
- monitoring research and evaluation undertaken on cervical cancer screening; and
- the provision of secretariat services to screening committees and working groups.

1.10 It also provides advice to the Australian Government Minister for Health and Ageing on cervical screening matters.

1.11 A further role for the department is the administration of funding for the program.

[13] Department of Health and Ageing, *National Cervical Screening Program: About the Program* [Internet], Canberra, 2006, available from <http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/cervical-1lp> [accessed 23 January 2007].

NCSP funding

1.12 NCSP is funded via multiple funding arrangements and sources, including subsidies and broad banded funding. DoHA administers Australian Government funding assistance to the States and Territories for their cervical screening programs through the Public Health Outcome Funding Agreements (PHOFAs).[14] DoHA also administers funding for the taking and processing of Pap smears through Medicare. In addition, DoHA administers funding through health program grants to certain providers for the processing of Pap smears in public and private sector pathology laboratories. Program funding is also provided directly by State and Territory governments.

1.13 As PHOFA and health grant funding is not allocated to specific public health activities such as NCSP, it is difficult for the department to estimate how much of that funding is allocated to cervical screening activities. As a consequence, DoHA is reliant on irregular cost effectiveness studies and AIHW reports on public health expenditure to gain an insight into total program funding.

1.14 The most recent cost effectiveness study was completed in 2004, utilising 1999–2000 data. The study reported that the total cost to government (both Australian Government and State/Territory governments) for NCSP in 2000 was approximately $119 million. The report also estimated that it cost the department $820 000 to administer NCSP. Given the changes to the program over recent years, the age of this data limits its usefulness.

1.15 The AIHW released its most recent public health expenditure report, entitled *National Public Health Expenditure 2004–05*[15], on 19 January 2007. In 2004–05, NCSP expenditure funded via Medicare benefits amounted to $62.8 million.[16] This was made up of $33 million in benefits for general practitioner consultations, $22.9 million for pathology testing and $6.8 million for benefits associated with collecting samples.[17] As noted above, this does not include Australian Government funding under the PHOFA agreements; nor

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[14] The PHOFAs are bilateral funding agreements between the Australian Government and each State and Territory. They provide broad banded and specific purpose funding from the Australian Government to the States and Territories for a range of public health programs. DoHA has reported that the chief advantage of broad banding some public health payments lies in allowing States and Territories the flexibility to manage local service funding needs and priorities within the total pool of funds allocated to them.

[15] Australian Institute of Health and Welfare, *National public health expenditure report 2004–05*, Canberra, 2007, available from <www.aihw.gov.au> [accessed 30 January 2007].

[16] This figure is rounded.

[17] AIHW, op. cit., p. 33.

funding under health program grants. Also not included is funding provided from State and Territory sources.

1.16 DoHA officers have advised that more timely estimates of expenditure would be valuable for the ongoing monitoring of the program. The department is currently exploring options to establish a methodology to support more timely monitoring of NCSP expenditure.

2000–01 audit

Background

1.17 A performance audit of NCSP within the, then, Department of Health and Aged Care (DHAC), was conducted in 2000–01. The audit objective was to provide an assurance to Parliament that DHAC's administration of NCSP was sound.

1.18 The original audit report (Australian National Audit Office (ANAO)—Audit Report No.50, 2000–01) was tabled in June 2001. The report contained four recommendations. Of these, three were directed to DHAC (now DoHA) and one recommendation was jointly directed to DHAC and to the Health Insurance Commission (now Medicare Australia).

Overall conclusion

1.19 In its 2000–01 audit, the ANAO concluded that DHAC's administration of NCSP was generally sound. Notwithstanding, the ANAO identified areas for improvement, including: NCSP committee and working group structures; secretariat support to NCSP committees and working groups; quality assurance reporting for pathology laboratories analysing Pap smears; and stewardship of the pathology quality assurance process.

Developments since 2000–01 audit

Human Papillomavirus vaccination program[18]

1.20 Human Papillomavirus (HPV) is a sexually transmitted infection that can be linked to nearly all occurrences of cervical cancer. While over 200 types of HPV have been identified, two high-risk types, HPV types 16 and 18, account for around 70 per cent of all cervical cancer.

[18] The information in this section was sourced from: Department of Health and Ageing, *Fact Sheet: Australian Government Funding of Gardasil®,* [Internet], Canberra, 2006, available from <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/gardasil_hpv.htm> [accessed 31 January 2007].

1.21 On 29 November 2006, the Australian Government announced funding for an HPV vaccination program at a cost of $436 million between 2006–07 and 2009–10. The funded vaccine, which is currently one of two approved HPV vaccines for use in Australia, prevents infection from HPV strains 16 and 18.

1.22 In spite of the establishment of a vaccination program, DoHA considers that screening will remain the primary method in the detection and prevention of cervical cancer, as vaccination does not guarantee 100 per cent protection from cervical cancer.

Revised clinical guidelines

1.23 The care of women who have an abnormal Pap smear result is governed by guidelines developed by the National Health and Medical Research Council (NHMRC). These guidelines inform health care providers of recommended best practice.

1.24 In June 2005, the NHMRC approved guidelines entitled *Screening to Prevent Cervical Cancer: Guidelines for the Management of Asymptomatic Women with Screen Detected Abnormalities*. These guidelines replaced existing 1994 guidelines, which were rescinded. The new guidelines were implemented from 3 July 2006.

1.25 DoHA has reported that the new guidelines were formulated in line with NHMRC standards for clinical practice guidelines to assist women and health professionals to achieve the best outcomes in the management of abnormal Pap smear results. It was also reported that the guidelines were based on epidemiological and scientific evidence and a more developed understanding of the role of HPV in cervical cancer.

Pathology laboratory performance

1.26 Pathology laboratories conducting cervical cytology are accredited by the National Association of Testing Authorities Australia (NATA)[19] and the Royal College of Pathologists of Australasia (RCPA) to ensure that they operate in accordance with established standards. The earlier audit report commented on the period of accreditation for pathology laboratories performing cervical cytology, which can be up to three years, and the potential for a laboratory's performance to deteriorate between accreditation inspections. The ANAO subsequently recommended that the department and

[19] NATA is Australia's national laboratory accreditation authority. NATA accreditation recognises and promotes facilities competent in specific types of testing, measurement, inspection and calibration.

Medicare Australia investigate options for more frequent monitoring of pathology laboratory performance.

1.27 On 11 March 2002, the Minister for Health and Ageing announced the suspension of NATA accreditation for three pathology laboratories due to adverse quality assurance reports in relation to poor cervical screening. These performance issues were identified via the standard round of accreditation inspections. As a result, the identified laboratories were refused funding under the Medicare Benefits Scheme, and in the case of one laboratory, NATA found that: '…the laboratory does not have the people and resources required for satisfactory performance of the functions for which accreditation is sought.'

Revised principles and undertakings

1.28 Under section 23DNA of the *Health Insurance Act 1973* (the HIA), the Minister for Health and Ageing, or a delegate, may determine principles that outline eligibility for premises to be approved as an accredited pathology laboratory.

1.29 In 1999, the *Health Insurance (Accredited Pathology Laboratories–Approval) Principles 1999* were released. A revised set of principles was developed by the Government in 2002 in consultation with the pathology industry, as well as Medicare Australia and the NATA. The revised principles, entitled the *Health Insurance (Accredited Pathology Laboratories–Approval) Principles 2002,* were signed by the, then, Minister for Health and Ageing on 13 November 2002.

1.30 In announcing the November 2002 package of measures, the Minister stated that amendments to the principles included:

- establishing an improved early warning system to identify poorly performing laboratories as soon as problems arise;
- strengthening the links between accreditation by NATA and approval for Medicare benefits purposes;
- speeding up the current review, action and appeal processes, while still providing for natural justice, so that laboratories cannot continue to be eligible for Medicare benefits while they are appealing an adverse decision by NATA;
- strengthening links between quality assurance programs and accreditation by requiring pathology companies to provide information about their performance in quality assurance programs; and
- spot checks of laboratories to be undertaken without notice.

1.31 The current version of the principles came into effect on 1 July 2006.

Committee structures

1.32 In the period since the original audit, there have been significant changes to committee structures under NCSP. These changes are examined in Chapter 2 of this paper, *Improving Committee Performance.*

This audit

Audit objectives and scope

1.33 The objective of this audit was to assess the progress made by DoHA and Medicare Australia in addressing recommendations from ANAO Audit Report No.50, 2000–01.

Audit methodology

1.34 The ANAO established criteria to guide the audit in determining whether DoHA and Medicare Australia have implemented the recommendations. The ANAO then wrote to DoHA and Medicare Australia at the commencement of the audit to request information on the implementation of the recommendations from the earlier audit. Following receipt of responses, the ANAO:

- interviewed DoHA/Medicare Australia officers;
- reviewed DoHA/Medicare Australia data and documentation;
- reviewed relevant literature; and
- met with key stakeholders.

1.35 This audit was conducted in accordance with ANAO Auditing Standards at a cost of $243 000.

Relevant audits and reviews

1.36 Relevant published reviews and audit reports taken into account in conducting this audit include:

- Philips Fox, 2005, *Review of Enforcement and Offence Provisions of the Health Insurance Act 1973 as they Relate to the Provision of Pathology Services Under Medicare—Final Report to the Department of Health and Ageing*, Canberra.

- Corrs, Chambers and Westgarth, 2002, *Evaluation of the Australian Pathology Laboratory Accreditation Arrangements for the Department of Health and Ageing*, Canberra.
- Department of Health and Ageing, 2002, *Report of the review of Commonwealth legislation for pathology arrangements under Medicare –final report*, Canberra.
- Australian National Audit Office—Audit Report No.50, 2000–01, *The National Cervical Screening Program*, Canberra.

Report structure

1.37 The audit's findings are organised into the following four chapters:

- Chapter 2: Improving Committee Performance (Recommendation 1);
- Chapter 3: Enhancing Secretariat Services (Recommendation 2);
- Chapter 4: Improving Quality Management (Recommendation 3); and
- Chapter 5: Strengthening Governance (Recommendation 4).

2. Improving Committee Performance

Background

2.1 In the earlier audit, the ANAO found DoHA, stakeholders, the National Advisory Committee (NAC) and the NAC working group members generally supported committee structures. Notwithstanding, it was considered that there might be value in looking at alternative methods of operating the committee and its working groups by merging working groups. Some stakeholders also expressed to the ANAO a desire for enhanced lines of communication between committees and working groups.

2.2 The ANAO recommended that DoHA investigate amalgamation of working groups and examine lines of communication. The ANAO considered that structural changes and enhanced lines of communication would further improve the performance of the program.

2.3 In its response to the 2001 audit, DoHA agreed with the recommendation, stating that the department had for some time (and prior to the commencement of the audit) been considering amalgamating working groups. DoHA also stated that lines of communication between NACs and working groups were adequate, but that it would consult with the NACs and working groups on possible improvements.

2.4 In its response, to this audit, DoHA stated that it had implemented the recommendation through the restructuring of committee arrangements under NCSP.

ANAO's findings

Implementation

2.5 As part of its assessment of the actions taken by DoHA to implement the recommendation, the ANAO considered the steps taken to restructure screening committees and working groups, including departmental reviews and broader sector reviews.

