

# Health Care Technology in Australia

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## OVERVIEW OF AUSTRALIA

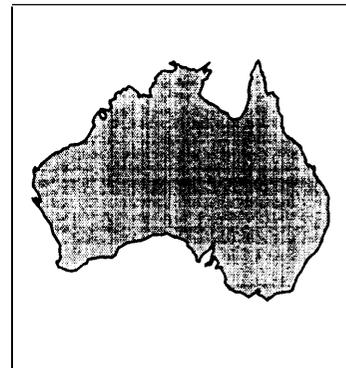
**A**ustralia, which lies southeast of Asia between the Indian and Pacific oceans, consists of the smallest continent (and the world's largest island—approximately 4,000 km from east to west and 2,000 km from north to south) as well as the island of Tasmania. About a third of the continent is uninhabitable; in another third the rainfall is too low to permit close settlement. The climate varies from tropical to alpine, with very limited rainfall in the deserts in the center of Australia.

### I Population Characteristics

The country's population in 1992 was 17.4 million (17). The population is highly urbanized; 85 percent of Australians live in urban areas, and 65 percent live in the six state capitals. The main concentration is in the southeast, predominantly in the coastal zone. The crude fertility rate is 15.4 births per 1,000 population. Since the establishment of New South Wales as a British Colony in 1788, Australia's population growth has been dominated by European settlement, with immigration from Asian countries becoming more significant in recent years. Aborigines and Torres Strait Islanders (descendants of the country's inhabitants prior to European settlement) make up 1.4 percent of the population.

### Government and Political Structure

The current political structure follows the federation of the former colonies into the commonwealth in 1901 and the basis for government is set out in the Constitution. Legislative power of the commonwealth is vested in a Parliament consisting of the Queen, a Senate, and a House of Representatives. The system of government follows the Westminster system; Australia's Parliament was modeled on the six state Parliaments, which were in-



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turn modeled on the British House of Commons. Parliaments of all states except Queensland are bicameral. The two major territories in the country—the Northern Territory and the Australian Capital Territory—are self-governing and unicameral.

The relative powers of the commonwealth and states have evolved considerably since federation through “cooperative federalism” and interpretations of the Constitution by the High Court of Australia (96). In its development of governmental relationships through the High Court, Australia has followed a pattern that is closer to the United States than to the British experience; many features of the commonwealth Constitution are based on the U.S. Constitution.

### The Economy

Primary production plays an important role in Australia’s economy, and the country is a major exporter of food and minerals. The Gross Domestic Product (GDP) in 1991/92<sup>1</sup> was \$386 billion,<sup>2</sup> and the average annual growth rate of the GDP was 3.4 percent from 1981 to 1990, with declining or lower growth since then.

Japan is Australia’s major trading partner, and trade links with other Asian countries are strengthening. In 1991/92, the value of exported goods and services was \$68.8 billion, of which 23 percent was composed of agricultural and related products and 57 percent of nonrural exports (3). Manufactured goods constituted 55 percent of exports, of which 14 percent comprised food, beverages, and tobacco; 21 percent, basic metal products; and 8 percent, machinery and equipment. Foreign exchange earnings from tourism totaled \$7.2 billion. Imports are dominated by manufactured goods.

### HEALTH STATUS OF THE POPULATION

The marked decline in death rates in Australia since the late 1960s continued up to 1990 (13).

Life expectancy at birth increased, and the difference in life expectancy between males and females narrowed slightly to 6.1 years. The life expectancy for females was 80 years; for males, 73.9 years (in 1990).

These trends largely reflect declines in death rates from diseases of the circulatory system. This group of diseases remains the leading cause of death, however, and was responsible for 45 percent of all deaths in 1990. Death rates for injuries also continued to decline steadily. Deaths and incidence rates for cancers, responsible for 26 percent of deaths in 1990, have been steady for some years. In 1990 the infant mortality rate was 8.2 per 1,000 live births (13).

In 1988 there was slightly more than one hospital admission for every five people. For males the highest admission rate was for the category of “diseases of the digestive system,” followed by “injury and poisoning.” Complications of pregnancy and childbirth were the leading cause for admission for females, followed by diseases of the genito-urinary system. For children up to 14 years old, the leading causes were diseases of the respiratory system, injury and poisoning, and diseases of the digestive system. For the older age groups (65 years and over), diseases of the circulatory system, neoplasms, and diseases of the digestive and respiratory systems were the most common reasons for hospitalization (13).

According to the 1989/90 health survey conducted by the Australian Bureau of Statistics (ABS), 30 percent of males and 29 percent of females aged 18 or over reported excellent health status, with a further 50 percent considering their health good; only 20 percent of males and 21 percent of females reported their health status as fair or poor (2). Sixty-four percent of males and 60 percent of females reported one or more long-term health conditions—most commonly eye sight disorders, arthritis, hay fever, back trouble, asthma, hypertension, deafness and eczema or dermatitis.

<sup>1</sup> 1991/92 (and similar references to years) refer to the Australian fiscal year, which runs from July 1 through June 30.

<sup>2</sup> Dollar figures in this paper are Australian dollars. In early 1994, the value of the Australian dollar was about \$US0.7.

In 1988 one or more disabilities were reported by 16 percent of Australians, with 13 percent reporting being handicapped in some way by their disability (13). Most frequently, disabling conditions were those of the musculoskeletal system and connective tissue, hearing loss, and conditions of the circulatory system.

Some of Australia's major health concerns are common to those in other developed countries, including the major causes of illness and death—heart disease, stroke, and cancer. Efforts have been made through health promotion strategies to reduce the prevalence of risk factors for those diseases. A recent estimate of the cost of diet-related disease is \$3.6 billion a year, with premature deaths due to poor diet contributing 36,600 potential years of life lost in 1989 (27).

Various concerns regarding women's health are being addressed through a series of initiatives, including cancer screening programs and strategies to manage osteoporosis. Substantial government programs have been put in place to assist the prevention and treatment of HIV infection.

Some problems that are more specific to Australia include high rates of skin cancer, including malignant melanoma (associated with exposure to high levels of sunlight) and asthma. Asthma deaths in Australia have continued to increase, with mortality rates higher than those in England and Wales, Canada, and the United States (103). The reasons for this high prevalence remain uncertain (91).

Like other countries, Australia has experienced differentials in health status that are strongly linked to employment and socioeconomic status. Amongst employed males, those whose occupations are classified as professional or technical have the lowest death rate, whereas those in occupations classified as transport/communications have the highest—with a differential of 87 percent. Most major causes of death show strong occupational linkages. In addition, the numbers of serious chronic and recent illnesses and average days of reduced activity reported by men and women rise as family income decreases (13). There are also concerns regarding the health status of certain migrant groups and their use of health

services—particularly migrants with significant cultural differences from most Australians and those with poor English skills.

Yet another concern is the very large differential between the health of Aborigines and Torres Strait Islanders and that of other Australians. Aboriginal health has improved over the last two decades but remains substantially worse than that of other Australians. Overall life expectancy at birth is 15 to 17 years less than that for the total Australian population. Considerably higher mortality levels are experienced by young and middle-aged adults, and the infant mortality rate is three times that for all Australians. Diseases of the respiratory system, complications of pregnancy and childbirth, and injury and poisoning have been the most frequent causes of hospitalization for Aborigines.

## THE AUSTRALIAN HEALTH CARE SYSTEM

### Organization and Funding

The health care system in Australia is pluralistic, complex, and only loosely organized (13). It involves all levels of government as well as public and private providers. Government has been playing an increasing role in financing health services, but most medical and dental care and some other professional services are provided by private practitioners on a fee-for-service basis.

After an amendment of the Constitution in 1946, the commonwealth was empowered to make laws on pharmaceutical, hospital, and sickness benefits and on medical and dental services. These powers and the extension of conditional specific-purpose grants under section 96 of the Constitution have enabled the commonwealth to expand its role in the health care system. The commonwealth government is primarily concerned with funding programs and the development of broad policies. It influences policymaking and health services through financial arrangements with state and territory governments, provision of benefits and grants, and regulation of health insurance. State and territory governments are responsible for providing most health services, including public hospital systems, mental health services.

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public health regulation, and licensing. The main responsibilities of local governments are in environmental control and a range of personal, preventive, and home care services.

Since 1956 the commonwealth has introduced benefits schemes covering medical, pharmaceutical, hospital, and nursing home services funded through government budgets. Many other programs, including health promotion, control of alcohol and drug abuse, and the campaign against AIDS, have involved conditional grants to the states and territories. A universal health insurance plan—Medicare—has been in operation since 1984, administered by the commonwealth government.

The structures of the various commonwealth, state, and territory health authorities have undergone frequent changes. At the commonwealth level, the Department of Health became the Department of Community Services and Health in 1987 and subsequently expanded further to include housing and then local government. At the end of 1993, the name of the agency changed to the Department of Human Services and Health (DHS) (used throughout this chapter for both the current department and its predecessors). A separate statutory authority, the Health Insurance Commission (HIC), administers the Medicare program of universal health insurance and the Pharmaceutical Benefits Scheme.

At the state and territory level, some jurisdictions have combined health and community services functions. The momentum has been toward creating central agencies that delegate responsibilities in varying degrees to regional or area authorities (13). Because of each state's separate political development and the significant distances between major population centers, state governments have tended to take distinctive approaches to the provision and support of health care technologies (50). Differences between the states reflect varying philosophies on the level and organization of hospital and other services, population distribution, and development of centers of excellence.

In 1991/92, health care expenditure in Australia was \$33.2 billion, an average of \$1,900 per person (18). The commonwealth government provided \$13.3 billion; state and local governments, \$8.1 billion; and the private sector, \$9.5 billion. Since 1984/85, the proportion of total expenditure funded by governments has declined from 72 to 68 percent, with the private sector proportion rising correspondingly.

The government contribution is funded from general taxation revenues and a Medicare levy on taxable incomes. General distribution of funds from the commonwealth to the states and territories occurs through financial assistance grants whose amounts are determined by the Commonwealth Grants Commission. The states decide the proportion of those grants that are allocated to health services. Hospital funding grants, which totaled \$3.9 billion in 1992/93, are the main form of direct commonwealth assistance to the states and territories for health purposes (39).

For each health care technology included on the Medical Benefits Schedule, Medicare reimburses a proportion of the cost. If a technology is not included on the schedule, costs are typically paid by the patient; private insurance coverage is relatively limited. (For some high-cost technologies, funding has been provided through government grants with very limited private sector involvement.) Availability of Medicare benefits often has a major effect on a particular technology's diffusion. Once a technology is on the Medical Benefits Schedule, private providers are more likely to obtain it, knowing that payment for its use will be covered by insurance.

Capital grants that fund the acquisition of high-cost technologies are a means for government to achieve controlled introduction and distribution of health care technologies, which have remained largely in the public sector; to some extent this has also applied to lower-unit-cost technologies within the public hospital system, where the allocation of resources (including additional commonwealth grants) is determined by the state governments.