Departmental reviews

2.6 In January 2001, DoHA wrote to the NAC chairs of BreastScreen Australia (BSA) and NCSP to advise them that a review would be conducted to determine the efficiency, cost-effectiveness, operation, and support for all

population health advisory committees and working groups, including an examination of the rationalisation of committees.

2.7 As part of the broader examination of population health committees, DoHA carried out two external reviews of its screening advisory committees. The first review, the Cancer Screening Committee Structures Review (CSC Review), identified options for streamlining operations and increasing the efficiency and effectiveness of committee arrangements. The CSC Review findings were presented to the BSA and NCSP NACs in February 2002.

2.8 Departmental records indicated that stakeholders had difficulty accepting the restructuring recommendations from the CSC Review, as proposed changes were perceived to erode the prominence and achievements of the existing breast and cervical screening programs.

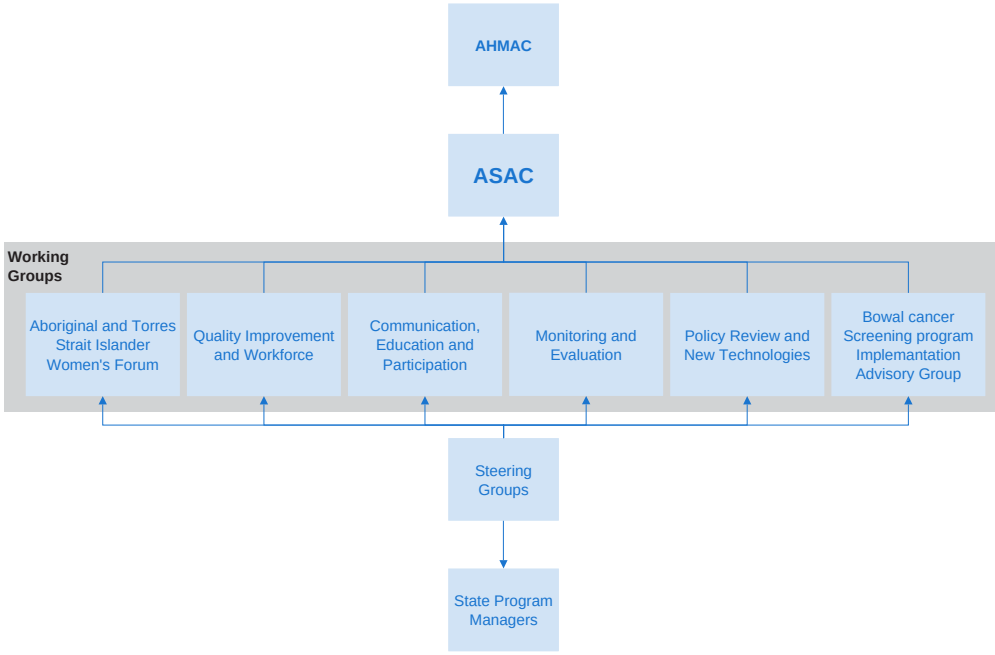
2.9 As a result, the Minister extended the terms of BSA and NCSP NACs until June 2003, while the findings of the CSC Review were given further consideration. The NACs of BSA and NCSP were subsequently disbanded when their extended terms expired. As a consequence, there was no official advisory body for BSA and NCSP from July 2003, pending the establishment of alternative committee arrangements.

2.10 DoHA commenced the second review in August 2003. The objective of this review, the Population Screening Section Committee Structures Review (PSSCS Review), was to identify areas of duplication between committees. The PSSCS Review's findings were reported to DoHA in October that same year and the 'concept' of the Australian Screening Advisory Committee (ASAC) was formed. The recommendations of the PSSCS Review were supported by DoHA, with the department seeking Ministerial approval for revised committee arrangements in February 2004.

2.11 ASAC was subsequently established by Ministerial approval, with tenure of five years. The Minister invited ASAC nominations in July 2004, with the inaugural ASAC meeting held in September 2004. ASAC membership included representation from the Australian Government and State/Territory governments. It also comprised members with expertise in epidemiology, population health, gastroenterology, gynaecological oncology, general practice, consumer matters and Aboriginal and Torres Strait Islander issues. Its role was defined as the peak advisory body for screening issues (the ASAC structure is shown in Figure 2.1).

Figure 2.1

ASAC structure



Source: ANAO from DoHA information.

2.12 As mentioned earlier, with the disbanding of the NACs in June 2003 there was no advisory body for screening issues until the first meeting of ASAC in September 2004. This meant that there was a period of 15 months without a peak advisory body for screening issues.

2.13 The Minister, in a July 2004 letter to prospective ASAC members, commented on the impact of the absence of a screening advisory committee during this period. The Minister's letter states that: 'This has left a considerable gap in progressing discussions on screening issues.'

2.14 DoHA advised the ANAO that, although the NACs were an important source of advice for screening issues, the department had access to other avenues of advice during this 15 month period, such as the AIHW, State and Territory program managers, the Medical Services Advisory Committee, and former NAC members.

Australian Health Minister's Advisory Council review

2.15 As illustrated in Figure 2.1, the screening advisory committees of NCSP provide policy advice to Australian Health Minister's Advisory Council

(AHMAC) on screening issues, which in turn supports initiatives to further develop the program.[20]

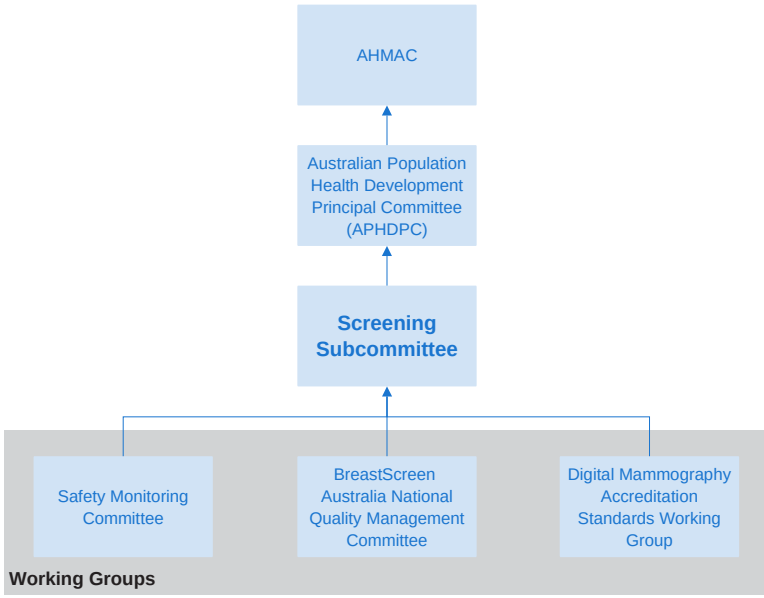
2.16 Following a review of its population health subcommittees in 2006, AHMAC proposed a major rationalisation. AHMAC subsequently established two new principal health committees, the Australian Health Protection Principal Committee and the Australian Population Health Development Principal Committee (APHDPC). A national standing subcommittee on screening (Screening Subcommittee) was also established under APHDPC. Membership of the Screening Subcommittee comprises Australian Government and State/Territory government officials.

2.17 The Screening Subcommittee provides advice to AHMAC, via APHDPC, on emerging population screening issues, oversees generic issues related to national screening programs, and provides leadership and national policy direction. It also provides a forum for Australian Government and State/Territory governments to discuss operational issues related to screening matters. The Screening Subcommittee held its inaugural meeting in October 2006 (the Screening Subcommittee's structure is shown in Figure 2.2).

[20] AHMAC's charter is to provide effective and efficient support to the Australian Health Ministers' Conference, by:
- advising on strategic issues relating to the coordination of health services across the nation and, as applicable, with New Zealand; and
- operating as a national forum for planning, information sharing and innovation.

Figure 2.2

Screening Subcommittee structure



Source: ANAO from DoHA information.

2.18 With the establishment of the Screening Subcommittee, DoHA decided to disband ASAC because it considered that ASAC had not been functioning well. In particular, the department considered that there were confused lines of communication between ASAC and its stakeholders. DoHA subsequently recommended to the Minister's office the recasting of ASAC as an expert advisory group, with responsibility for advising the Minister and the department. Ministerial approval was subsequently sought and granted for the establishment of an expert, high level advisory committee—the Australian Advisory Committee on Screening (AACS).

2.19 The department advised that there was a delay in the establishment of the AACS pending Ministerial approval to establish the committee. In April 2007, members of ASAC and its working groups were formally notified of the disbanding of ASAC and its working groups and the establishment of AACS. The formal notification was provided almost 12 months after the last meeting of ASAC.

2.20 Some stakeholders expressed disappointment to the ANAO that the new NCSP committee structures separated jurisdictional and expert representatives. It was also considered by these stakeholders that the revised committee structures had resulted in unclear lines of communication.

2.21 The ANAO suggests that DoHA monitor lines of communication between the Screening Subcommittee and AACS to ensure that arrangements are effective.

Managing implementation

2.22 To effectively implement an audit recommendation or review recommendation requires:

- sound planning;
- effective assessment of risk; and
- robust monitoring.

Planning

2.23 The ANAO noted a lack of a structured approach to planning DoHA's actions to implement recommendation 1 from the earlier audit report. Considering the many changes in the NCSP committee and working group structures since the previous audit, a functional plan would have assisted DoHA to coordinate implementation activities and avoid delays in establishing new committees and the resulting gaps in committee coverage.

Risk management

2.24 A key finding from the original audit was that the department had not prepared a risk management plan for the administration of NCSP. As a consequence, the department was not in a position to show that significant risks to NCSP had been identified, assessed, ranked, treated, monitored and reviewed. In response, DoHA informed the ANAO that a risk management plan would be developed for 2000–01. However, the ANAO found that there was no record of a plan for the years 2000 to 2005.

2.25 As at February 2007, a draft plan was available for 2005–06 and a risk management plan had been finalised for 2006–07. The department has informed the ANAO it will endeavour to ensure that a risk management plan for NCSP is in place in future years.

Monitoring

2.26 DoHA's internal audit committee is responsible for monitoring departmental progress on implementation of ANAO recommendations. Program areas reported to the audit committee between 2001 and 2004 on progress to implement the recommendations from the 2001 audit. These progress reports outlined actions to implement recommendation 1, including committee reviews and committee/working group structural changes. DoHA's Audit and Fraud Control Branch assessed the actions outlined in the program area's June 2004 progress report as satisfactorily completing implementation of the recommendation.

Conclusion

2.27 DoHA has implemented recommendation 1.

2.28 Since the earlier audit, DoHA has comprehensively restructured committee arrangements for NCSP. The department commissioned two reviews to examine communication arrangements and to inform its restructuring of NACs and working groups. The review process also incorporated a comprehensive consultation process with stakeholders.

2.29 However, DoHA did not apply similar rigor to inform its decisions regarding subsequent committee restructures. A targeted review process, which included effective consultation, would have provided:

- the department with an opportunity to explore the benefits and costs of alternative committee structures; and
- stakeholders with the opportunity to raise issues, and to suggest options for change.

2.30 The absence of a peak advisory body for screening issues and lengthy delays in the establishment of new committees were undesirable outcomes from the restructuring process. The department would have been in a better position to avoid this outcome had it employed a structured approach to planning implementation activities and managing risks to the timely implementation of revised committee arrangements.

3. Enhancing Secretariat Services

Background

3.1 In the earlier audit, the ANAO noted that an important role for the department in the administration of NCSP was the provision of secretariat services to committees and working groups. The ANAO found that there was no agreement or protocols between DoHA and committees/working groups governing the provision of secretariat services. The ANAO considered that protocols would provide a measure by which DoHA could ensure the adequate provision of secretariat services.

3.2 Accordingly, the ANAO recommended that DoHA and the National Advisory Committee (NAC) develop protocols for the provision of secretariat services. The ANAO considered that the establishment of protocols would enhance accountability of the secretariat and provide members with a realistic expectation of the services to be provided.

3.3 In its response to the earlier audit, DoHA stated that it agreed with the recommendation and that committee arrangements would be revised at the end of their terms of appointment, including consideration of protocols for the provision of secretariat services.

3.4 In its response to this audit, DoHA stated that it had implemented the recommendation through the establishment of operating guidelines for advisory committees formed under NCSP.

ANAO's findings

Implementation

3.5 The ANAO considered a number of factors as part of its assessment of the actions taken by DoHA to implement recommendation 2 from the earlier audit, including:

- processes adopted to develop protocols and establish service levels;
- stakeholder consultation;
- the way in which protocols were established; and
- the methods used to monitor the ongoing suitability and currency of the protocols.

Developing guidelines/establishing service levels

3.6 The Cancer Screening Committee Structures Review (CSC Review), discussed earlier, included an assessment of the workload of the NAC secretariat and a discussion of the allocation of secretariat time to committee support tasks. The review also reported the views of NAC and working group members on secretariat support. In addition, the review team analysed the cost of supporting the existing committee structure and the revised structures proposed by the review.

3.7 The department concurrently explored the option of outsourcing the secretariat function for the NAC and its working groups. This activity culminated in a *Secretariat Service Review Report*. The report included four recommendations, including one recommendation that stated: 'Continue providing secretariat support for the National Advisory Committee from the Central Office of the Department and revise Operational Guidelines to enhance this service.'

3.8 The department advised the ANAO that a template for secretariat operating guidelines may have been used as the basis for the creation of Australian Screening Advisory Committee (ASAC) guidelines. In developing the guidelines for Australian Advisory Committee on Screening (AACS), the program area also referred to the department's *Committee Servicing Manual*.[21] The purpose of the manual is to provide better committee servicing by promoting a preferred and consistent style in departmental administration.

3.9 The ANAO also found that the departmental secretariat worked with the Chair of the Screening Subcommittee to establish administrative processes and procedures.

Establishing guidelines

3.10 DoHA established ASAC operating guidelines in 2004. These guidelines were discussed and agreed at the inaugural meeting of ASAC, with a revised version reissued in 2005. After ASAC was disbanded, its guidelines were used to inform the drafting of the Screening Subcommittee operating guidelines. These guidelines were also discussed and agreed at the inaugural meeting of the Screening Subcommittee and issued in October 2006. DoHA has

[21] This manual was created by the Committee Support Unit, which is part of DoHA's Business Group and has a stated aim of providing: '…advice to staff involved with committees to enable them to meet their administrative requirements for the successful conduct of committee meetings and payments to their members.'

also provided the ANAO with draft (as at February 2007) operating guidelines for AACS.

3.11 In general, the guidelines outline the secretariat services to be provided, which comprise operational, technical and administrative support. A detailed description of secretariat services to be provided by DoHA is also specified in the guidelines, such as preparations for meetings, production of reports, agendas, papers, minutes of meetings and follow-up action. The guidelines also address financial considerations regarding members' travel costs, the clearance of payments, contract management, dealings with the media, and links within the department.

3.12 The ANAO considers that the operating guidelines adequately describe the services that the secretariat could reasonably be expected to provide. The ANAO also noted that the department, through consultation with relevant committees, established committee work plans that outlined the activities to be undertaken by the committees and supported by the department.

Guidelines management

3.13 Guidelines have historically been reviewed, amended, updated and re-issued by the department as required by changes to committees or committee arrangements. DoHA has indicated that the Screening Subcommittee will endeavour to review its operating guidelines on an annual basis, with a review date of October 2007 included as a footnote to the guidelines.

Compliance with service levels

3.14 During the earlier audit, the ANAO noted that: '…stakeholders expressed concern that meeting minutes were not always produced in a timely fashion, with some draft minutes not supplied to meeting participants until five or six months after the meeting.' As part of this audit, the ANAO sought to establish whether the department monitors the quality of its secretariat services.

3.15 As at February 2007, DoHA advised that there were no formal monitoring arrangements for the provision of secretariat services for previous national screening committees. The department has since advised the ANAO, that the Chair of the Screening Subcommittee has agreed to the development of a survey to monitor secretariat services, and that an agenda item addressing the issue will be included for the August 2007 meeting.

3.16 The ANAO subsequently examined the standards outlined in the operating guidelines and the secretariats performance against those standards. The operating guidelines for the current Screening Subcommittee outline the requirements for the distribution of agendas and minutes of meetings. The ANAO found that the secretariat's performance against established standards, as outlined in the operating guidelines, has been variable, for example, the late circulation of meeting minutes for endorsement by members.

3.17 In response to the ANAO's finding, the department has advised that it will endeavour to comply with operating guidelines by providing members with agenda papers two weeks prior to a meeting and provide minutes of meetings one month following a meeting.

Managing implementation

Planning and risk management

3.18 The actions required to implement recommendation 2 are relatively straight forward in nature and, therefore, would not necessitate the same level of planning and risk assessment as other recommendations from the earlier report. Notwithstanding, the ANAO considers that simple planning and a structured consideration of risks would have provided DoHA with greater assurance that:

- departmental resources were deployed efficiently; and
- risks were adequately managed.

Monitoring

3.19 The program area's initial progress reports to the department's audit committee stated that: '…protocols for the provision of secretariat services will be developed in light of the outcomes of the review of Screening Section Committees.' After it had assessed the outcomes of the review, the program area reported to the audit committee's June 2004 meeting, that: 'Protocols for the provision of secretariat services have been developed as part of the operating guidelines for the Australian Screening Advisory Committee.' DoHA's Audit and Fraud Control Branch assessed the actions outlined in the program area's June 2004 progress report as satisfactorily completing implementation of the recommendation.

Conclusion

3.20 DoHA has implemented recommendation 2.

3.21 The ANAO concluded that DoHA, in collaboration with committees/working groups and in accordance with departmental guidance, has established appropriate protocols for the provision of secretariat services for national screening committees established since the earlier audit.

3.22 The ANAO also acknowledges the department's intention to introduce a process to:

- review the guidelines on, at least, an annual basis, and update where required; and
- monitor the adequacy of the secretariat services it provides under NCSP. The proposed monitoring process should allow the department to identify issues, such as the timeliness of agenda paper and meeting minute distribution, and take corrective action where service levels are outside of those specified in applicable operating guidelines.

4. Improving Quality Monitoring

Background

4.1 As part of the earlier audit, the ANAO examined the quality of Pap smear analyses with a focus on performance monitoring and compliance action. The audit report outlined accreditation arrangements for pathology laboratories and discussed the requirement for accreditation in order for laboratories to receive Medicare benefits for pathology services.[22]

4.2 The audit also examined the period of accreditation, which can be up to three years, and commented on the lack of data available to accreditation and funding bodies between inspections. The ANAO considered that this lack of data limited the capacity of accreditation and funding bodies to effectively monitor the performance of individual laboratories.

4.3 The ANAO recommended that DoHA and the Health Insurance Commission (now Medicare Australia), in consultation with the pathology industry, explore options to improve performance monitoring of pathology laboratories undertaking cervical cytology. In particular, the ANAO sought an amendment to accreditation arrangements that would allow the annual provision to Medicare Australia of data on a pathology laboratory's performance against quantitative standards. The ANAO considered that this amendment would improve the Australian Government's ability to satisfy itself that services for which it is paying are of the required quality.

4.4 In its response to the 2001 audit, DoHA agreed with the recommendation and acknowledged the need for more regular reports on the performance of pathology laboratories against quantitative standards. Medicare Australia also agreed with the general thrust of the recommendation.

4.5 In its response to this audit, DoHA outlined the commissioning of an external evaluation of pathology laboratory accreditation arrangements and the department's commitment to implementing the recommendations from the evaluation. The department indicated that the evaluation called for a similar response to the issues underpinning recommendation 3 from the earlier audit report. DoHA's response also provides an overview of steps taken to implement the recommendation, including the establishment of projects to develop quantitative standards.

[22] It should be noted that only those pathology laboratories receiving Medicare benefit payments are subject to accreditation arrangements for pathology laboratories.

4.6 The department's response also raises the pathology industry's concerns regarding rankings and performance assessment based on the use of quality assurance program (QAP) data. DoHA reported that some members of the pathology industry are concerned that that the interpretation of QAP data could be inappropriately or unfairly applied during accreditation inspections. As a consequence, some laboratories may seek to:

- manipulate their results to avoid a poor ranking;
- treat their quality assurance samples differently than patient samples; or
- select a quality assurance provider that does not have systems to identify poor performers.

4.7 Medicare Australia's response to this audit reiterated DoHA's policy responsibility for the matters underpinning this recommendation.

ANAO's findings

Implementation

4.8 In the earlier audit report, the ANAO commented on the complexity of the pathology quality assurance process. This complexity is necessarily reflected in recommendation 3, which comprises several important elements. These elements include stakeholder consultation, access to data, accreditation conditions, quantitative standards and performance reporting. Recommendation 3 was also jointly made to both DoHA and Medicare Australia. Therefore, in order to form an opinion on the actions taken to implement the recommendation, the ANAO considered the following:

- roles and responsibilities of DoHA and Medicare Australia;
- relevant departmental reviews;
- DoHA's engagement with stakeholders;
- access to quality assurance data; and
- the development of appropriate performance standards.

Roles and responsibilities

4.9 As noted earlier, recommendation 3 was jointly made to both DoHA and Medicare Australia. As such, an examination of the actions taken to implement the recommendation would be guided by the roles and responsibilities of the respective agencies. In addition to seeking a response from each agency at the commencement of the audit, the ANAO also met with departmental and Medicare Australia officers to explore this issue.

4.10 DoHA advised the ANAO that due to its policy role, the department has oversight of the accreditation process and is responsible for the effectiveness of pathology accreditation arrangements, including the frequency of laboratory reporting.

4.11 Medicare Australia advised the ANAO that its responsibilities under the *Health Insurance Act 1973* (the HIA) do not include responsibility for the accreditation function. While Medicare Australia maintains an interest in this area, DoHA has policy responsibility and is therefore ultimately accountable for the effectiveness of the accreditation function.

4.12 In light of the above responses, the focus of the ANAO's fieldwork for recommendation 3 was directed toward DoHA.

Departmental reviews

4.13 In 2001, DoHA commissioned Corrs Chambers Westgarth to conduct an evaluation of Australian pathology laboratory accreditation arrangements (Corrs Review). The evaluation report (Corrs Report) was completed in July 2002. The review concluded that the current Australian pathology laboratory accreditation arrangements were fundamentally sound and should be maintained. Notwithstanding, the Corrs Review recommended a range of strategies in the form of recommendations, to improve the performance of the pathology system.