## Medical Research and Policy Coordination

Coordination of medical research at a national level is largely the responsibility of the National Health and Medical Research Council (NHMRC). Its principal committees are concerned with medical research, health care, public health, public health research and development, and health ethics. The Council, which obtains funding through the federal budget, is the major funding source for medical research in Australia.

In 1991/92 the NHMRC provided \$105 million in basic research funding through its Medical Research Committee, including \$67 million in project and program grants and nearly \$18 million in block grants to research institutes. About \$5 million was provided for projects through the Council's Public Health Research and Development Committee.

Other research, particularly related to health services and health promotion, is supported by DSHS. Some states and the Northern Territory provide infrastructural support for medical research institutes established in association with universities and teaching hospitals. In some cases (notably in Victoria), revenue from tobacco taxes has been used to support health research and health promotion activities.

There have been relatively few attempts to channel research toward the development of new or modified health care technologies. The NHMRC's funding tends to support basic research projects in particular areas; specific downstream products are relatively uncommon. The NHMRC also channels research funds to defined areas of public health need (e.g., research on asthma). Evaluation research (through requests for proposals on specific topics) is also funded by NHMRC and DSHS.

Some research on potential commercial products has been supported by the commonwealth's Department of Industry, Technology and Regional Development. Many of its programs have, however, been directed toward assessing specific proposals rather than focusing research on particular types of technology. An interesting recent initiative has been the development of cooperative

research centers (CRCS) in various fields of science and technology. A CRC, typically a consortium of research and commercial agencies, undertakes basic and applied research with a view to developing commercial products; matching funds are provided by the commonwealth government. Some of the CRCs cover areas of health care, including eye research and technology, insulin and cellular growth factors, vaccine technology, cardiac technology, tissue growth and repair, and cochlear implant, speech, and hearing research.

Responsibility for the development of national health statistics lies largely with the Australian Institute of Health and Welfare (AIHW), the ABS, Worksafe Australia, and the DSHS. The first three are statutory bodies and their functions, responsibilities, and constraints are defined by their enabling legislation.

One mechanism for Australian governments to discuss matters of mutual interest concerning health policies and programs is provided by the Australian Health Ministers' Conference (AHMC) and its advisory body, the Australian Health Ministers' Advisory Council (AHMAC). AHMAC includes commonwealth, state, and territory health ministers; New Zealand and Papua New Guinea health ministers attend meetings as observers. AHMAC consists of the heads of Australian health authorities and the chair of the NHMRC. It is concerned with health services coordination across the nation. Some of its standing committees deal with organ registries and donation, women's health, and communicable diseases. Recently, additional coordination has been achieved through joint meetings with the Standing Committee of Social Welfare Administrators.

## Health Expenditures and Health Services

In real terms, health expenditures are continuing to grow at a relatively steady rate. As a proportion of GDP, health expenditure in 1991/92 was 8.6 percent; the increase from the previous year's proportion of 8.2 percent was largely the result of low

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growth in real GDP during the recession ( 17). For the six years from 1984/85 onwards, health expenditure as a proportion of GDP was almost constant at around 7.8 percent.

The largest component of recurrent health expenditure (43 percent) is attributed to hospitals. Most personal health care is paid for through Medicare, and all residents of Australia (except foreign diplomats and dependents) are eligible for Medicare benefits. The amounts that a patient can claim for general practitioner services are set at 85 percent of the schedule fee for each item on the benefits schedule. Diagnostic services entail higher out-of-pocket expenses for patients.

Doctors are not obliged to abide by schedule fees, but if they bill the Health Insurance Commission directly for a service, the amount payable is the Medicare benefit and the patient is not required to pay any additional amount. The proportion of all services direct billed in this way increased from 45 percent in 1984/85 to 60 percent in 1990/91 (13).

Agreements among governments enable all patients covered by Medicare to obtain free care at public hospitals from appointed doctors. Private insurance can be purchased to cover the charges of private hospitals and for private status in public hospitals. Private insurance funds also sell coverage for services not covered by Medicare (particularly private dentistry, physiotherapy, chiropractic services, and appliances) and for prescribed medicines not covered by pharmaceutical benefits.

For private patients in hospitals, the Medicare benefit is 75 percent of the schedule fee, and the gap between the benefits obtainable by the patients and the fees charged is insurable. In other circumstances, the gaps between fees and the amount that can be claimed by patients cannot be covered by private insurance. Patients who receive social security are not usually required to pay the gap between schedule fees and Medicare benefits. A safety-net "threshold" above which full schedule fees are reimbursed applies to all patients.

Pharmaceutical benefits are provided for prescribed items purchased at retail pharmacies; items are listed on a schedule. Unsubsidized pre-

scribed items can also be purchased in pharmacies, and many drugs are available without a prescription. When listed prescribed items are supplied, the pharmacist recoups the cost through a patient contribution and a commonwealth subsidy. Safety-net arrangements limit the amount to be paid by a patient in any calendar year.

In 1990/91, the total cost of drugs was about \$1.8 billion. This included \$985 million through the Pharmaceutical Benefits Scheme (PBS) and other commonwealth programs, \$127 million for private prescriptions, and \$200 million for hospital drug use (13).

Some tension exists between the commonwealth policies and programs and those of the states and territories. Areas of debate include the level of grant funding to be provided by the commonwealth for state-operated programs and whether certain services provided through state institutions are reimbursable under Medicare (and therefore a charge on the commonwealth). The AHMAC has helped resolve some of these difficulties, but negotiations on the funding of services and division of responsibilities can still be protracted. Tension also exists between health authorities generally and medical and other health care professions regarding the degree of support provided through Medicare and other mechanisms for particular services and technologies. A major focus of debate is the perceived pressure on the public hospital system because of the limited availability of certain technologies.

### Proposals for Change

In recent years the commonwealth, states, and territories and the private sector have collaborated to improve hospital information and financial systems, hence to increase the effective use of hospital resources. This collaboration has entailed the development of "casemix systems." A Casemix Development Program, introduced in 1988, provided approximately \$30 million in funding over five years (13). Activities funded to date have been directed toward developing patient record information systems in hospitals, examining ways in which different types of patients can be classi-

fled in casemix groups, developing suitable computer software, improving the understanding of relative costs of treating different types of patients in hospitals (diagnosis-related group cost weights), and using casemix information to examine the appropriateness and quality of hospital care. The health ministers agreed in 1992 that the adoption of uniform national casemix classifications and of cost and service weights should be addressed so as to advance structural reforms within the Australian health care system.

In 1991 the commonwealth government put in place a national health strategy. Over a two-year period the strategy was intended to focus on institutional, community, and personal health services primarily concerned with treating and caring for the ill, and also to consider activities that foster good health (66). The strategy project released a series of about 20 papers on a wide range of issues; their substance and recommendations have provided input for further consideration of changes to the health care system.

## CONTROLLING HEALTH CARE TECHNOLOGY

The introduction and diffusion of health care technologies in Australia is determined by a complex interaction of market forces, public funding, and regulation (12). Nongovernmental parties, including professional groups, equipment suppliers, consumer organizations, third-party payers, local service administrations, and medical specialists all exert significant influence, and the introduction of a particular technology may not always be consistent with health care priorities. (For example, the establishment of laser comeal sculpting services was a result of decisions made by individual specialists without the involvement of health policy makers.) In some areas, such as the introduction of pharmaceuticals, there have been strong legislative provisions and regulatory control. More commonly, however, the major method of control is financial.

## Regulation of Pharmaceuticals

Major changes to the way drugs are regulated have been introduced in the 1990s, updating a system developed largely in the 1970s. The first comprehensive program for appraising the safety and efficacy of pharmaceuticals was developed by the commonwealth during the early 1970s, with some additional regulatory measures imposed by the states of New South Wales and Victoria. The federal controls applied to imported pharmaceuticals and to products registered under the PBS. For these categories of product, the Therapeutic Goods Act and the Customs (Prohibited Imports) Regulations could be applied, requiring assessment of safety and efficacy (compliance with label claim).

Until recently, much weaker controls existed for pharmaceuticals manufactured in Australia that were not registered under the PBS, including over-the-counter preparations. Control of these was to some extent effected by state regulations, which included provisions for joint commonwealth-state inspections of manufacturing premises. The control of locally manufactured products has now been strengthened by an amendment to the Therapeutic Goods Act.

The approach to evaluating new products paralleled that used by the United States and Sweden. Pharmaceuticals were evaluated in accordance with a New Drug Formulation document developed by the commonwealth; chemistry and quality control, animal and human safety, and efficacy for each preparation were to be described by manufacturers. Following a detailed assessment by the DSHS, which included some chemical and pharmacological testing of new products, pharmaceuticals that met the evaluation requirements were certified for use by the Australian Drug Evaluation Committee (ADEC). An Adverse Drug Reactions Advisory Committee coordinated post-marketing surveillance.

Long-standing concerns within the pharmaceutical industry about the slowness of the evaluation

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procedure generated pressure for streamlining. This pressure was increased by such issues as the perceived need for "fasttracking" of approvals for new drugs for treating AIDS. The pharmaceutical industry had also expressed concern about the rate of government reimbursement available through the PBS and had suggested that commonwealth policies were unduly restrictive on industry in the prices they could charge for drugs covered by the PBS.

These concerns eventually led to an inquiry regarding the drug evaluation system (20), including extensive informal discussion and bargaining as well as formal hearings (29). An important issue identified by the inquiry was a perceived overemphasis on safety and efficacy over timeliness. Recommendations included the adoption of strict target deadlines for evaluation and easier access to experimental drugs. The review also suggested greater use of evaluation reports from other countries, building on programs that had already been started in Sweden and Canada.

Proposed administrative reforms included reduction of "dead time" while drug applications were pending and a decrease in the need to reformat data by accepting European Community data formats. It was further recommended that routine evaluation of all individual patient data be discontinued to reduce the costs to industry and the Department and to facilitate the use of evaluations undertaken abroad. Preparation of product information after marketing approval was to be speeded up. The ADEC was to cease its involvement with more routine matters and to return to providing expert advice on difficult clinical issues and considering appeals of rejected applications. The findings of the inquiry were accepted by the government and have led to substantial changes in the drug evaluation program.

Availability of drugs subsidized by the commonwealth under the PBS is achieved through the Pharmaceutical Benefits Advisory Committee (PBAC), which makes recommendations on which products should be listed on the schedule. The PBAC is required to take into account the cost-effectiveness of drugs when making such recommendations. Since 1993, industry applica-

tions for listing under the PBS have had to include formal evidence of cost-effectiveness (34). The guidelines for industry to follow in preparing their applications are intended to be flexible and pragmatic while remaining linked to theoretical foundations. They do, however, pose challenges to industry and to government officials (31). Some emerging issues are the shortage of analytical expertise, selection of comparative therapies, degree of accuracy of estimates of incremental health benefits, and consistency of levels of evidence (69).