4.14 Two of the Corrs Report recommendations addressed a similar theme to that of recommendation 3 from the earlier ANAO audit report, in that they sought the regular performance reporting to NATA to inform the identification of poorly performing laboratories. The Government agreed with these recommendations and assigned responsibility for implementation to DoHA, RCPA Quality Assurance Programs Pty Ltd (RCPA QAP)[23] and NATA.

[23] RCPA QAP offers external quality assurance programs across all disciplines of pathology to support the scientific and medical communities in Australia, New Zealand and overseas countries.

Stakeholder consultation

4.15 The ANAO found that, in response to the findings of the earlier audit report, the National Pathology Accreditation Advisory Council (NPAAC)[24] convened quality assurance workshops in June and November 2001, at which the problems with the quality assurance system were discussed by stakeholders.[25] The issue that underpinned recommendation 3—that of more regular reporting of laboratory performance—was raised by a number of stakeholders.

4.16 DoHA arranged further meetings with representatives of NATA, RCPA, RCPA QAP and the, then, HIC to discuss pathology laboratory accreditation arrangements, including those that related to recommendation 3. Attendees also discussed draft approval principles which outline the process for accrediting pathology laboratories, recommendations from the Corrs Review, Australian Government funding to develop a set of performance indicators and the establishment of a Performance Indicator Group.

Provision of quality assurance data

4.17 The earlier audit commented on the importance of the timely provision of pathology laboratory performance data, upon which an assessment could be made to identify poorly performing laboratories between accreditation inspections.

4.18 The ANAO found that regular performance data on laboratory performance was available to RCPA QAP, but that this information was not available to Medicare Australia (or NATA in its role as Medicare Australia's accreditation provider). As a consequence, a decision on the accreditation status of poorly performing laboratories could only be made following an accreditation inspection by NATA, which could be up to three years.[26] To

[24] NPAAC advises the Australian Government and State/Territory health ministers on matters relating to the accreditation of pathology laboratories. NPAAC plays a key role in ensuring the quality of Australian pathology services and is responsible for the development and maintenance of standards and guidelines for pathology practices. NPAAC is made up of representatives from all States and Territories, nominees from peak professional bodies and DoHA.

[25] The workshops were attended by representatives from NPAAC, the Australian Institute of Medical Scientists, RCPA, the Australian Association of Pathology Practices, the Medical Testing Accreditation Advisory Committee, NATA, the Pathology Services Accreditation Board-Victoria, the Health Insurance Commission, RCPA QAP, the Quality Assurance Working Group-National Cervical Screening Program, the Australian Society for Microbiology, the Australian Association of Clinical Biochemists, the Australian Council on Health Care Standards, and the Royal Australian College of General Practitioners, DoHA-NCSP, and DoHA-Diagnostics and Technology Branch.

[26] DoHA advised the ANAO that not all pathology laboratories are on a three year accreditation cycle. Those laboratories that are of concern to NATA are reviewed on a more regular basis. Data provided by Medicare Australia indicated that 61 per cent of laboratories are approved for less than three years.

address this issue, the ANAO recommended that, as a pre-requisite for accreditation to perform cervical cytology, laboratories agree to the annual provision of performance data to Medicare Australia (in practice this would be NATA in its role as accreditation provider).

4.19 Under section 23DNA of the *Health Insurance Act 1973* (HIA), the Minister for Health and Ageing, or a delegate, may determine principles that outline eligibility for premises to be approved as an accredited pathology laboratory. It is through this instrument and related undertakings that the department is able to specify the conditions under which pathology laboratories operate, such as conditions governing the provision of quality assurance data to accreditation or funding bodies.

4.20 In early 2002, DoHA met with stakeholders to discuss a range pathology accreditation issues, including the issue of access to performance data. A particular focus of this and subsequent meetings was to inform the development of revised pathology laboratory principles and Approved Pathology Authority (APA)/Approved Pathology Provider (APP) undertakings. It was through this process that draft pathology laboratory principles and undertakings were developed and provided to the Minister for endorsement.

4.21 On 13 November 2002, the then Minister signed the revised pathology laboratory principles and APA/APP undertakings, which included a requirement for laboratories to provide an independent body (NATA) with performance data.[27] The date of effect of the new instrument was 1 January 2003.

Quantitative standards

4.22 In response to the Corrs Review recommendation to use external quality assurance program data as a possible tool for early identification of poorly performing laboratories, an NPAAC steering committee was established to consider the development of key performance indicators (KPIs). The first meeting of the steering committee was held on 18 June 2002. At this meeting, members discussed possible mechanisms for identifying poorly

[27] Specifically, the APP undertaking states: 'On request from an independent body, I undertake to provide the independent body with copies of all quality assurance program reports and related information relating to the conduct of my activities as an APP' and the APA undertaking states: 'On request of an independent body, the authority undertakes to provide the independent body with copies of all quality assurance program reports and related information relating to the authority and any of its employees.'

performing laboratories. The members subsequently agreed that the continued development of KPIs would require an injection of funds.

4.23 In March 2003, DoHA entered into a funding agreement with the RCPA to develop a set of quantitative standards (KPIs) based on QAP data and: '…explore the means to collect, analyse and report on data from participating laboratories in shorter time-frames to enable comprehensive feedback to laboratories and to instigate any corrective action decreed appropriate.' The project period was to end on 31 January 2004, with DoHA indicating in its response to the ANAO that the project was completed in January 2004. However, evidence collected during fieldwork indicates that the final project report was not provided to the department until late July or early August 2004.[28]

4.24 In October 2005, DoHA entered into a second funding agreement with the RCPA to implement and evaluate the KPIs developed under the earlier project. Under the funding agreement, a Steering Group and Professional Review Committees were established to facilitate achievement of the agreement objective. The Steering Group was to include Medicare Australia and DoHA representation, with the department also represented on the Professional Review Committees (PRCs). The project period was to end on 1 September 2006. The department advised that it has recently varied the contract to extend the project period until the end of the 2006–07 financial year.

Assurance

4.25 As the department has funded the RCPA to develop quantitative standards against which the college's members may ultimately be assessed, the ANAO sought information from DoHA on the processes that it has employed to gain an assurance over the appropriateness of the standards. The ANAO sought to determine whether the department had an independent means of validating the appropriateness of quantitative standards developed by the RCPA.

4.26 The department informed the ANAO that it 'trusts' the RCPA, as the RCPA has a genuine interest in protecting the integrity and reputation of pathologists. DoHA also stated that:

> …the Department's faith in the Key Performance Indicators developed through this process largely rests on the expertise and ethics of the large

[28] The ANAO and DoHA was unable to verify the date on which the report was received by the department as there was no record on DoHA's files of the date the final report was received by the department, or when the report was accepted, or when the acquittal was received, or when the acquittal was accepted.

number of pathologists and other professionals involved in the PRCs and the steering committee, including NATA representatives. In addition, the Pathology Section currently employs two very experienced former laboratory scientists, who could provide informed comment on the proposed KPIs.

Managing implementation

Planning

4.27 The ANAO noted the lack of a structured planning approach to guide the actions taken by DoHA to implement the recommendation from the earlier audit report and the subsequent recommendations from the Corrs Review. Given the complex nature of pathology quality assurance and the number of tasks required to support regular reporting against quantitative standards, the ANAO considers that implementation should have been guided by a functional plan. A plan would have identified an appropriate timeframe, allocated specific responsibilities, and established resource requirements.

4.28 Effective planning also provides the foundation on which progress can be monitored. The lack of a plan to guide actions to implement the recommendations made monitoring progress difficult, particularly for new staff.

4.29 Furthermore, there was no evidence to support an opinion that an impact analysis of introducing measures to identify poorly performing laboratories had been undertaken by the department. The ANAO considers that analysis of this nature would have more fully explored some of the issues that were encountered during the funded projects, such as the work load of NATA.

Risk management

4.30 There were a number of issues that arose during the course of the KPI development and implementation projects that highlighted the importance of effectively managing risks stemming from changes to pathology quality assurance processes.[29] However, the ANAO found that there was no structured approach to risk management relating to the implementation of the recommendation.

[29] For example, project steering group participants were required to establish the parameters for the conduct of the funded project, including actions to be taken if the performance of a laboratory, which was voluntarily participating in the project, was found to be poor. Any action needed to balance the impact on the voluntary participation of laboratories if accreditation was under threat, against the primary obligation to protect public health.

4.31 The ANAO also noted that, given the complexity surrounding the establishment of KPIs for cervical cytology, there is a risk that the KPI implementation project may conclude that the KPIs are not a suitable measure of laboratory performance. The department could more effectively manage this risk by adopting a structured approach to risk management. Otherwise, at the conclusion of two funded projects valued at $400 000 and six years after the ANAO made its recommendation, the department may have to undertake further work to establish quantitative standards for cervical cytology.

Monitoring

4.32 The program area's reports to the audit committee included reference to a number of activities, including stakeholder meetings, external reviews, work to revise pathology principles, and department funded projects to develop KPIs. In its final report to the audit committee in June 2004, the program area outlined the role of NATA and the revised reporting arrangements under new pathology principles, including the obligation for laboratories to provide data to NATA. DoHA's Audit and Fraud Control Branch assessed the actions outlined in the program area's June 2004 report as satisfactorily completing implementation of the recommendation.

Timeframe for implementation

4.33 DoHA acknowledged to the ANAO that progress on implementing recommendation 3 has been slow and suggested that this was because it had to maintain the 'buy in' of stakeholders/laboratories while introducing change.

4.34 The ANAO found that delays to the implementation of recommendation 3 and the Corrs Review recommendations were also partly due to:

- contract management delays; and
- protracted negotiations over indemnity for RCPA due to an anticipated increase in risk exposure arising from its role in the KPI development project.

Contract management

4.35 The ANAO identified a number of weaknesses in contract management. These weaknesses included:

- execution of agreements after the project period had commenced;
- varying a funding agreement after the project period had ended;

- delays in the provision of 'milestone' reports;
- lack of documentation to indicate receipt and acceptance of funded 'milestone' reports; and
- delays in concluding agreements.

4.36 Similar weaknesses in the management of funding agreements within another area of the department[30] were recently brought to DoHA's attention with the tabling of Audit Report No.41, 2005–06, *Administration of Primary Care Funding Agreements*. In its response to Audit Report No.41, the department indicated that the findings: '…apply specifically to aspects of the administration of primary care funding agreements, and not to the operations of the Department as a whole.' The findings from this follow-up audit indicate that problems with the administration of contracts/agreements may be more wide-spread and actions taken by the department to respond to Audit Report No.41 may need to be applied more broadly across the department.

Conclusion

4.37 The ANAO acknowledges that DoHA, as the agency with policy responsibility, is working to introduce more regular reporting of pathology laboratory performance against established standards. The ANAO also recognises that the development and implementation of a scheme to identify laboratories of concern, through regular reporting against quantitative standards, is complex and necessitates input from technical experts and requires sufficient time to undertake effective consultation with stakeholders.

4.38 The ANAO considers that actions taken by DoHA adequately respond to the issues identified in the 2001 audit report. While acknowledging the current absence of annual reporting of quality data to Medicare Australia, the ANAO noted:

- the actions taken by the department and Medicare Australia to facilitate the provision of external quality assurance data to NATA through revised pathology laboratory principles and undertakings; and
- the establishment of projects to develop quantitative standards against which laboratory performance can be assessed, and the subsequent piloting of developed standards.