Despite the control exercised by the commonwealth government over pharmaceuticals' distribution and use, information about most aspects of their use is poor (13). Information from DSHS indicates that between 1980/81 and 1990/91, the real price per prescription issued through pharmacies increased by 34 percent. Average expenditures per person on prescription drugs increased by almost 240 percent—about twice the increase in the Consumer Price Index. The number of prescriptions per person increased by 16 percent and the price per prescription increased even more. Much of the increase in prices was due to the switch to newer, more costly drugs. Expenditures on drugs by public hospitals have decreased since the mid-1980s, essentially through the transfer of costs to the commonwealth (PBS) by reducing the supply of drugs to patients on discharge.

### I Regulation of Medical Devices

Systematic assessment of the safety and efficacy of medical devices is less well developed than is the program for pharmaceuticals. A formal process of evaluation of medical devices by DSHS was implemented in the mid-1980s (under the Therapeutic Goods Act). The most comprehensive component of this program has been the establishment of a national register. Companies marketing medical devices in Australia must register their name and description with DSHS, which triggers an appraisal of product labeling. A Therapeutic Devices Evaluation Committee appointed by the commonwealth minister provides

recommendations on the import, export, and production of devices.

Beyond this, more detailed evaluation is undertaken for a limited number of categories of device that are prescribed by regulation. This list now extends to drug infusion systems, cardiac valve prostheses, cardiac pacemakers and accessories, intrauterine devices, intraocular lenses, intraocular viscoelastic fluids, and biomaterials of human and animal origin. For such products, departmental evaluations look at evidence of safety, efficacy, and the manufacturer's quality control process. Because such appraisals are resource-intensive, DSHS has moved to establish priorities to take account of major areas of need (22).

### Financial Controls for Health Care Technology

As noted earlier, the main avenues open to governments for controlling the use of health care technologies (including procedures) have been financial—either through budgets for hospitals and clinic services (at the state level), through rate-setting for procedures funded through the Medicare and PBS programs, or through the allocation of grants for specific technologies or services. It is generally recognized that these are crude and imperfect ways of influencing the diffusion of technology and that control by regulation can only be partial (1 2).

Inclusion of items on the Medical Benefits Schedule is dominant in any consideration of payment for medical services, including technologies. Toward the end of the 1980s, 75 percent of all medical services in Australia were eligible for Medicare benefits, which covered a high proportion of the total costs. A further 18 percent of all medical services were provided to in-patients in public and repatriation general (i.e., Veterans') hospitals; the remainder was composed of veterans' services, workers' compensation, public laboratories, and community services (13).

Given the prominence of the Medicare program in recent years, the listing of new technologies on the Medical Benefits Schedule and reimbursement policies for technologies already in place are

of major significance. Listing on the schedule is gained after submissions from professional groups to DSHS, which considers in detail both cost and efficacy data.

To date there has been no systematic linking of Medicare Benefits Schedule appraisals with health care technology assessment. Similarly, reviews of older technologies on the schedule have not drawn systematically on data from Australian assessments. From time to time recommendations in reviews of particular technologies by Australian assessment bodies have influenced subsequent decisions for listing. For example, computed visual perimetry was included on the schedule following an assessment (76), and reimbursement for use of a portable fluoroscope was not supported after the national assessment body expressed concerns about it (75).

Variations in technology use by different practitioners have concerned the commonwealth government for many years. Although there will always be some variation among medical practitioners, some appear to be overusing services as judged by data obtained by the HIC (which is responsible for administering the payment of Medicare Benefits). Pursuit of such practitioners through the courts has had limited success. The HIC has more recently begun providing feedback to practitioners whose level of use of technologies is considerably above average. This appears to be having some success as an educational process, although the long-term effects remain to be seen.

Governments can control the introduction of certain technologies that have high capital costs by funding their purchase in limited numbers. Commonly, costs are shared by the commonwealth and one or more state governments. Such approaches appear to be successful in the short to medium term and have been undertaken, for example, in the introduction of renal lithotripsy services, where initial restriction of government support to two sites prevented early diffusion of the technology (8). Such approaches seem to be essentially stopgap arrangements prior to the wider diffusion of technologies under Medicare funding, through health program grants from the

commonwealth, or public hospital funding provided by the states.

### 9 Regulation of the Placement of Services

Regulation of the placement of services has generally been the responsibility of state governments and has typically been associated with some financial control over public sector facilities. States have at times followed the suggestions and recommendations offered by guidelines on specialty services but often have reacted more to local pressures and imperatives. The placement of very specialized services has in recent years been directed by a policy on nationally funded centers adopted by AHMAC (discussed later).

Some control over the use of medical devices is exerted at the state level, particularly under radiation health legislation, which is used by some states to license various sites to operate technology such as radiotherapy equipment. In Victoria the introduction of certain new technologies was effectively controlled for several years by certificate of need (CON) provisions under the State Health (Radiation Safety) Act. State approval was required before certain equipment could be installed and operated. This legislation was applied to the introduction of new diagnostic scanners (particularly computed tomography (CT) and magnetic resonance imaging (MRI)) and to restrict lithotripsy introduction. No other state has adopted CON legislation and the Victorian use of this approach now appears to be at an end.

The background to the Victorian initiative has been described by Duckett (33), who commented that at that time, commonwealth and state incentives worked in opposite directions. For CT scanning, for example, commonwealth incentives for both capital and recurrent expenditure were covered by the Medical Benefits Schedule fee, thereby encouraging installation of scanners (as all costs were covered). State incentives were an attempt to regulate CT scanner acquisition.

#### Quality Control and Accreditation

Quality control requirements for health care technology services funded by governments are

not mandatory in most areas, and standards and practice in this area are still evolving. A survey of hospitals in 1987 found that hospital quality assurance programs were embryonic and that although peer review was fairly common, its effectiveness had not been assessed (90).

A significant force in hospital and other institutional quality assurance has been the Australian Council on Health Care Standards (ACHS), established in 1974 by the Australian Hospital Association and the Australian Medical Association as an independent body to promote and encourage the efficient provision of best quality health care. It develops and implements national standards of care through an accreditation program in cooperation with professional bodies.

ACHS policy requires that health care facilities evaluate the care and services they provide in order to be eligible for full accreditation. This formal evaluation involves medical, nursing, allied health, and administrative staff. If granted, accreditation may be for one or three years, depending on the degree of compliance with guidelines.

As of April 1993, 379 hospitals were accredited by ACHS, accounting for 73 percent of private hospital beds and 59 percent of public hospital beds in all states and territories. Accreditation of hospitals is perceived as a useful means of raising and maintaining standards, but it does not necessarily reflect an institution's access to funding for the use of a particular technology or service. ACHS is in an early stage of widening its activities to cover extended care and day procedure facilities. Results of follow-up surveys published by ACHS suggest that accredited hospitals are active in responding to recommendations made by surveyors. Some areas, notably medical record content, continue to be resistant to change, however.

In 1989 ACHS, in collaboration with medical colleges and other professional bodies, began the Care Evaluation Program, which involves the development of objective clinical indicators that reflect the process and outcomes of patient care. Development of the indicators stemmed in part from the medical colleges' requirement for a greater clinical component in the accreditation process and ACHS' wish to have greater clinical

involvement in quality assurance and a more defined role for clinician surveyors. National standards are to be established that are specific for disciplines and facilities but that account for case-mix and illness severity. Hospital-wide medical indicators have been developed by the Royal Australian College of Medical Administrators in conjunction with ACHS. Their use became a formal requirement for accreditation in 1993, and they are being phased in gradually.

The ACHS programs have given Australia a coherent framework for improving the quality of its health care institutions. However, even with the Council's effort, there are limits to what has been achieved even for those hospitals that are accredited. Coverage of ACHS accreditation is far from complete, and participation in the program is not mandatory.

National pathology laboratory accreditation came into being with amendments to the Federal National Health Act. Accreditation is awarded on the basis of laboratory inspections by the National Association of Testing Authorities using standards developed by the National Pathology Accreditation Advisory Council. Only those premises that provide pathology services to be reimbursed through Medicare are obliged to become accredited (outside of Victoria), but in practice, a large majority of laboratories are accredited, including all significant public sector facilities. One of the requirements for accreditation is that laboratories participate in appropriate quality assurance programs, typically those offered by the Royal College of Pathologists of Australasia and the Australian Association of Clinical Biochemists. Pathology laboratory accreditation has generally been regarded as successful in raising the standards of pathology services. While accreditation has had no obvious effect on levels of use of pathology testing, it has, in association with licensing costs, been one factor in restricting to a very low level all nonlaboratory pathology use in Australia.

## HEALTH CARE TECHNOLOGY ASSESSMENT

Health care technology assessment in Australia is undertaken by university groups, private consultants, and health authorities, but its major direction for over a decade has been set by national advisory bodies established by governments with secretariats provided by health authorities. Assessments from other sources have at times been influential, but the work of the national committees has had the most obvious effects on health authorities' opinions about health care technologies and on the formulation of policy.

Interest in health care technology assessment outside the context of the regulatory appraisal of pharmaceuticals developed during the late 1970s. A number of concerns and options were addressed in the report of the Committee on Applications and Costs of Modern Technology in Medical Practice (97), which was established to address the increasing costs of medical investigations and patient care. It considered various effects of technological developments on medical benefits and public hospital costs, with some emphasis on diagnostic methods that were then emerging as a significant area of concern. Certain key issues relating to technology assessment were clearly identified in this committee's report:

Modern technology has increased the diagnostic capability and therapeutic effectiveness of doctors. It has made significant contributions to improvements in . . . health and . . . quality of life . . . . However, it has been suggested that the extra resources consumed through further increases in the use of modern technology may have only marginal benefits in terms of further improvements in health . . . . Both [doctors and patients] now tend to be less willing to accept diagnoses that have been arrived at solely on the basis of clinical examinations.

The report viewed technology assessment as one of several long-term measures to improve the effectiveness of technological services in the

**TABLE 2-1: Australian National Health Technology Assessment Agencies: Terms of Reference**

**Australian Health Technology Advisory Committee (AHTAC)**

Identify, gather data on, and assess new and emerging health technologies and highly specialized services, including their safety, efficacy, effectiveness, cost, equity, accessibility, and social impact in the context of the Australian health care system.

Assess and develop guidelines for established health technologies and highly specialized services in light of their history of use.

Determine methods of and priorities for assessment of health technologies.

Advise the Australian Health Minister's Advisory Council (AHMAC) on requests relating to the assessment of technologies in the context of AHMAC'S nationally funded centers policy,

**National Health Technology Advisory Panel (NHTAP)**

Identify, gather data on and, where appropriate, assess new and emerging health technologies, including their safety, efficacy, effectiveness, cost, accessibility, and social impact in the context of the Australian health care system.

Review and assess established health technologies in light of their history of use,

Determine methods of and priorities for assessment of health technologies, and issue guidelines on these topics.

Make recommendations on appropriate areas of research into health technologies.