[30] Primary and Ambulatory Care Division.

4.39 Therefore, the ANAO considers that DoHA has sufficiently explored the issue of performance reporting with the pathology industry and, as a consequence, has adequately implemented this recommendation.[31] Notwithstanding, the ANAO considers that DoHA's efforts to date have been hampered by:

- the lack of effective management of the implementation of the recommendation from the 2001 audit report and the subsequent recommendations from the Corrs Review;
- the absence of effective risk management approaches; and
- weaknesses in contract administration practices.

4.40 These administrative weaknesses have introduced delays and contributed to a situation where, after almost six years, quantitative standards are yet to be established. The ANAO suggests that DoHA assign priority to establishing quantitative standards (either KPIs or other standards as developed) and instituting a reporting regime that effectively identifies laboratories of concern on an annual basis, as a minimum.

Further issues

Pathology quality assurance framework

4.41 DoHA's initial response to this audit referred to the negative effects on external quality assurance program participation, where QAP data is used to monitor laboratory performance. DoHA's response reflects the pathology industry's concerns that using QAP data for a regulatory purpose may cause some laboratories to: '…manipulate their results to avoid poor ranking, or treat their QAP samples differently from patient samples.' The ANAO also noted that the current accreditation framework permits laboratories to: '…participate in a QAP run by a provider that does not currently have a system to identify relatively poor performers.' The potential for 'cheating' or 'gaming' of QAP results was also raised by stakeholders during KPI project meetings.

4.42 The potential for pathology laboratories to manipulate their QAP results is particularly problematic as QAP data will be used to assess performance against the proposed KPIs. The effectiveness of the KPI process will also be undermined if pathology laboratories are able to avoid scrutiny of

[31] It should be noted that the ANAO has not formed an opinion on the adequacy or appropriateness of the KPIs developed and piloted under the two funded projects.

their performance by selecting a QAP provider that does not have a system to identify poor performers.

4.43 Further exploration of these matters is outside the scope of this follow-up audit. The ANAO will, however, use this information to assist it to determine the nature and extent of any future work that it may undertake in this area.

5. Strengthening Governance

Background

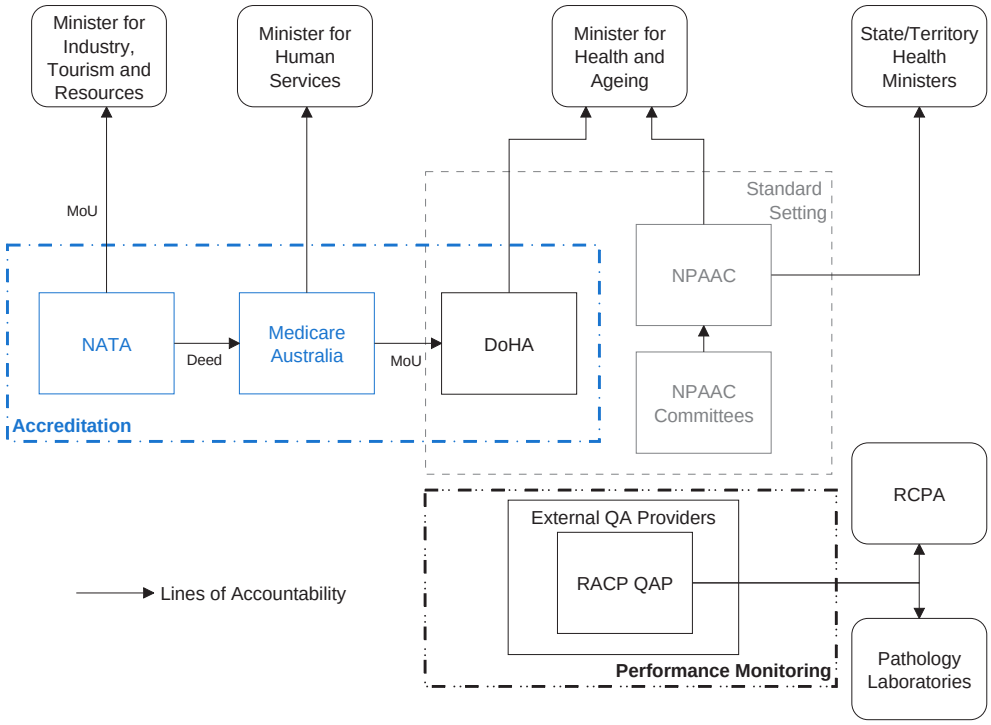
5.1 The 2001 audit examined the roles and accountabilities of participants in the quality assurance process for gynaecological (cervical) cytology. The report explained that pathology quality assurance has three components:

- standard setting;
- accreditation against standards; and
- monitoring of performance against standards (which includes external quality assurance programs).

5.2 Figure 5.1 shows current participants in each of the three components of the pathology quality assurance process and also provides an overview of current accountability arrangements.

Figure 5.1

Pathology quality assurance process



DoHA	Department of Health and Ageing
NATA	National Association of Testing Authorities Australia
NPAAC	National Pathology Accreditation Advisory Council
RCPA	Royal College of Pathologists of Australasia
RCPA QAP	RCPA Quality Assurance Programs Pty Ltd

Source: ANAO.

5.3 The earlier cervical screening audit identified that, while there were in excess of five committees or organisations involved in the process, overall responsibility for oversight of all participants within the process had not been assigned. As a consequence, the ANAO was unable to identify a position or body with clear responsibility for the oversight of the quality assurance process.

5.4 In the earlier 2001 audit, the ANAO considered that without clearly defined responsibility for oversight of the pathology quality assurance process and authority to address any identified deficiencies:

- activities of participants in the process may not be properly coordinated;
- accountability for the process as a whole is not possible;
- risks to the success of the process may not be identified and addressed;
- the quality of services provided to women and their doctors may not reach the required standards; and
- the benefits possible from an organised approach to cervical screening may be reduced.

5.5 The ANAO recommended that DoHA take steps to assign responsibility for oversight of all elements of the process, including standard setting, accreditation against standards and monitoring performance against standards. It was suggested that these steps could include the establishment of a new committee or an extension to the terms of reference of an existing committee.

5.6 In its response to the earlier audit, DoHA indicated its agreement to the recommendation and acknowledged the need for a committee to provide oversight of the pathology quality assurance process. The department also suggested that it may be appropriate for the terms of reference of the National Pathology Accreditation Advisory Council (NPAAC) to be extended to include oversight of quality assurance processes and that further investigations would be undertaken as a matter of priority.

5.7 In its initial response to this follow-up audit generally, and recommendation 4 specifically, DoHA outlined:

- changes made as an outcome of an independent review of pathology laboratory accreditation;
- the continuing role of NPAAC and its subcommittees with regard to standards for cervical screening; and
- the production of guidelines on pathology standards.

ANAO's findings

Implementation

5.8 As part of its assessment of the actions taken by DoHA to implement recommendation 4 from the earlier audit, the ANAO considered:

- the review process adopted to assess the status of stewardship;
- the role of NPAAC in the oversight of the pathology quality assurance process; and
- the department's engagement with stakeholders.

Departmental reviews

5.9 In response to a departmental request in March 2002, the Corrs Review team expanded its terms of reference to include an investigation of the issue of stewardship of the pathology quality assurance process. The Corrs Review subsequently made two recommendations which specifically addressed the issue of stewardship.

5.10 The Corrs Review considered that the appointment of an HIC (now Medicare Australia) contract manager would assist to address the issue of stewardship raised by the ANAO.[32] A recommendation was made to this effect.

5.11 The Corrs Review also recommended that DoHA allocate responsibility for stewardship to a senior officer in its Diagnostics and Technology Branch to receive regular, structured reports from the Medicare Australia contract manager on the overall quality of pathology services, and to initiate any necessary policy responses to those reports.[33]

5.12 In response to the Corrs Report, the Government agreed 'in principle' with the first recommendation and stated that DoHA would liaise with the, then, Australian Council for Safety and Quality in Health Care (ACSQHC)[34], regarding the second recommendation.

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[32] Corrs Chambers Westgarth Lawyers, 2002, *Evaluation of Australian Pathology Laboratory Accreditation Arrangements (Corrs Report)*, *Executive Summary*, pviii, available from <http://www.aodgp.gov.au/internet/wcms/publishing.nsf/content/health-pathology-accred-index.htm-copy3> [accessed 16 April 2007].

[33] ibid.

[34] Now the Australian Commission for Safety and Quality in Health Care. The commission reports to the Australian Health Ministers' Conference and has the following functions:

5.13 As a result of measures introduced in response to the Corrs Review[35], the department considers that it is now better able to:

- coordinate the activities of participants in the process;
- identify and address emerging risks; and
- have greater confidence in the quality of pathology services supported by Medicare benefits.

NPAAC's role

5.14 In its response to the 2001 audit, DoHA stated that it may be appropriate for NPAAC's terms of reference [Order-in-Council] to be extended to include oversight of quality assurance processes, indicating it would investigate the assignment of responsibility as a matter of priority. NPAAC's Order-in-Council was subsequently amended to expand its membership. However, the amendment did not address stewardship of the pathology quality assurance process.

5.15 While NPAAC's Order-in-Council was not changed to reflect broader responsibilities, the department has advised the ANAO that, in practise, NPAAC is the steward of the pathology quality assurance process.

5.16 The issue of stewardship of quality assurance of cervical cytology is to be the subject of further review by NPAAC. At its March 2007 meeting, NPAAC agreed to refer the stewardship issue to a standards review committee for further consideration.

Stakeholder consultation

5.17 The primary means by which the department explored the issues underpinning recommendation 4 with stakeholders was through the Corrs

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- leads and coordinates improvements in safety and quality in health care in Australia by identifying issues and policy directions, recommending priorities for action, disseminating knowledge, and advocating for safety and quality;
- reports publiclyon the state of safety and quality including performance against national standards;
- recommends national data sets for safety and quality, working within current multilateral governmental arrangements for data development, standards, collection and reporting;
- provides strategic advice to Health Ministers on 'best practice' thinking to drive quality improvement, including implementation strategies; and
- recommends nationally agreed standards for safety and quality improvement.

[35] DoHA has advised that these measures include:
- all pathology accreditation requirements being clearly defined and given legal enforceability through the Principles;
- NPAAC being the sole body responsible for developing or endorsing standards for inclusion in the Principles; and
- the roles of Medicare Australia and NATA being defined and clearly delineated in both the Principles and their Deed of Agreement.

Review, outlined above, and through the quality assurance workshops, outlined in Chapter 4. A key reason to hold these workshops was to discuss the oversight of the pathology quality assurance process.

5.18 At the November 2001 quality assurance workshop, representatives were advised that a minor amendment to the NPAAC Order-in-Council would be required for NPAAC to take on the role of steward. There was no record to indicate that representatives agreed to amend the NPAAC Order-in-Council to accept the role of steward. Representatives did, however, agree that the Minister for Health and Ageing had ultimate responsibility and, therefore, stewardship of health matters, including pathology quality assurance.

Developments

5.19 Given the period of time that has passed since the earlier audit and developments in pathology accreditation arrangements over this period, the ANAO sought to establish whether the findings that led to recommendation 4 remained valid.