Make recommendations on educational measures for promoting the appropriate use of health technologies,

**AHMAC Superspecialty Services Subcommittee (SSS)**

Develop guidelines for superspecialty services, defined as highly specialized services for relatively rare diseases or which are unusually complex and costly. Guidelines should include the potential for integration, coordination, and rationalization of superspecialty services. Guidelines are submitted through AHMAC to the Australian Health Ministers' Conference for approval.

SOURCE D M Halley, 1994

health care system. The committee recommended that an expert national panel be established to advise on the scope of new technology; whether medical benefits should be paid for its use and, if so, whether it should be restricted to specific locations; and likely changes in patterns of use of related technology.

**D The Formation and Operation of National Advisory Bodies**

A National Health Technology Advisory Panel (NHTAP) was established by the commonwealth in mid-1982 (table 2-1). As envisaged by the Sax Committee, its membership balanced various interests and included representatives of the medical profession, hospitals, the health insurance industry, and manufacturing, as well as technical specialists. The DSHS chaired and provided a secretariat for the Panel, which reported to the federal minister for health and had broad terms of reference.

The Panel selected MRI as its first topic and produced its first report in 1983. This influential assessment was a major input to policy on MRI. The MRI report established a process used by the Panel in later work: detailed consideration of available literature plus consultation with professional bodies, manufacturers, and health authorities, culminating in a synthesis of available information. Particular focuses were on clinical, technical, safety, and utilization data (cost data were also included but without duplicating activities undertaken by the DSHS). The Panel was also involved in two major assessments involving primary data collection: the MRI study that followed from the first report and one on dry chemistry pathology analyzers. Both were coordinated by technical committees that included representatives from appropriate professional bodies.

The Panel produced numerous assessment reports as administrative arrangements evolved.

TABLE 2-2: Technologies Assessed by the National Health Technology Advisory Panel (NHTAP)

Year	Topic	Originator of request
1983-90	MRI, MR spectroscopy	NHTAP
1984	Medical Cyclotron Facilities	Federal Minister
1985	Lasers in medicine	NHMRC
1985, 1987	Renal extracorporeal shock wave lithotripsy	DHSH
1986, 1989	Bone mineral assessment	DHSH
1986	Digital subtraction angiography	DHSH
	Vestibular function testing	DHSH
	Surgical stapling	Industry
	Lasers in gynecology	Professional body
	Oxygen concentrators	NHTAP
1987-90	Nonlaboratory pathology testing	AHMAC
1987	Endoscopy	Professional body
1988	Digital radiology	NHTAP
	CT scanning	NHTAP
	Portable fluoroscope	DHSH
	Screening Mammography	AHMAC
	Biliary extracorporeal shock wave lithotripsy	NHTAP
	Dynamometry for low back pain	Accident Compensation Org
1989	Coronary angioplasty	NHTAP
	High energy radiotherapy equipment	State Health Authority
	Computerized perimetry	DHSH
1990	Extracorporeal Membrane Oxygenation	AH MAC
	Cerebrovascular embolization	AHMAC
	Positron emission tomography	DHSH

KEY AHMAC = Australian Health Ministers Advisory Council, DHSH = Department of Human Services and Health, NHMRC = National Health and Medical Research Council

SOURCE D M Halley, 1994

During 1987/88 support for the Panel was transferred to the Australian Institute of Health (AIH) which had recently been created as a statutory authority. A review of NHTAP in 1988/89 endorsed the concept of an impartial and independent Panel and the continued operation of a health technology unit within the AIH (98). The unit's primary function would be to support the work of the Panel, but it also would conduct reviews of existing and significant emerging technologies, act as a reference center, and maintain a database, including primary data on health care technologies in Australia. The Institute continued to provide research and secretariat support to the Panel until it was subsumed by the Australian Health Technology Advisory Committee (AHTAC) in 1990.

NHTAP faced realities and problems common to other medical and health technology assess-

ment agencies (44). These include the time taken to collect and analyze information and occasional tensions with policy makers seeking prompt advice; difficulties in securing resources to support data collection on a range of technologies; restrictions on time for meetings and the relatively few technologies that could be considered in detail; and the tendency to focus on "big-ticket" items.

NHTAP produced 41 reports covering the technologies listed in table 2-2. The Panel secretariat undertook most of the research and drafting tasks. The quality of the reports was enhanced by an ongoing dialogue with health professional groups and with industry; the Panel sometimes was able to follow up on technologies after the initial report and provide updated advice.

In a number of assessments, resource allocation was considered in some detail, although this did

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not always include economic analysis. The more common approach undertaken by the Panel was to include cost analyses without proceeding to full economic evaluation. However, in these and other reports, many of the concepts embedded in models of economic assessment of health care technologies were taken into account (32).

Health authorities were major targets for NHTAP assessments—particularly DSH with respect to technologies that were potential candidates for funding through Medicare. About half the referrals received by the Panel came from health authorities, but in some cases NHTAP initiated work on its own to provide early warning of potentially significant developments.

Although many of its recommendations were concerned with the adoption of technology and guidance on appropriate, phased introductions, in various instances the Panel also offered suggestions to professional bodies on the appropriate use of medical devices or procedures.

Another initiative in the early 1980s was the creation by the AHMAC predecessor of a Superspecialty Services Subcommittee. It developed guidelines for highly specialized services catering to relatively rare diseases or those that entailed unusually costly or complex forms of treatment. This initiative was motivated by increasing pressures on state health authorities to organize and fund more complex services within their hospitals. The Subcommittee, which was composed of commonwealth and state officials, relied on individual health departments to provide research support as resources became available.

Aided by professional bodies and other centers of expertise, the Subcommittee compiled information on the use, demand, distribution, and appropriate operation of various health services. Its publications provide general background descriptions of services followed by guidelines on such issues as bed requirements, sizes of units, geographic distribution, design of facilities, equipment requirements, and relationships with other services and staffing. The development of these guidelines proved to be demanding. Needed

**TABLE 2-3: Guidelines by Superspecialty Services Subcommittee (AHMAC)**

Year	Topic
1982	Burn treatment
1983	Cardiac surgery
	Level 3 neonatal intensive care (updated 1990)
1985	Bone marrow transplant services
	Genetic disorders
1987	Cancer treatment services
1988	Major plastic and reconstructive surgery
1989	Acute spinal cord injury services
1990	Refractory epilepsy centers

SOURCE D M Halley, 1994

data were hard to obtain, and there were problems in achieving consensus on what were effectively a set of standards for specialized health services throughout the country (44).

The Subcommittee prepared nine guidelines with one major update (table 2-3). Most of the guidelines are valuable resource documents and continue to be widely regarded, although their recommendations are not necessarily followed by all jurisdictions.

### Current Structure of Assessment Entities

In 1990 both the Panel and the Subcommittee were subsumed by a new body, the Australian Health Technology Advisory Committee (AHTAC) which was to report to the Health Care Committee of the National Health and Medical Research Council (NHMRC). This change was in line with a move to establish stronger links between AHMAC and NHMRC and to involve NHMRC more closely in advising health authorities on health services and technology.

Still in its early stages of development, AHTAC retains some of the characteristics of NHTAP. Its membership provides a range of expertise and is drawn from diverse sectors. AHTAC will be regarded as a source of advice to AHMAC

and DSHS on various matters, and may also receive requests for advice through the Health Care Committee. AHTAC is tending to follow the NHMRC practice of convening a working party for each project.

AHTAC'S work to date has been dominated by references on Nationally Funded Centers passed to it by AHMAC. The Committee is also continuing with the Subcommittee's work on guidelines preparation, which seems likely to be a significant ongoing function. Another likely undertaking is the preparation of brief statements on technologies, particularly for patients and the general public; the Committee's place within the NHMRC structure may provide a particular advantage in drawing on networks and achieving publicity. The Committee's reports are issued through the NHMRC system, and all are endorsed by this body (table 2-4 lists AHTAC'S publications to date).

AIHW undertakes health technology assessments in addition to its work in support of AHTAC, following the general directions recommended in the review of the earlier Panel. This work includes assessments initiated by the Institute or requested by other agencies, including DSHS; collation and publication of statistics on health care technologies in Australia; and participation in collaborative work with hospitals and other centers. (Assessments published by the Institute are listed in table 2-5.) In addition, on behalf of AHMAC the Institute undertook a major assessment project on screening for breast and cervical cancer.

Following a project undertaken for DSHS, in 1991 the Institute started a series of emerging technology briefs intended to provide prompt advice to health authorities and managers on new medical devices and procedures that seemed likely to have a significant impact on the health care system (table 2-6). There has been some collaboration with Canadian agencies in the preparation of these briefs. Briefs on current issues dealing with more established technologies have also been developed.

In some cases assessments that have been undertaken by the Institute have formed the basis for

**TABLE 2-4: Publications of the Australian Health Technology Advisory Committee**

<b>Year</b>	<b>Topic</b>
1991	Consensus statement on clinical efficacy of MRI
1992	Renal stone therapy Liver transplantation programs Statement on sleep disorders Guidelines for renal dialysis and transplantation
1993	Liver transplantation programs--2nd review Treatment of sleep apnea Statement on laser corneal sculpting Renal lithotripsy Heart and lung transplantation programs
1994	Low power lasers in medicine Treatment options for benign prostatic hyperplasia
<b>Briefs (Nationally Funded Center Assessments)</b>	
1990	Alfred Hospital, Melbourne cardiac transplantation unit
1991	Pediatric cardiac transplantation Stereotactic radiosurgery
1992	Craniofacial surgery Bone marrow transplantation using unmatched donors
1993	Queensland cardiac transplantation service

SOURCE D M Halley, 1994

subsequent evaluation by AHTAC or other groups. For example, the statement on laser corneal sculpting followed an emerging technology brief and then a discussion paper by the Institute, which were in turn followed up by AHTAC. In other areas—for example, in a discussion paper on telemedicine (25)—the Institute has undertaken broader reviews that have served as resource documents for health authorities and other interested parties.

The National Center for Health Program Evaluation, which is partly funded through NHMRC and is part of Monash University in Melbourne, has had some involvement with health technology assessment matters. Its work has included cost-utility analysis of treatments for biliary disease, evaluation of whole body protein monitors, and assessment of laser treatment of benign prostatic hyperplasia.

TABLE 2-5: Assessments by Australian Institute of Health and Welfare

Year	Short title	Origin and use by advisory bodies
1989	Angioplasty and Other Percutaneous Interventions	Source material for NHTAP and SSS evaluations
1990	Tinted Lenses in Reading Disability Options for Stereotactic Radiosurgery Screening Mammography Technology Gadolinium Contrast Agents in MRI Developments in PACS Medical Thermography Laparoscopic cholecystectomy	Follow-up to preliminary work in DSHS Source material for NHTAP and AHTAC Referred from AHMAC committee Referred from DSHS Follow-up to NHTAP assessment Follow-up to preliminary NHTAP work AIH
1991	Implantable Cardiac Defibrillator Biliary Lithotripsy (also 1992, 1993) Boron Neutron Capture Therapy Laser Corneal Sculpting	AIH Trial funded by Commonwealth and Victoria Inquiry from NHMRC Source material for AHTAC
1992	Assessing MRI in Australia Lasers in Angioplasty Minimal Access Surgery Cochlear Implants Peripheral Angioplasty Products for Office Pathology Testing Cardiac Imaging	Position paper on national assessment AIH Source material for AHTAC Referred by industry Suggested to NHTAP Referred from DSHS Interest from State authorities
1993	Telemedicine Lasers in Medicine New Technologies for Cervical Cancer Screening and Treatment Treatment of Menorrhagia and Uterine Myomas Treatment of Benign Prostatic Hyperplasia Health Technology and the Older Person Technologies for Incontinence Social Impact of Echocardiography	AIHW Follow-up of NHTAP review Referred from DSHS AIHW, source material for AHTAC AIHW, source material for AHTAC Australian Science and Technology Council AIHW, source material for AHTAC Study by La Trobe University/St. Vincent's Hospital, Melbourne
1994	Hip Prostheses Minimal Access Surgery--Update Intraoperative Radiotherapy Laparoscopic Cholecystectomy in Canada and Australia Magnetic Resonance Imaging at the Knee Pap Smear Examinations Under Medicare	Source material for AHTAC Referred from State health authority Joint studies with CCOHTA Follow-up from earlier AHTAC discussion Referred from DSHS

SOURCE D M Halley, 1994

### Funding for Health Care Technology Assessments

Core funding for the national advisory body (NHTAP and now AHTAC) and AIHW has mainly been provided via annual appropriations of the commonwealth's health portfolio. The level of funding has been about the same for some years. In 1994 AHTAC received direct annual funding of

about \$80,000, plus \$90,000 provided by AHMAC for work related to Nationally Funded Centers, superspecialty services guidelines, and other referrals from the Council. Direct salary-related and administrative funding for the AIHW technology assessment function is roughly \$400,000 per year.

TABLE 2-6: AIHW Health Technology Briefs

Year	Topic
1991	Laser corneal sculpting Radiofrequency catheter ablation Cervical loop diathermy New laparoscopic procedures
1992	Endovascular coronary stents Helium lasers in corneal sculpting Cardiomyoplasty Collagen Implant therapy for treatment of stress incontinence Excimer lasers in coronary angioplasty Technologies for treating benign prostatic hyperplasia Cerebral oximetry Magnetoencephalography (MEG) Cultured skin Magnetic resonance angiography Laparoscopically assisted hysterectomy Transurethral lithotripsy
1993	Lasers in dentistry Coronary atherectomy Radiolabeled monoclonal antibodies in diagnostic imaging Fall otopscopy Focused extra corporeal pyrotherapy Levonorgestrel IUD for menorrhagia
1994	Digital mammography Dedicated MRI extremity scanners Stereotactic Image-guided surgery
<b>Health technology issues</b>	
1993	Carotid endarterectomy Diagnostic hysteroscopy Prostheses for total hip replacement Implantable defibrillators Helical CT scanners Cholesterol screening and associated interventions

SOURCE D M Hailey, 1994

In practice, other funding has generally become available on a short-term basis for the national advisory body, and the Institute receives grants from DSHS and other sources. In 1990, \$200,000 was made available by DSHS for specific small projects under the auspices of NHTAP, which were ad-

ministered by AIH. The Department continues to provide evaluation funding for projects that are broadly related to current policy—including, for instance, support for a randomized trial of laparoscopic cholecystectomy, work by AHTAC on minimal access surgery, and a review of technologies for cervical cancer screening undertaken by AIHW.

In general, over the last decade the level of funding for the health technology assessment provided some assurance of continuity, but it remains at a modest level, limiting what can be achieved. Additional resources would permit more detailed economic studies, more consistent follow-up of technologies after their initial evaluation, wider coverage of technologies, and greater focus on patient perspectives.

### Impacts of Health Care Technology Assessment

The early studies of MRI and dry chemistry pathology testing (where local primary data collection was being undertaken) and assessments of medical cyclotrons and renal lithotripsy, all were prompted by policy considerations and the results were used in the decisionmaking process (40,41).

Possible measures of impact and the conditions for these to occur were described and applied to a review of 24 technologies assessed by NHTAP (43). The Panel's reports appeared to have had a significant influence in the short to medium term for 11 of 20 technologies assessed through 1988; major recommendations were accepted, and subsequent governmental or other action was taken. Sixteen reports proved useful as source and educational materials, as judged by requests and literature citations. As an indirect indicator of impact, there was a steady growth in the number of requests for reports, and some publications were used in university courses.

The influence of Australian assessments of 10 health technologies (by NHTAP, AU-I and AHTAC) was discussed in more detail by Drummond and coworkers (32), who felt that the assessments met important criteria (e.g., whether evaluation questions were clearly specified, alternatives ad-

dressed, follow-up studies undertaken, and policy and practice influenced). The evaluations were influential, although the impacts of some of them had yet to be fully established given the interval between receipt of advice and policy formulation. As in other countries, the most obvious successes, in terms of policy being informed by assessment, have been linked to the possible introduction of a technology. The evaluation mechanisms available and their influence on the actual use of technologies become less certain after diffusion.

A further analysis noted that the impact of assessments by advisory bodies was greatest when local primary data were collected and the technology was not yet available or had just been introduced (42). The data generated by the various assessments was important, but perhaps equally significant was the commitment made by governments to support data collection in the first place. Each of the assessed technologies was seen as significant in policy terms so that evaluation funding was made available to hospitals and other institutions.

Assessments of eight technologies considered under the Nationally Funded Centers policy faced difficulties because of limited data and time for analysis but were nonetheless very successful: almost all the recommendations were accepted by AHMAC. In these cases the influence on policy is more obvious and direct, given the relatively narrow focus (i.e., to fund or not fund from a particular pool of money under set criteria) and the clear wish of health authorities for advice. Of 18 assessments undertaken by AIHW, five were used as input for subsequent NHTAP and AHTAC evaluations, all but two seemed to provide significant source material, and eight appeared to significantly influence policy or further research.

A survey undertaken by AHTAC of government agencies and other recipients of assessment reports showed that many considered the background information, the data on use, caseload, effectiveness, and cost, and the recommendations to be generally useful. The background information seemed of rather more immediate help to some policy makers than the cost/economic analyses. The scope of the assessments in most cases was

seen as generally relevant or (less often) very relevant; to some extent this probably reflected the difficulty of capturing the immediate policy interest of the moment. Although the reports were seen as generally timely by a most survey respondents, only a small proportion thought they were "very timely."

The impact of health care technology assessment has been most readily visible in the decisions of health authorities and other funding sources. The effects on patterns of clinical practice is less certain; they have probably been more limited, but detailed studies have yet to be undertaken. The review of the impact of NHTAP assessments drew attention to the probable increased acceptance by professional bodies of the need for evaluation and critical consideration of health technologies (43). Changes to clinical practice maybe slow, however: some influences of health technology assessment will be felt only over the long term. The further review of 10 technologies suggested that in five cases, assessment had probably affected clinical practice; it was too early to make such a judgment for another two cases (32).

In some areas there maybe reluctance to accept new evidence. An Australian randomized trial was among several studies that demonstrated that antenatal fetal heart rate monitoring had no detectable effect on mortality or morbidity in high-risk cases (65). However, during the year after the trial ended, use of the technology in the hospital increased 16-fold, and it extended to less and less appropriate groups (64). This technology continues to be widely applied some years later.

A recent initiative of NHMRC has been the formation of a Quality of Health Care Committee that is responsible for preparing clinical practice guidelines. Three guidelines currently under development cover treatment of breast cancer, ischemic heart disease, and depression in adolescents. This approach offers the potential to strengthen the impact of assessment by providing a further channel for the results of individual evaluations.

The appraisals of impact indicate a need for improved dialogue among concerned parties, the desirability of timely advice, and the need for

realistic linkages with the policy processes and methods of practice. There is an unmet need for systematic appraisal of a greater range of technologies and for follow-up after their introduction. This in turn points to the need for a wider constituency in health care technology assessment, with input from hospitals and other organizations.

Both NHTAP and AHTAC have involved clinicians (as well as other experts) in the assessment process, both through consultation during development and through comment and debate on drafts at the review stage. Public involvement in the work of the national advisory bodies has so far been limited, although NHTAP included a consumer representative; such representation is standard practice with NHMRC committees, including AHTAC. If there are significant moves toward organizing consensus conferences, a form of assessment that has not been widely used in Australia, public involvement may increase. Further development of advisory statements by AHTAC (making use of the NHMRC distribution process) might also increase public involvement.

Health technology assessment is well established in Australia and has influenced health policy. However, limitations on resources, the degree of coverage of technologies, and the extent to which initial assessments can be followed up are concerns that need addressing as technology assessment proceeds in Australia. It would also be desirable to achieve better coordination of evaluation groups and to complement existing successful patterns of assessment with further use of more formal methods, such as detailed cost-effectiveness studies and meta-analyses. Finally, greater use could be made of health technology assessment by policy makers, health care providers, and funders.

## **Policies on Specific Technologies and Pharmaceuticals**

### ***Nationally Funded Centers***

In 1989, Australia's health ministers agreed to a policy supporting certain highly specialized or high-cost technologies that typically only one or

two centers in the country might provide. This policy, applied by AHMAC, is aimed at ensuring access for all Australians to approved high-cost, low-demand services and avoiding unnecessary duplication. Support is provided on a relatively short-term basis; renewal of funding is subject to a review of the technology and of the centers that are providing it. The expectation is that in many cases, Nationally Funded Center status will be discontinued as technologies diffuse further.

Support for Nationally Funded Centers is provided through a special fund created by a portion of each state's Medicare grant. The policy rests on agreements reached between governments, rather than on legislation. Proposals for funding are made by individual states, with submissions prepared by the hospitals that intend to establish or develop the technology. Most of the funding has so far been applied to transplantation services.

Proposals for support under this policy are referred by AHMAC to AHTAC for evaluation against two sets of criteria. The first set is designed to establish the suitability of the technology as judged by measures of safety, efficacy, national demand, and need to concentrate services for cost-efficiency and best performance. The second set of criteria relates to the suitability of the proposed site in terms of established expertise, research programs, and support services. Each technology funded is eventually reviewed by AHTAC to determine whether support should continue or if the technology should be regarded as a superspecialty service funded by individual states.

Application of the policy to new proposals can be illustrated by the evaluation of technologies for treatment of arteriovenous malformations (AVMs) and other cerebral lesions. Evaluation of cerebrovascular embolization was carried out by NHTAP and completed by AHTAC (80). Proposals were assessed from a center in Perth with a long record of research in this technique and from hospitals in Sydney and Melbourne. It was accepted that embolization demanded high levels of skill and integration of specialties, that technology development continued to be significant, and that it was a useful approach to managing small

numbers of patients at significant risk of major neurological deficit or death. In view of the estimated national caseload and the developing expertise in the eastern states, the establishment of two national centers was recommended—in Perth and in Sydney. After AHMAC accepted this recommendation, a budget was developed on the basis of assessment data. Both centers will collect clinical and cost data for subsequent review by officials and evaluation by AHTAC.