5.20 The ANAO initially examined the operating environment to determine whether there had been any changes in the number and role of participants involved in the quality assurance process. In addition, the ANAO considered the findings of relevant reviews and studies.

Participants involved in the quality assurance process

5.21 A table was included in the 2001 audit report to explain the complicated nature of the pathology quality assurance process and to inform the reader as to the number of participants involved in the process. As part of this audit, the number of participants at the time of the earlier audit was compared with the number of participants currently involved in each of the three elements of pathology quality assurance. Since 2001, the number of participants has not changed substantially.

5.22 In responding to this follow-up audit, DoHA indicated that its oversight of the pathology quality assurance process is restricted to those bodies with which the Commonwealth has a contractual relationship, such as those bodies that are directly involved in setting standards and accrediting against them. It is in this context that the department provided Table 5.1 to illustrate that those bodies involved in setting standards and accrediting against them are ultimately responsible to the Minister for Health and Ageing.

Table 5.1

Participants with a direct involvement in pathology laboratory standards and accreditation

Organisation	Responsibilities	Accountability
NPAAC	Ensure appropriate standards are in place, against which pathology laboratories can be assessed. Provide advice to Governments on policy for accreditation.	Australian Government Minister for Health and Ageing and State and Territory Ministers
NPAAC committees, including Document Review and Liaison Committee (DRL) and drafting committees	Provide advice to NPAAC on pathology accreditation issues, with input from relevant experts and stakeholders.	NPAAC
NATA	Assess pathology laboratories against NPAAC standards. Provide advice to Medicare Australia on whether individual pathology laboratories meet standards.	Medicare Australia, as the delegate of the Australian Government Minister for Health and Ageing.
Medicare Australia	Decide whether to award individual pathology laboratories Accredited Pathology Laboratory status, which allows Medicare reimbursement for pathology services. Provide advice to pathology accreditation issues to NPAAC, through DRL.	Department of Health and Ageing, under a business practice agreement. Medicare Australia undertakes this role as the delegate of the Minister for Health and Ageing. Minister for Human Services
Department of Health and Ageing	Provide policy advice to the Minister for Health and Ageing and Medicare Australia on pathology accreditation. Provide support to NPAAC in setting standards and implement standards through the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles*. Liaise with Medicare Australia, NATA, and others on pathology accreditation issues.	Minister for Health and Ageing

Source: DoHA.

5.23 The department considers that, in achieving appropriate governance arrangements for quality assurance of pathology, bodies that directly and indirectly participate in providing pathology services, establishing standards for those services, and accrediting services against those standards are represented on committees (including NPAAC), and are consulted outside these formal processes where relevant.

5.24 As identified by DoHA, there is a wide range of bodies with an interest in promoting the quality of pathology services provided in Australia. This range of bodies was the focus of the original 2001 recommendation that related to all three elements of the pathology quality assurance system:

- standard setting,
- accreditation against standards; and
- monitoring of performance against standards.

5.25 While standard setting and accreditation components are acknowledged by DoHA as two components of the overall process, external quality assurance also plays a key role. This role is expected to increase significantly if the KPIs, which are based on external quality assurance data, are adopted as a means of identifying laboratories of concern. The ANAO also notes that bodies that perform external quality assurance services, such as RCPA QAP, are not accountable to the Minister for Health and Ageing. This was also the case at the time of the earlier audit and was a key finding that led to the development of recommendation 4.

5.26 In response to the ANAO's observations regarding responsibility for external quality assurance providers, the department provided the following comment:

> While laboratories are held accountable for their enrolment and performance in external quality assurance programs, external quality assurance providers are generally private organisations. The contractual relationship for the provision of external quality assurance services is between laboratories and providers. NPAAC has specified criteria that laboratories should use in choosing an external quality assurance provider, including whether the provider is approved by a recognised accreditation body and supported by relevant professional associations. However, as there is generally no direct contractual relationship or flow of funding from the Australian Government to external quality assurance providers, there is no simple mechanism by which QAP could be subjected to direct Commonwealth oversight.

Reviews

5.27 As noted earlier, the department requested the Corrs Review team to broaden its scope to investigate a number of additional matters, including the issue of stewardship of the quality assurance process. In one of its progress reports, the review team indicated that it concurred with the ANAO's original finding, stating that the: '…lack of a central body to undertake this stewardship role [is] a key deficit in the pathology system.' As outlined earlier, the review made two recommendations to address the perceived deficit.

5.28 The Australian Council for Safety and Quality in Health Care (ACSQHC) also supported the intent of the ANAO's original recommendation. In its July 2003 consultation paper on standards setting and accreditation systems in health, the ACSQHC made the following statement:

> There is no single body responsible for the overall safety and quality of health care. In relation to pathology quality assurance processes, the Australian National Audit Office (ANAO) in its 2001 audit of the National Cervical Screening Program was unable to identify a position or body within the Australian health care system with clear oversight responsibility, and identified a number of consequent risks. The ANAO recommended that the Department of Health and Ageing should take steps to assign responsibility for the overall stewardship of the pathology quality assurance process. This lack of oversight of safety and quality is evident across the health care system and is potentially a significant deficit.[36]

Managing implementation

5.29 The department had not planned the implementation of recommendation 4. Formal planning is a valuable tool that would have provided DoHA with a structured approach to managing the risks associated with implementing the recommendation and subsequently monitoring progress.

Risk management

5.30 The risks to the timely implementation of recommendation 4 were not identified and addressed by the department. The absence of effective risk management practices may have contributed to delays in implementation of the recommendation and a situation where, after six years, this recommendation is yet to be implemented.

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[36] Australian Council for Safety and Quality in Health Care, 2003, *Standards Setting and Accreditation Systems in Health: Consultation Paper, July 2003,* available from <http://www.safetyandquality.gov.au> [accessed 3 April 2007].

Monitoring

5.31 The program area's progress report to DoHA's audit committee in December 2001 stated that recommendation 4 was complete. However, in June 2002 the status of recommendation 4 was changed to not complete. The program area had changed its response stating that a decision would be made regarding an appropriate body to oversee the pathology quality assurance process once the findings of the Corrs Review were released.

5.32 In 2004, DoHA's Audit and Fraud Control Branch assessed the actions outlined in the program area's June 2004 report as satisfactorily completing implementation of the recommendation. However, the ANAO found that the reported progress information to the audit committee, which was deemed to satisfactorily address the recommendation, did not relate to implementation of recommendation 4, but rather to actions taken to implement recommendation 3.

5.33 The ANAO also noted other inconsistencies between the progress reported to DoHA's audit committee and file evidence. For example, a progress report to the audit committee indicated that NPAAC, at its 15 June 2001 workshop, had agreed to assuming stewardship of the pathology quality assurance framework. However, NPAAC meeting minutes indicate that: 'This issue was briefly discussed at the Quality Assurance Workshop on 15 June 2001, although it was not clearly agreed who would take on this role.'

5.34 The audit committee's monitoring function is an important control that provides an assurance to the departmental executive that ANAO recommendations have been actioned. The ANAO, therefore, suggests that the program areas within the department take care to ensure that reported information is accurate.

Conclusion

5.35 Having regard to Recommendation 4, the Department accepted at the time of the original audit that there would be merit in seeking single stewardship to provide effective national oversight of quality assurance processes for pathology. However, it subsequently became evident that the approach envisioned at that time was not feasible. Having considered the recommendations in an external review (the Corrs Report) and consulted widely with the stakeholders, the Department has introduced measures to strengthen the pathology accreditation system and now believes that it has fully achieved an effective level of oversight. Accordingly, the Department

considers that while the original recommendation was not implemented as first envisaged, it has in place a coherent system with clear and appropriate degrees of accountability for each participant and does not propose to take any further action on Recommendation 4. However, as part of its continuous improvement process, the Department will continue to work with all relevant stakeholders to further improve the pathology accreditation system and the overall quality of pathology services provided to the Australian community.

5.36 Taking DoHA's response into account, the ANAO has concluded that the Department has partially implemented recommendation 4, noting that a decision was made by DoHA that the steps it has taken to date provide the Department with an effective level of oversight of the pathology quality assurance processes for cervical screening. In particular, the Department has taken steps to improve stewardship of the pathology quality assurance process by introducing measures designed to clarify degrees of accountability for individual participants that have a contractual relationship with the Commonwealth. Given the range of participants involved in the quality assurance processes for cervical screening and the important role of quality assurance in providing comfort that appropriate standards for pathology laboratories are being set, applied and monitored, the ANAO considers that, as indicated by the Department, this is an arrangement that DoHA should monitor to ensure that its level of oversight continues to be effective.

Ian McPhee
Auditor-General

Canberra ACT
16 August 2007

Appendices

Appendix 1: National Cervical Screening Program

Cervical cancer

Cervical cancer is now the eighteenth most common cause of cancer death in [Australian] women.[37] One in 183 Australian women will develop cancer of the cervix in their lifetime. Cervical cancer affects the cells lining the cervix, which is the lower part of the womb or uterus as it joins the inner end of the vagina. Like other cancers, cervical cancer is a disease where normal cells change, begin to multiply out of control and form a growth or tumour.[38] If not caught early enough, the disease can spread to other parts of the body. The main symptoms of cervical cancer are unusual bleeding from the vagina, and sometimes an unusual vaginal discharge. However, these symptoms do not always indicate that pre-cancerous changes are taking place. The Pap smear, which is described in more detail below, is an effective means of identifying whether unusual symptoms indicate that further examination and treatment is required.

A cervical cancer can take ten or more years to develop, but before this, the cells may show pre-cancerous changes. These early changes can be detected by a Pap smear. With early treatment, there is an excellent chance of a full recovery. There are two levels of severity of these precancerous lesions, low-grade abnormalities and high-grade abnormalities, with the higher-grade lesions more likely to develop into cancer.

The Pap smear is the most common way to detect pre-cancerous changes, which rarely cause any symptoms. The test involves a doctor inserting a speculum into the vagina and gently scraping the surface of the cervix. This process collects cells that are transferred onto a slide or into a special liquid, which is then sent to a pathology laboratory for assessment. Pap smears are offered by general practitioners, gynaecologists, family planning clinics, hospital outpatient clinics and in some circumstances, nurse practitioners or other health workers.

If the Pap smear suggests a pre-cancerous change, a doctor is able to look directly at the cervix by inserting an instrument called a colposcope into the

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[37] Australian Institute of Health and Welfare, Media Release, *Overall cervical cancer rates declining, but still higher for Indigenous women* [Internet], Canberra, 2005, available from <http://www.aihw.gov.au/mediacentre/2005/mr20051125.cfm> [accessed 17 April 2007].

[38] Australian Institute of Health and Welfare, *Cervical Screening in Australia 2003–2004* [Internet], Canberra, 2006, p.90, available from <http://www.aihw.gov.au/publications/index.cfm/title/10359> [accessed 17 April 2007].

vagina. Using a special stain the doctor can highlight any suspicious areas, pre-cancerous or cancerous. The doctor will then take a tissue sample (a biopsy) of the suspicious area for further examination by a pathologist.

Pre-cancerous changes are relatively easy to treat and curable in nearly all cases. The type of treatment offered to the woman depends on whether the type of change observed is low- or high-grade, the woman's age and general health, whether she wants to have children, and her preferences.