Initial interest in establishing stereotactic radiosurgery, also used in the treatment of AVMS and certain types of cerebral tumor, related to introduction of the gamma knife, a focused array of gamma radiation from cobalt 60 sources. However, it became apparent that there had been significant developments in the alternative approach of the focused linear accelerator (linac). The technology was assessed by AHTAC in 1992 in response to applications for funding from centers in Perth and Sydney. AHTAC took the view that the focused linac option was more realistic and that because of the probable diffusion of this approach and the comparatively limited additional expertise required (compared with that found in major radiotherapy units), the technology would not be appropriate for Nationally Funded Center status (8). This position was accepted by AHMAC. Funding of radiosurgery units is therefore a matter for individual state governments.

The ongoing review process for Nationally Funded Centers can be illustrated by assessments of programs for liver transplantation services that were supported at three centers—in Sydney, Brisbane, and Melbourne. AHTAC considered liver transplantation in terms of criteria specified under the policy: whether the technology was continuing to evolve, whether further diffusion would lead to additional costs and inefficiencies, and whether the move to superspecialty status would adversely affect access to such services. In an initial review the Committee considered that technical development was still significant, further diffusion was not appropriate (particularly to smaller centers of population), and the situation should be reviewed again in two years (7). The follow-up review concluded that technical develop-

ment had plateaued, further proliferation would be unlikely to generate significant inefficiencies, and a move to superspecialty status would not adversely affect access. The recommendation was for discontinuation of Nationally Funded Center status for the centers (10); it was accepted by AHMAC.

### Highly Specialized Drugs

Following the states' concerns over rapid growth in the use of expensive specialized drugs provided through the public hospital system, discussions by AHMC and AHMAC led to an agreement on funding for such services and the establishment of a Highly Specialized Drugs Working Party (HSDWP). This entity selects drugs for inclusion in funding arrangements, monitors new highly specialized drugs that are potential candidates for inclusion, and monitors the way in which drugs supplied under the program are used. Decisions on listing drugs are made by the Pharmaceutical Benefits Advisory Committee. The criteria for selection of a drug for funding specify that ongoing medical supervision is required; the drug is for treatment of chronic medical conditions, not acute inpatient episodes; the drug is highly specialized, is subject to marketing approval by the commonwealth, and has a high unit cost; and there is an identifiable patient target group.

In addition to erythropoietin (discussed later in the case study on end-stage renal disease), the program was also initially applied to the supply of cyclosporine to patients through public hospitals, with grants of \$25.1 million being made to states and territories in 1991/92. Subsequently, the HSDWP has focused especially on drugs for management of AIDS. Forward estimates for commonwealth funding of zidovudine (AZT) in 1992/93 were \$12.9 million. Recommendations have been made on listings and prices for didanosine, desferoxamine, and ganciclovir. In each case supply of the drugs is handled by the public hospitals. States provide funding for an initial period, after which the commonwealth meets all subsequent costs subject to receipt of usage data based on individual patient records.

## Case studies

### TREATMENTS FOR CORONARY ARTERY DISEASE

#### Coronary Artery Bypass Grafting (CABG)

CABG commenced in Australia in 1970, and usage rates have increased steadily ever since. The status of CABG was considered briefly in guidelines prepared by the Superspecialty Services Subcommittee (100). At that stage, CABG procedures accounted for about 75 percent of all cardiac surgery caseloads in some states, after a period of rapid growth in use of the technique. The Subcommittee predicted that CABG caseloads would stabilize at about 500 procedures per million people. Recommendations did not address CABG per se but included minimum caseload levels for a cardiac surgery service of 200 adult patients per year within two years of inception, with a longer term goal of at least 1,000 patients per year. The Subcommittee's guidelines helped the New South Wales Health Department make a decision to limit the number of centers for such surgery; the guidelines were less influential in other states.

In 1991 there were 12,694 operations for coronary artery disease (CAD), all but 45 involving bypass grafting—an increase of 11 percent over 1990 (85). This amounts to 669 operations per million, which is substantially above the original Subcommittee estimate even after the diffusion of coronary angioplasty. Of these operations, 11,586 were without concomitant procedures. Mortality nationally was 2 percent (6 percent for the 7 percent of all bypass procedures that were reoperations). The number of grafts per patient in 1990 stabilized over the previous six years at just over three.

There was no national evaluation of CABG, although the National Heart Foundation has monitored the use and diffusion of the technology for

many years. Published accounts of Australian work appear to be limited to descriptions of experience and outcomes for small series of patients. Diffusion of the technology has been determined largely by decisions of individual hospitals and state health authorities and by the availability of reimbursement through Medicare benefits. The initial growth of bypass surgery was particularly rapid in South Australia and Western Australia; there is now a more even coverage. Rates of surgery continue to increase in all states; in 1991 they ranged from 834 per million in New South Wales to 548 per million in Queensland.

#### Percutaneous Transluminal Coronary Angioplasty (PTCA)

PTCA was introduced in Australia in 1980. In 1991, 5,726 procedures were undertaken at 20 units (18 percent were repeat procedures), a 17 percent increase over 1990. The number of procedures per unit averaged 286 (ranging from 11 to 656), performed by 81 physicians (84). The overwhelming majority of procedures were for single vessel disease; procedures for double-vessel disease decreased from 10.2 to 8.1 percent between 1989 and 1991. Procedures on more than two vessels are still uncommon.

The primary success rate in 1990 was 91 percent, an increase of about 3 percent over five years. In 91 percent of all cases, indications for PTCA were stable or unstable angina, with acute myocardial infarction (AM I) accounting for 4 percent and prognostic reasons for 2 percent; 9 percent of procedures were performed on patients with CABG grafts. In 1991, 127 patients (2.2 percent) required CABG after PTCA during the same hospital admission, about three-quarters within 24 hours as emergency operations for complications. Over a 10-year period the rate of CABG

post-PTCA has fallen from initial values of 11 to 12 percent. The overall rate for AMI following PTCA is 2 percent over a 10-year period, with no clear trends over the last seven. The mortality rate for PTCA was about 0.4 percent between 1980 and 1991.

Coronary angioplasty was assessed by NHTAP, drawing on a review commissioned by AIH (79,93). The Panel's assessment looked in some detail at the indications for PTCA, efficacy, complications, and cost in comparison with bypass surgery and medical therapy; distribution of services in Australia; and institutional requirements. The Panel commented that each form of therapy (CABG, PTCA, and medical) had its own range of indications but that these overlapped substantially. It recommended the development of guidelines for PTCA, noting that these would need to be reviewed as results emerged from trials comparing CABG and PTCA for treating multi vessel disease.

NHTAP also noted that there was a potential for substantially increased use of PTCA in Australia, with replacement of some CABG procedures, increased use after AMI, and use for patients considered too frail for CABG or whose condition was not considered serious enough for surgery. The danger of overuse was also flagged—for example, for patients whose angina was satisfactorily controlled by medication, asymptomatic patients, and those for whom the cause of symptoms was uncertain. The Panel also saw a possibility of underuse, particularly in the public sector, as the result of funding constraints on public hospitals. This could lead to loss of productivity, unnecessary use of CABG, and inadequate medical treatment with costs that could have been avoided if PTCA were more readily available. A possible reason for the modest growth of PTCA use in Australia (which has eased since preparation of the NHTAP report) is the limited capacity of cardiac catheterization laboratories.

There was no formal training program for PTCA in Australia, although all practitioners had in fact been trained under supervision (largely in the United States). Because peer review processes in Australia are strong, hospitals would be unlikely

to award angioplasty privileges unless the practitioner had adequate experience. The Panel found no apparent immediate need for the introduction of credentialing for Australian users of PTCA.

### Costs of PTCA and CABG

NHTAP estimated a cost for a single PTCA procedure of approximately \$7,100, including an angiogram and other tests. Average cost per patient to the health care system, which also included CABG for a proportion of cases including later elective procedures, was \$9,400. In comparison, the estimated cost of CABG was \$10,500, rising to \$11,700 in average cost per patient if complications were taken into account. No allowance was made for repeat CABG or PTCA, which would be required by many patients within 10 years of the first CABG procedure. In comparison, the costs of medical treatment of angina would vary widely, perhaps between \$1,500 and \$10,600 over a 10-year period.

The Panel recommended further analysis of the costs and benefits of PTCA by AIH in consultation with professional and government bodies. It also urged that appropriate professional bodies (in consultation with health authorities) consider the desirability of an accreditation system for institutions providing PTCA services.

### Recent Developments

PTCA services have continued to grow, but although the Cardiac Society of Australia and New Zealand has developed guidelines, accreditation provisions have not yet been applied further to institutions and specialists. Because of funding constraints and other priorities for assessment, the proposed analysis of costs and benefits has yet to be undertaken. The question of more comprehensive guidelines for cardiac interventions is now being addressed by AHTAC, in part as a follow-up to the original cardiac surgery guidelines produced by the Subcommittee. The NHMRC's Quality of Health Care Committee is addressing the question of practice standards in this area.

It might have been expected that as PTCA became more accepted, possible CABG cases that

would have required only one or two grafts would be increasingly referred to angioplasty and that simple bypass procedures would make up a smaller proportion of the total (79). In fact, the proportion of CABG procedures requiring one or two distal anastomoses has fallen only slightly since PTCA was introduced, suggesting that PTCA might not be substituting for CABG to any major extent in Australia. International developments in this area have been followed with interest in Australia, but the use of CABG and PTCA has been determined largely by funding and organizational priorities and, to some extent, by assessment input from NHTAP and AIH.

Statistics collected by the National Heart Foundation show that the application of newer technology as an extension of PTCA and CABG has so far been quite modest. Thrombolytic therapy was used prior to angioplasty in 7.4 percent of all cases in 1991. Until recently, atherectomy was performed by only a few centers, and its level of use is low (42 cases in 1991). It seems to be regarded as an extension of PTCA, especially for application to extensively calcified or occluded lesions.

Use of coronary stents is increasing slowly (used in 50 PTCA procedures in 1990 and 78 in 1991), leading to increased costs (14). There are also issues related to patient selection criteria, appropriate training, and the need for appraisal of new stent designs and their use in Australia. The Institute saw coronary stents as a developing, additive technology that would find a useful but limited niche in algorithms for management of CAD.

The application of lasers for coronary artery disease has not yet occurred in Australia except for a brief trial in Perth. A review of lasers in angioplasty concluded that there was no evidence that laser treatment could replace balloon angioplasty, although lasers might play a limited role in the recanalization of complete or nearly complete obstructions (25). At that stage none of the lasers being evaluated overseas looked so promising as to make the case for evaluation in Australia particularly attractive. A more recent Australian review has concluded that laser coronary angioplasty is still a developing technology and that cost-effec-

tiveness has not yet been established (28). On the basis of expected potential caseload, use of an excimer laser would cost \$50,000 to \$60,000 per year per hospital, with no clear indication at this stage of benefits or of complication rates (15)

Proven methods for treatment of CAD are well established in Australia, and access to them is generally good. Waiting list data are at present not generally available, but there are some indications for Western Australia. According to recent information for elective procedures in that state, median waiting times are about one week for PTCA and about one month for cardiothoracic surgery. The numbers of cases on the cardiology and cardiothoracic lists were halved between June 1992 and June 1993 (55).