There is a range of treatments for pre-cancerous changes, including cryosurgery (freezing), cauterisation (burning also called diathermy), laser surgery, or loop or cone biopsies. In a small number of instances a hysterectomy may be necessary, especially if changed cells are found inside the opening of the uterus and the woman does not want to have children in the future.

For invasive cancer, cone biopsy or hysterectomy is generally performed. If the cancer cells are only detected on the surface of the cervix, it may be treated by a cone biopsy. If it has invaded more deeply into the cervix, a hysterectomy is generally performed. In advanced cases, a radical hysterectomy is needed to remove the cervix and uterus along with a margin of tissue around the cervix and lymph notes from the pelvis. Radiotherapy is sometimes used as well as surgery, and for more advanced cases it may be used on its own.

Background to the Organised Approach to screening for Cervical Cancer[39]

Australian women have been screened for cervical cancer since the 1960s. Since then, Pap smears have been the usual means of screening women for changes that may indicate pre-cancerous developments. Pap smears are usually taken by general practitioners, with the resulting Pap smears read by pathology laboratories. The taking and processing of Pap smears by eligible practitioners attracts a Medicare subsidy.

Mortality from cervical cancer decreased during the 1970s and 80s due to the finances expended by Australian Government, State and Territory governments and the efforts of medical practitioners. Notwithstanding, it was

[39] This background information was sourced from the earlier audit report, which inturn sourced the information from:

- Centre for Health Program Evaluation and University of Melbourne, 1995, *Victorian Evaluation of the Commonwealth/State Program 'The Organised Approach to Preventing Cancer of the Cervix, The Organised Approach—Who's Organising?*'
- A Joint Commonwealth/State Initiative Managed by the Western and Central Sydney Area Health Service, New South Wales Cervical Screening Program Strategic Directions (1996–1999).

believed more could be achieved. Prior to 1991, while 90 per cent of squamous[40] cervical cancer was preventable through screening, only about 50 per cent of potential cases were being prevented. This fact prompted Australian Health Ministers to commission an Australian Government funded evaluation of existing services and possible alternative and improved service provision through targeted pilot projects. This evaluation culminated in the Australian Health Minister's Advisory Council (AHMAC) Cervical Cancer Screening Evaluation Report (CCSER).

The CCSER reported that significant elements of an organised screening pathway for cervical cancer did not exist in Australia. In addition, the report suggested that optimal impact was not being achieved for a number of reasons. These included:

- lack of an agreed screening policy, including a target age group and re-screening interval and insufficient efforts to increase uptake among all women at risk;
- poor access by women to service providers of choice;
- other barriers to screening, ranging from negative attitudes to screening to simply forgetting;
- absence of fail-safe systems to follow-up women with abnormalities;
- lack of agreement on appropriate management; and
- the absence of a national framework to monitor and co-ordinate recruitment, recall, management of abnormalities and quality assurance.

AHMAC received the report in late 1990 and invited the Australian Government to conduct discussions on the recommendations. The responses, which came out of these discussions, were set down in the document *Cervical Cancer Screening an Organised Approach*. In this document, the importance of the following elements were identified:

- Screening women at two yearly intervals. Screening should commence at age 20 or within one to two years of first sexual intercourse,

[40] Of the several types of cervical cancer, squamous cell carcinoma is the most commonly seen. Squamous cell carcinoma of the cervix is usually preceded by non-malignant abnormalities. These abnormalities once detected through a Pap smear test may be treated successfully. The ability of these cancer precursor abnormalities to be detected and treated ensure this cancer is suited to a screening program. (Australian Institute of Health and Welfare, *Australia's Health 1996*, AGPS, p. 71).

whichever is the later and finish when the women reaches age 70, if she has a history of normal Pap smears.

- The development of a comprehensive communication strategy to explain the policy on screening to service providers and women.
- Formal recruitment and recall plans for identifying target population groups, particularly those assessed as being under-screened, such as older and Aboriginal women, and identifying appropriate strategies for recruitment and recall with an indicative time frame.
- Appropriate goals, including participation rates and process targets, and reduction in morbidity and mortality from cervical cancer.
- Monitoring and evaluation of State and Territory programs, by States and Territories, and development of broad strategies for accomplishing stated goals.
- The possible establishment of cervical cytology registries in States and Territories.
- Quality assurance for test taking, test reading and notification of results.

Based upon these principles, the Organised Approach to Preventing Cancer of the Cervix was established in June 1992 by the Australian Government and States/Territories. The approach encapsulated 11 internationally recognised elements of the cervical cancer-screening pathway. These elements are set out below:

- recruitment;
- Pap smear taking;
- Pap smear reporting;
- notification of Pap smear results;
- management of women with abnormal Pap smears;
- quality assurance and monitoring;
- accreditation;
- policy;
- coordination;
- funding; and
- education and research.

In 1994, an evaluation of the Organised Approach to the Prevention of Cancer found that the number of women participating in screening had risen alongside a reduction in the total number of Pap smears taken due to compliance with two yearly screening protocols. It was noted, however, that the greatest increase in participation occurred in women under 35 years. This group was also known to be a lower risk than women over 35. Consequently, the evaluation recommended that the Australian Government implement strategies that target older women, rural women and hard to reach groups such as Aboriginal women and women from non-English speaking backgrounds.

Participation in the National Cervical Screening Program

NCSP aims to reduce morbidity and deaths from cervical cancer, in a cost-effective manner through an organised approach to cervical screening. The Program encourages women in the target population to have regular Pap smears.[41]

Participation data reported in the earlier audit show that, in the 1990s, NCSP achieved a small but consistent increase in participation rates among the target population of women aged 20–69, throughout Australia. During the period from 1992–94, an estimated 61 per cent of women were screened, with this figure rising to 63.9 per cent in 1997–98.[42] More recent data, 2004–05, show a participation rate of 61.0 per cent among the target population.[43]

[41] Department of health and Ageing, *National Cervical Screening Program—About the Program* [Internet], Canberra, 2006, available from <http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/cervical-1lp> [accessed 17 April 2007].

[42] Commonwealth of Australia, 2000, *A Decade of Change, A Report on Australia's National Cervical Screening Program 1989—1999*, Canberra, p.7.

[43] Australian Institute of Health and Welfare, *Cervical Screening in Australia 2004–2005*, p.ix [Internet], Canberra, 2007, available from < http://www.aihw.gov.au/publications/index.cfm/title/10457> [accessed 25 June 2007].

Appendix 2: DoHA's Full Response

Comments on ANAO Proposed report *National Cervical Screening Program–Follow-up Performance Audit* **(11 July 2007)**

5. Strengthening Governance

Recommendation 4 of the National Cervical Screening Program ANAO Performance Audit in 2001 was made because of concerns that without 'clearly defined responsibility for oversight of the pathology quality assurance process and authority to address any identified deficiencies:

- activities of participants in the process may not be properly coordinated;
- accountability for the process as a whole is not possible;
- risks to the success of the process may not be identified and addressed;
- the quality of services provided to women and their doctors may not reach the required standards; and
- the benefits possible from an organised approach to cervical screening may be reduced.'

The Department agrees with the underlying concern that there should be effective oversight of the pathology accreditation process and considers that the current pathology accreditation system is a coherent system with clear and appropriate degrees of accountability for each participant.

Pathology Accreditation System

There are a number of requirements a pathology test must meet in order to be eligible for reimbursement under Medicare. One of these is that the test must be performed at an Accredited Pathology Laboratory (APL) which is owned by an Approved Pathology Authority (APA).

APL status is granted to laboratories by Medicare Australia, as the delegate of the Minister for Health and Ageing. The criteria used by Medicare Australia to decide whether APL status should be granted are set out in the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles* (the Principles).

In order to perform testing eligible for Medicare reimbursement, a pathology laboratory must generally:

- be accredited by NATA as meeting all relevant NPAAC standards, including:

- having a quality management system consistent with international standards;
- having supervision and staffing arrangements appropriate for a laboratory conducting the range of testing accredited;
- being enrolled in a suitable external quality assurance program for all areas of testing, where such a program is available; and
- meeting standards set for particular areas of testing as well as for general laboratory arrangements; and

- be granted APL status by Medicare Australia, on the basis of accreditation advice from NATA and meeting other regulatory requirements.

NPAAC

The Principles includes two schedules that specify the accreditation materials (or standards) that are used in assessing whether a laboratory meets required standards. The accreditation material is developed and maintained by the National Pathology Accreditation Advisory Council (NPAAC). The role of NPAAC is to advise the Commonwealth, State and Territory Health Ministers on matters relating to the accreditation of pathology laboratories. NPAAC plays a key role in ensuring the quality of Australian pathology services and is responsible for the development and maintenance of standards and guidelines for pathology practices. NPAAC is made up of representatives from all States and Territories, nominees from peak professional bodies and the Department of Health and Ageing.

NPAAC regularly reviews its existing standards as well as developing new standards where these may be required. This includes convening expert committees to consider standards in detail and making proposed standards available for public consultation. All NPAAC draft standards are also considered by its Document Review and Liaison Committee, which includes representation from NATA, Medicare Australia and other relevant organisations. Once NPAAC has given its endorsement to a new or revised standards document, it is referred to the Department for inclusion in the Principles.

NATA

The Principles define NATA as the independent body and require Medicare Australia when making decisions about APL status to consider the most recent reports provided by NATA and to give greater weight to the view of NATA than to any other views put forward about the laboratory.

NATA is the national organisation for conformity assessment of technical operations such as laboratories, inspection bodies and reference material producers. By way of a Memorandum of Understanding, the Commonwealth Government recognises NATA as the sole national accreditation body for establishing and maintaining competent laboratory practice.

In relation to pathology accreditation, NATA's assessment program is run jointly with the Royal College of Pathologists of Australasia, allowing accreditation to be a peer review process.

Details of how NATA is to perform its role in pathology accreditation are included in a Deed of Agreement with Medicare Australia. This requires NATA to assess all APLs within certain timeframes, to advise Medicare Australia of any changes affecting accreditation, to maintain a web page providing information about the accreditation of laboratories, and to indemnify Medicare Australia against action arising from NATA's functions under the Deed, among other things.

As well as advising which area/s of testing a laboratory is accredited to perform, NATA also advises Medicare Australia which of the five categories of laboratory specified in the Principles a laboratory fits. The category of laboratory is based on the kind of testing conducted and affects supervision requirements and the ability to establish Approved Collection Centres for the collection of pathology specimens.

Medicare Australia

As noted above, Medicare Australia decides whether to grant APL status to pathology laboratories, as a delegate of the Minister of Health and Ageing and in accordance with the Principles.

Other than in exceptional circumstances, the Principles require Medicare Australia to refuse or revoke a laboratory's accreditation where NATA has made an adverse accreditation report.

Medicare Australia has systems in place to ensure that Medicare benefits are not paid for any pathology tests conducted by a pathology laboratory that are outside the scope of its accreditation.

The Department and Medicare Australia work closely together in relation to a broad range of issues and activities in relation to pathology, including the pathology laboratory accreditation arrangements.

Corrs Report

As is noted in the draft report, in December 2001, the Department commissioned Corrs Chambers Westgarth to conduct a comprehensive *Evaluation of the Australian Pathology Laboratory Accreditation Arrangements* (the Corrs Report), which was completed in July 2002. The ANAO recommendations were referred to Corrs for consideration. The Corrs Report concluded that 'the current Australian pathology laboratory accreditation arrangements are fundamentally sound and should be maintained' and made a large number of recommendations for changes to strengthen pathology accreditation.

The Corrs Report identified a number of aspects of the pathology accreditation system at that time that could have contributed to a lack of co-ordination and accountability that was raised as a risk by the ANAO. Some relevant issues identified included:

- some groups not having appropriate representation on NPAAC;
- NPAAC's process of standards development did not always ensure that the need for new standards had been rigorously considered and that standards were developed in a consistent and transparent way;
- accreditation of laboratories against documents that had not been considered by NPAAC and were not included in the Principles;
- lack of clear performance criteria for NATA in its conduct of assessments and reporting to Medicare Australia;
- lack of clarity in the Principles about the role of NATA and how it differed from the role of Medicare Australia; and
- lack of clarity in information provided to laboratories about the roles of NATA and Medicare Australia in the accreditation process, and the consequences of failing to meet NPAAC standards.

The principal recommendation made in the Corrs Report to address the ANAO's Recommendation 4 was:

> *That pending any initiatives by the Australian Council for Safety and Quality in Health Care to develop stewardship and overarching quality monitoring structures, the (Department) allocates responsibility to a senior officer in the Diagnostics and Technology Branch to receive regular, structured reports from the HIC contract manager on the overall quality of pathology services, and to initiate any necessary policy responses to those reports.*

This was a very different solution from that contemplated at the time of the original ANAO audit. On advice from the Department, the Minister did not accept the recommendation to appoint a person to receive reports, because there was concern about a single person being able to take responsibility for stewardship and that Medicare Australia would not have the relevant expertise to generate such reports. However, it was agreed that the Department would consult the Australian Council for Safety and Quality in Health Care in relation to this issue. To date, overarching quality monitoring structures have not been an accepted feature of the broader health system.

Many other Corrs Report recommendations aimed at strengthening the pathology quality assurance system were accepted and implemented. These changes have clarified the roles and responsibilities of the bodies involved in the pathology accreditation system. Relevant changes included:

- clarifying the role of NPAAC, by ensuring that standards documents are only included in the Principles after approval by NPAAC;
- changing the membership composition of NPAAC, to include consumer representation and representation from the Human Genetics Society of Australasia and the National Coalition of Public Pathology;
- clarifying the legislative status of accreditation materials, by ensuring that only materials listed in the Principles are used in the laboratory accreditation process;
- amendment of a range of legislative instruments and other official documents, including the Principles and the APA and APP undertakings;
- implementation of a revised Deed of Agreement clarifying the roles and responsibilities of Medicare Australia and NATA in relation to accreditation of laboratories and granting of APL status; and
- ensuring that information about the accreditation status of laboratories is publicly available on the NATA website.

In response to Corrs Report recommendations, the Department also commissioned further reports on NPAAC's approach to standard setting, the evaluation of public health risks posed by testing funded by sources other than Medicare, and the enforcement and offence provisions of the Health Insurance Act relating to pathology. The recommendations of these further reviews are being considered and implemented and are expected to further strengthen pathology accreditation and support quality pathology services more broadly.

External Quality Assurance (or External Proficiency Testing)

The ANAO has expressed particular interest in the role and accountability of organisations that provide external quality assurance programs to pathology laboratories, the most significant of which is the RCPA QAP Ltd.

The current relevant pathology accreditation standards are in *Standards for Pathology Laboratory Participation in External Proficiency Testing Programs*, NPAAC 2004. This document is currently under review, as NPAAC has a policy of reviewing its documents on a three year cycle. The standards require all laboratories 'to be continuously enrolled, participate and perform to an acceptable standard in external proficiency testing programs that cover all test methods performed in the laboratory where such programs are available'. The purpose of this is to allow pathology laboratories to assess their own performance of specific tests or test procedures, monitor continuing performance, and compare their results to those of other laboratories. The document includes details of the criteria laboratories should consider in choosing an external quality assurance program and the requirements that must be met by suppliers of proficiency testing programs, including information that must be provided to allow accreditation. As with all other NPAAC standards, compliance with external quality assurance is assessed by NATA, which then provides advice to Medicare Australia. The document emphasises that:

By itself, proficiency testing is only one measure of laboratory performance. In assessing the overall performance of a laboratory, all aspects of the quality system must be considered. (p8)

Conclusion

As a result of changes made in response to the Corrs Report, the direct participants in the pathology accreditation system are now coordinated and made accountable, principally through:

- all pathology accreditation requirements being clearly defined and given legal enforceability through the Principles;
- NPAAC being the sole body responsible for developing or endorsing standards for inclusion in the Principles; and
- The roles of Medicare Australia and NATA being defined and clearly delineated in both the Principles and their Deed of Agreement.

As a result, the Department is now better able to coordinate the activities of participants in the process, to identify and address emerging risks, and to have greater confidence in the quality of pathology services supported by Medicare benefits. The Department considers that the changes made since 2001 to strengthen the pathology accreditation system have also addressed the underlying concerns that led to Recommendation 4.

Within the decentralised health system, there are many individuals, organisations and other bodies that could be considered to be participants in the pathology accreditation system. For example, pathology laboratories, owners of pathology laboratories (including State and Territory Governments), individual pathologists and scientists, and providers of external quality assurance programs all have a stake in pathology accreditation. In addition, there is a range of organisations that have an interest either in promoting and improving the quality of pathology services, or the quality of the health system more broadly. In considering appropriate governance arrangements for the pathology accreditation system, the Department considers that they need to cover only those bodies that are directly involved in setting standards and accrediting against them. Bodies that are not directly involved may be given representation, where appropriate, on NPAAC, DRL and other committees, and are consulted where relevant.

Should the ANAO wish to include a table in its report, Table A indicates the roles of bodies directly involved in the pathology accreditation system.

While the Department is continually seeking to improve the pathology accreditation system, the Department considers that, as it currently exists, it is a coherent system with clear and appropriate degrees of accountability for each participant.

Table A: Pathology Laboratory Standards and Accreditation–Direct Involvement

Organisation	Responsibilities	Accountability
NPAAC	Ensure appropriate standards are in place, against which pathology laboratories can be assessed. Provide advice to Governments on policy for accreditation.	Australian Government Minister for Health and Ageing and State and Territory Ministers

Organisation	Responsibilities	Accountability
NPAAC committees, including Document Review and Liaison Committee (DRL) and drafting committees	Provide advice to NPAAC on pathology accreditation issues, with input from relevant experts and stakeholders.	NPAAC
NATA	Assess pathology laboratories against NPAAC standards. Provide advice to Medicare Australia on whether individual pathology laboratories meet standards.	Medicare Australia, as the delegate of the Australian Government Minister for Health and Ageing.
Medicare Australia	Decide whether to award individual pathology laboratories Accredited Pathology Laboratory status, which allows Medicare reimbursement for pathology services. Provide advice to pathology accreditation issues to NPAAC, through DRL.	Department of Health and Ageing, under a business practice agreement. Medicare Australia undertakes this role as the delegate of the Minister for Health and Ageing. Minister for Human Services
Department of Health and Ageing	Provide policy advice to the Minister for Health and Ageing and Medicare Australia on pathology accreditation. Provide support to NPAAC in setting standards and implement standards through the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles*. Liaise with Medicare Australia, NATA, and others on pathology accreditation issues.	Minister for Health and Ageing

ADDITIONAL INFORMATION FROM DEPARTMENT OF HEALTH AND AGEING (23 July 2007)

Under the constitutional arrangements underpinning the provision of health care in Australia (including a prohibition on the civil conscription of medical practitioners by the Commonwealth), oversight of the quality of health services is shared between the Commonwealth and the States and Territories. States and Territories have primary responsibility for ensuring the competence of individual practitioners, and the Commonwealth restricts the payment of Medicare rebates to practitioners appropriately registered by the States and Territories. The Commonwealth also restricts the payment of certain benefits (such as pathology) to services provided in accredited facilities.

In recognition of this shared responsibility for quality assurance, in 2005 the Australian Health Ministers' Conference agreed to establish the Australian Commission on Safety and Quality in Health Care to provide advice on strategies to continue to improve the quality of health services. The Commission is currently reviewing the role of accreditation in improving the safety and quality of health care, and is due to report to Ministers in December 2007.

In November 2006, the Commission released a discussion paper which noted that changes to health service accreditation would require 'coordinated action by governments, private health funders and providers, accrediting and standards setting bodies and a broad range of stakeholders, including consumers' and proposed a uniform approach to accreditation that, inter alia, would identify 'mechanisms that detect and respond to systems failures'. In its submission in response to this discussion paper, the Department noted that the current system for pathology accreditation is regarded as 'one of the best in the world', and also acknowledged that 'a comprehensive national effort is needed to support continuous improvement in the safety and quality of health care'.

Within Australia's federated health system, there is a range of organisations that have an interest in promoting and improving the quality of pathology services, and the quality of the health system more broadly. For example, pathology laboratories, owners of pathology laboratories (including State and Territory Governments), individual pathologists and scientists, and providers of external quality assurance programs all have a stake in assuring the quality of pathology services.

In achieving appropriate governance arrangements for quality assurance of pathology, bodies that directly and indirectly participate in providing pathology services, establishing standards for those services, and accrediting services against those standards are represented on committees (including the National Pathology Accreditation Advisory Council–NPAAC), and are consulted outside these formal processes where relevant.

NPAAC is responsible for the development and maintenance of standards for pathology laboratories. Accreditation against these standards is conducted by the National Association of Testing Authorities (NATA).

Pathology laboratories are required by NPAAC standards 'to be continuously enrolled, participate and perform to an acceptable standard in external proficiency testing programs that cover all test methods performed in the laboratory where such programs are available'. These external proficiency or quality assurance programs are provided by a range of different organisations, including professional societies, not-for-profit organisations and companies.

The largest provider of external quality assurance for pathology laboratories is the RCPA Quality Assurance Programs Pty Ltd (QAP), a company established by the Royal College of Pathologists of Australasia (RCPA), which itself is a not-for-profit professional body incorporated under the NSW Companies Act 1936, and a member of NPAAC.

During accreditation visits, NATA assessors review a laboratory's enrolment and performance in external quality assurance programs, to ensure that accreditation standards are being met. Under the Approved Pathology Authority undertaking, pathology providers agree to provide copies of all quality assurance program reports to NATA, and to authorise any provider of a quality assurance program (such as QAP) to release information and reports to NATA. NATA's assessment review includes looking at issues such as:

- whether the laboratory is enrolled in quality assurance programs for all test methods;
- whether the laboratory is participating fully and performing adequately in those programs; and
- how the laboratory is responding to any outliers in its performance.

If NATA has concerns about a laboratory's enrolment or performance in external quality assurance, this could affect the laboratory's accreditation.

While laboratories are held accountable for their enrolment and performance in external quality assurance programs, external quality assurance providers are generally private organisations. The contractual relationship for the provision of external quality assurance services is between laboratories and providers. NPAAC has specified criteria that laboratories should use in choosing an external quality assurance provider, including whether the provider is approved by a recognised accreditation body and supported by relevant professional associations. However, as there is generally no direct contractual relationship or flow of funding from the Australian Government to external quality assurance providers, there is no simple mechanism by which QAP could be subjected to direct Commonwealth oversight.

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