Areas for consideration are achieving suitable balance between the different methods and resolving any problems of coverage in the public sector. A specific concern is the continuing growth of both CABG and PTCA despite earlier expectations that angioplasty might replace the surgical procedure to a large extent.

A further issue, identified in the NHTAP assessment, is the pressure placed on public hospital budgets by demand for PTCA services. Many public hospitals have imposed severe rationing on the number of PTCA procedures that they perform. Their costs are significant, and the benefits have accrued to the patient and the commonwealth rather than the state and the hospital (because of decreased commonwealth-funded medication and quicker return to normal activity). The situation has changed somewhat since a Medicare schedule benefits item for PTCA became available. This problem illustrates the type of funding debate that can occur between commonwealth and state governments.

The influence of technology assessment on this area has been relatively modest. The early Subcommittee report was helpful to some state governments, but although later assessments have been considered by policy makers and professional bodies, there is no evidence that they have exerted any major influence. Other factors have proved more significant.

## MEDICAL IMAGING (CT AND MRI)

### I Computed Tomography (CT)

CT scanning was introduced into Australia in the mid- 1970s with the acquisition of head scanners by private radiology practices. There appears to have been no systematic early evaluation of CT scanning. Opit and Dunt (89) analyzed the level of need for CT head scanning in a defined population and were among the first to express reservations about the number of machines that would realistically be needed for this new technique.

The private sector dominated the early stages of CT diffusion; the only governmental control was imposed by certain state authorities in terms of various units installed in public hospitals under their jurisdiction. Reimbursement for CT examinations rapidly became available through Medicare.

In early 1984 the Royal Australasian College of Radiologists (RACR) issued a statement on CT scanning that outlined suggested uses for the technology and gave details and suggestions for its distribution. An overview of health care technology assessment at that time noted that although the statement contained useful data, further appraisal involving other organizations in the health care system was now needed (44).

A synthesis report by NHTAP considered patterns of use of CT in Australia and its clinical role, costs, safety aspects, and clinical value (77). By mid- 1987 there were at least 170 CT units in Australia, 118 in the private sector and 52 in the public sector; at that stage, installation of public hospital units had become more widespread. It appeared that on a per capita basis, Australia offered higher levels of CT services (10.8 scanners per million residents) than any European country, but lower than the United States and Japan.

Although CT services were widely disseminated in Australia, there appeared to be room for improving the pattern of distribution, including keeping public hospital facilities under review and perhaps widening coverage to include smaller population centers. However, even taking into account the earlier methods that CT had replaced

and widening indications for its use, it was not possible to account for the very large increase in numbers of examinations in recent years.

The Panel also drew attention to studies in other countries that suggested that use of CT scanners was unrewarding for patients with headaches and normal neurological findings, and to a Western Australian study that evaluated the use of CT in private neurological practice (52). Sixty patients had a CT scan before consultation, and 95 percent of those were normal. Of the 83 patients referred for CT after neurological consultation, 91 percent had normal CT findings. The Panel questioned the possible overuse of CT in this area.

Concern about certain applications of CT continues. In a series of 100 CT exams on 87 consecutive patients with low back pain or sciatica referred for specialist orthopedic opinion, 36 exams could be justified (of which 16 influenced management of the condition); 47 unnecessary exams were abnormal, but the abnormal findings were irrelevant. Some 75 percent of unnecessary scans would have been eliminated if somatic pain had been recognized and if the fact that CT does not contribute to an evaluation of such cases had been appreciated (94).

While accepting the technique's diagnostic excellence NHTAP noted that little quantitative information was available on how CT was being used in Australia or its effect on patient management, particularly outside major public hospitals. It recommended that a study be undertaken to determine the contribution of CT to patient care and the cost savings achieved through its use. It also recommended that professional bodies consider the development of guidelines for medical practitioners on the use of CT, including advice on appropriate indications for procedures, examination risks, costs, and expected benefits.

The first recommendation was considered in detail and a proposal for a study discussed by AHMAC. However, support for such an assessment was not approved largely because of disagreement between governments as to responsibilities for funding. The second recommendation (on guidelines) was taken up by NHMRC's Health Care Committee. Guidelines were subsequently pub-

lished (71) that drew on broader imaging guidelines developed by the Victorian Post-Graduate Foundation and the RACR (63) as well as on input from individual radiologists. The impact of these guidelines will probably not be apparent for some time and will depend on the degree of reinforcement by professional bodies.

The NHTAP report has been used as a source document by health authorities and has provided input for discussions on levels of reimbursement under Medicare. Medicare fees for CT have decreased in recent years, and the CT examinations eligible for payment under Medicare are specified in considerable detail in the benefits schedule. At the state level, replacement of older generation scanners has occurred in a number of public hospitals.

By November 1992 the total number of Australian CT scanners had reached 292, or 17 per million people (16), and in early 1994 it was approaching 350 (19). It appears probable that this increase will continue, given the comparatively lower numbers in Victoria following the earlier CON strategy in that state. On a per capita basis, numbers of services have increased by 115 percent over the last five years, and Medicare Benefits payments by 54 percent. There are still no quantitative data on how most CT services are being used and to what effect. The continuing proliferation of CT services maybe due to a combination of factors, including the availability of reimbursement under Medicare, support through the public hospital system, competition among hospitals and practices, and pressure from requests by referring physicians.

### **Magnetic Resonance Imaging (MRI)**

The introduction and diffusion of MRI in Australia has followed a different pattern than that of CT because of technology assessment, related policy decisions, and investment judgments by private radiology practices in the early 1980s.

Australia's program for introducing and evaluating MRI (45) had its origins in a synthesis report by NHTAP (73). MRI was regarded as an expensive, rapidly evolving, and promising diagnostic imaging method that should be assessed be-

fore any widespread diffusion within Australia was contemplated. The report recommendations were accepted by the commonwealth government, which acted with the states to implement an assessment of MRI. This support for the rational introduction of MRI was prompted to some extent by concerns at the level of use of CT scanning. Issues for the governments included the likely cost of the new technology, its realistic range of application, likely benefits when compared with existing methods, technical performance, and areas of weakness.

At the start of the Australian evaluation, little was known about the performance and clinical use of MRI. Information from other countries was of limited use in the Australian context. Many early studies were poorly done and, in any case, applicable to different health care systems. The Australian governments sought a broad assessment of the overall place of the new technology, meaning that a wide range of possible examinations and disease states had to be considered.

The study was carried out at radiology departments in five public hospitals with general direction by a technical committee of NHTAP and collation and monitoring of data by the Panel's Secretariat. Each MRI unit collected cost data according to a defined protocol; a minimum data set, completed for every patient, which provided information on demographics, history, MRI findings, and radiologists' assessment of the benefit of MRI at the time of examination; and 71 more detailed follow-up studies on selected groups of patients to assess the usefulness of MRI in the diagnosis and management of specific conditions. No government funding for MRI was available outside the program.

One specific study reported on 2,810 consecutive examinations at the Royal North Shore Hospital in Sydney, which provided follow-up data on 2,100 cases (99). The accuracy of MRI in a number of conditions was considered in detail, and clinical impact was assessed on the basis referring clinicians' opinions. The impact of the technique was apparent in 104 cases where surgery was avoided; in 55 where invasive procedures were avoided; in 151 where MRI led to surgery or im-

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proved surgical planning; and in 175 where a correct diagnosis was established after incorrect results from CT or other tests.

Another study considered the follow-up of 1,119 consecutive patients examined at the Sir Charles Gairdner Hospital in Perth who had been referred by specialists for imaging of brain or spine (47). MRI made a dominant contribution to the final diagnosis with neoplasia and vascular disorders but was less significant for white matter disease, including multiple sclerosis. In a high proportion of cases, other types of examination also influenced final diagnosis. MRI affected patient management in a high proportion of spinal examinations and in cases of cerebral neoplasm, with a lesser contribution to cases of cerebral vascular disorder and white matter disease. Although MRI was seen to be generally superior to other imaging methods, in practice it was often only one input to diagnostic and management decisions. For some cases, such as pituitary neoplasm and suspected acoustic neuroma, MRI replaced older tests and was not additive.

Following recommendations of NHTAP at the end of the assessment (82), the governments agreed on a policy to develop a network of teaching-hospital MRI units, with 18 to be placed in centers with major neurosurgical responsibilities. Government funding continues to be channeled only to such units, and reimbursement is not available for further services provided by private radiology practices except for limited numbers of "overflow" cases from public hospitals to designated private units. Decisions on levels of funding for the public MRI units have drawn on the cost data obtained in the assessment. The limited numbers of government-funded examinations at private units have had to comply with the MRI guidelines of a consensus statement developed during the assessment (6).

Despite this policy on limited government funding of services, the number of private radiology MRI scanners has increased substantially since the assessment (46). For most private units the caseload has been limited and dominated by workers' compensation cases. By early 1992 there were seven public and 16 private units in Australia, or

1.3 per million people—a somewhat lower proportion than in several European countries but now increasing to a projected 41 units by the end of 1994 (or 2.3 per million). There is concern that the proliferation of I may eventually lead to provision of services that are not cost effective and that much of the spread of the technology will have occurred outside the immediate influence of health authorities.

### **Influence of Technology Assessment**

The introduction and use of MRI were strongly influenced by the assessments undertaken by NHTAP (similarly, assessments have influenced the more recent introduction of positron emission tomography (PET) (74,83). In contrast, assessment effect on the use of CT have been limited to date, and it is too early to say whether the NHMRC guidelines developed following the Panel's report will have a major influence.

### **LAPAROSCOPIC SURGERY**

The most common of the well-established laparoscopic procedures (based on Medicare data) include laparoscopy for treatment of ovarian cysts, endometriosis and adhesions, and arthroscopic operations on the knee. These widely established techniques were introduced in the 1970s. Arthroscopic surgery to the elbow, wrist, shoulder, and ankle was added to the Medical Benefits Schedule in 1990 and 1991. The numbers of these newer arthroscopic procedures are still quite small. Therapeutic thoracoscopy, esophagoscopy, and uteroscopy have also been established for many years, but their numbers also are small (less than 1,200 per year for each) but increasing. Most of these laparoscopic procedures have replaced older more invasive procedures, although the number of additional knee arthroscopes has risen substantially (60).

Use of diagnostic hysteroscopy has increased considerably in recent years (from 1,000 payments under Medicare benefits in 1985/86 to almost 28,000 in 1991/92). Over the same period, payments for dilatation and curettage (D&C) have declined. Some replacement of the older tech-

nique may have occurred, although the Royal Australian College of Obstetricians and Gynecologists (RACOG) advises that diagnostic hysteroscopy is usually an adjunct to, rather than a replacement for, D&C. It is also regarded by the College as complementary to the radiological technique of hysterosalpingography rather than as an alternative. Since 1989/90 there has been increasing use of outpatient endometrial sampling, which is being seen by RACOG as less invasive and cheaper than hysteroscopy and probably as effective. The trend toward office-based procedures, with further reduction in hospital admissions for D&C, seems likely to continue.

### Laparoscopic Cholecystectomy

The more recent introduction of minimal-access surgical procedures has been dominated by developments and debate on laparoscopic cholecystectomy. The technique was assessed by AIH in 1990 following its introduction into Australia that year (58). Its early use was undertaken within major teaching hospitals. Diffusion within Australia has been rapid because of the acceptable up-front costs to hospitals, early eligibility for government reimbursement under Medicare, and public awareness and demand for a less invasive procedure. At present the benefits schedule fee for laparoscopic cholecystectomy is higher than that for the open procedure.

The early experience of teaching hospital units is illustrated by the results obtained as part of the Australian biliary lithotripsy evaluation (95). When compared with open cholecystectomy, a series of laparoscopic cases at the hospital showed decreased length of hospital stay and down time for the patient before returning to normal activities, and substantially decreased requirements for analgesia following the operation. Estimated costs of the laparoscopic procedure were lower than for open surgery, largely reflecting the decreased hospital stay. Such estimates of savings, however, do not necessarily take into account the full costs to a hospital of introducing such a procedure and the associated infrastructural changes.

A cost-utility analysis showed that the outcome of laparoscopic cholecystectomy was superior to both the open procedure and lithotripsy, unless subsequent evidence indicated a very high incidence of common bile duct damage (24). This study included an assessment of costs to patients associated with both forms of cholecystectomy and lithotripsy. The costs to patients per case were estimated at between \$1,800 and \$2,500 less for laparoscopic cholecystectomy than for open cholecystectomy (101). A further study has confirmed shorter hospital stays, lower costs, and faster recovery for laparoscopic cholecystectomy as compared to open surgery (53).

Diffusion of laparoscopic cholecystectomy has continued rapidly. In early 1993 the Royal Australasian College of Surgeons (RACS) advised that the technique was in place in all teaching hospitals and in most smaller surgical centers. The spread of the technique has been associated with an increase in total numbers of cholecystectomies.

An early estimate was that there had been a 26 percent increase in the rates of cholecystectomy in the first two years after introduction of the laparoscopic method, following a period of several years where rates for gallbladder removal were almost constant (68). Conversion rates for laparoscopic to open surgery were high during the first two years of use: Health Insurance Commission data indicated a level of over 14 percent. At that stage only an estimated 13 percent of potential savings to health program costs through use of the new method were being realized. Decreased costs per case for laparoscopic surgery appeared to be largely offset by the increased numbers of procedures.

The increase in the rate of cholecystectomies has subsequently slowed, although the number of procedures per year remains considerably higher than the levels prior to introduction of the laparoscopic method (49). The conversion rate has fallen with increasing experience with the procedure, to 8.4 percent in 1992/93. Possible reasons for the increase in surgery rates include extension of services to frailer patients, a wish to resolve symptomatic cases rather than watchful waiting,

application to asymptomatic cases, and applications to misdiagnosed cases (68).

Concerns remain regarding standards of performance of laparoscopic cholecystectomy in smaller centers, and in response, the RACS has developed accreditation and training procedures. There have been anecdotal accounts of serious complications following performance of laparoscopic procedures at smaller centers. Routine intraoperative cholangiography has declined by 66 percent since the introduction of laparoscopic cholecystectomy. It has been suggested that routine laparoscopic exploration of the bile duct should be adopted as a standard practice to permit treatment of common duct calculi at the time of laparoscopic surgery (37).

### Other Laparoscopic Procedures

Data on the other recently developed laparoscopic procedures are more limited. Laparoscopic appendectomy was first performed in Australia in the early 1980s (36). Since then its use has been restricted primarily to gynecologists treating chronic recurring lower abdominal pain in women. Although laparoscopic appendectomy is increasing in Australia, its uptake is likely to be slower than for laparoscopic cholecystectomy because training in the technique has not been widespread and because of the undesirability of applying laparoscopic procedure in an emergency situation (60). There is also some feeling that the laparoscopic procedure may offer limited advantages for hospitals and surgical staff and that there would be little improvement in recovery time for patients as compared with the open procedure.

The major impact of laparoscopic surgery on hysterectomy is expected to be through use of laparoscopically assisted vaginal hysterectomy (LAH) rather than the full laparoscopic procedure (59,67). Neither LAH nor laparoscopic myomectomy are yet in general use in Australia. The RACOG is developing training and accreditation protocols for LAH.

LAH offers uncertain advantages to service providers over abdominal or vaginal hysterectomy as cost estimates are sensitive to lengths of

stay, substitution rates, and instrument costs (59). However, if half of the abdominal hysterectomies performed for myomas were replaced by LAH, annual savings to the health care system could be on the order of \$2 million. Future attention may focus on options for reducing the costs of disposable instruments (currently about \$1,200 per case).

In terms of societal costs, LAH offers potential major benefits through considerable reduction in post-operative recovery (by four weeks) and probably in the cost of complications. Such factors are likely to increase the pressure for diffusion of LAH. A counterforce will be the availability of competing, minimally invasive approaches, including endometrial ablation or resection using diathermy. Endometrial ablation/resection is well established, with over 4,000 procedures funded through Medicare benefits in 1991/92 (59). During this period the rate of hysterectomy for menorrhagia in public hospitals declined by one-third.

Laparoscopic hernia repair was introduced into Australia in 1990 (21). This procedure's impact is expected to increase, although some centers do not regard the immediate advantages of the laparoscopic approach over a short-stay open repair to be clearcut, particularly in view of the experimental nature of the technology. If laparoscopic approaches for hernia repair ultimately result in faster recovery, decreased pain, and overall reduced costs, they are likely to be popular with both patients and organizations responsible for compensation payments, despite uncertainties about long-term recurrence (60).

Laparoscopic vagotomy has been performed in Australia (88), although its level of use is currently low; most patients are now treated with drugs. There still appears to be some uncertainty as to the appropriate technique for this procedure. Laparoscopically assisted bowel resection was introduced in 1991 at the Sydney Hospital, with the mobilized bowel taken out of the body via a laparotomy excision to perform the resection and form the anastomosis (102). At least some centers in Aus-

tralia appear to be moving toward the use of the full laparoscopic approach for this application.

Unanswered questions surrounding newer laparoscopic procedures relate particularly to assurance of appropriate training, availability of adequate caseload, mechanisms for appropriate follow-up of patients after laparoscopic surgery, and costs to hospitals through changes to infrastructure (48). Up-front costs of disposable instruments, which are preferred on technical grounds, are a chronic problem for hospital administrators. In a number of cases public hospitals have been using reusable equipment, accepting the less obvious cost of cleaning and sterilization plus the consequences for patients if these procedures are not performed adequately.

### The Impact of Technology Assessment

The impact of technology assessment on the use of laparoscopic procedures is uncertain. Several assessments have provided information to health authorities and professional bodies, but there has been no discernible influence in the short term on the use and organization of services. For example, the trends in use of laparoscopic cholecystectomy and diagnostic hysteroscopy have largely occurred as a result of influences other than formal evaluation. Possibly assessment may be more significant in the longer term as data from the initial phase of some techniques are more closely considered and guidelines are established. AHTAC is developing a report on minimal-access surgery that may provide further focus and help set directions for the future.

### TREATMENTS FOR END-STAGE RENAL DISEASE (ESRD)

Rates of ESRD treatment continue to rise in Australia. The Australia and New Zealand Dialysis and Transplant Registry has accumulated records on over 10,000 patients who have begun treatment for ESRD in Australia (30). In 1989 the treatment rate was 34.4 per 100,000 population.

These rates are rising largely because of an increase in the number of people over 60 years beginning dialysis. Diabetic nephropathy appears to

be involved in an increasing proportion of cases of renal failure treated by dialysis and transplantation. Compared with many other nations, Australia has a high level of a nephropathy caused by analgesic medicines, although new cases are declining (9). Recent data indicate that Aborigines may have a more extensive requirement for renal dialysis. The rate at which Aborigines began treatment was over three times that for all Australians, and there still may be much untreated disease.

Guidelines for renal dialysis and transplantation have been prepared by AHTAC (9). There appears to be little scope for identifying preventive strategies to lower the incidence of renal failure. Although renal transplantation is recognized as the preferred method of managing ESRD, dialysis remains the dominant treatment method. The transplantation rate has remained at about the same level for the last decade; in 1990 only 12 percent of dialysis patients received a transplant.

During the 1980s the number of home dialysis patients grew slowly, and the proportion relative to population has been declining. In 1989 there were 798 home continuous ambulatory peritoneal dialysis (CAPD) patients (4.6 per 100,000), 582 (3.5 per 100,000) home hemodialysis patients and 18 (0.1 per 100,000) home intraperitoneal dialysis (IPD) patients. Overall there were 16.3 dialysis patients per 100,000 population.

The overall median survival rate for patients with ESRD after five years of treatment is 61 percent; outcomes become poorer with increasing age. Variations in survival among different centers is substantial. For primary cadaver grafts after 12 months, there is a 22 percent variation in terms of patient survival and a 36 percent difference in graft survival between the best and the worst centers, AHTAC has recommended that every effort be made to elevate those units with poor results to an acceptable standard.

With regard to current service provision and expertise and the efficient use of staff and facilities, AHTAC considered a minimum of 30 transplant operations per year at each center to be desirable and recommended that centers that are not performing 20 operations per year should either cease transplantation altogether or increase their com-

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mitment. All dialysis units should be linked organizationally to a renal transplantation program (9).

Transplantation is the preferred treatment on cost grounds, with hospital hemodialysis the most expensive of the alternative approaches. Opportunities for home dialysis appear to be lacking. AHTAC recommended that new facility development be promoted in the following order of priority: transplantation facilities, home dialysis (including CAPD), satellite dialysis, and hospital dialysis. In addition, efforts should be made to minimize maintenance dialysis in hospitals. Renal treatment programs should review their policies on dialysis location for patients with a view to relocating suitable patients to satellite and home dialysis.

Major themes of the AHTAC guidelines document were the need to increase the rate of organ donations for transplants and to decrease the proportion of dialysis patients treated in hospitals. Changing community and professional attitudes toward organ donation have the greatest potential to alter ESRD'S impacts and to affect cost allocation. According to the Australian Coordination Committee on Organ Registries and Donation (ACCORD), the current donation rate is 13.5 organs per million per year. If all suitable potential donors were to become actual donors, this rate could be nearly doubled.

Insufficient kidney donation is a major problem in overcoming the backlog of patients awaiting transplantation (40 to 45 percent of dialysis patients). ACCORD is addressing organ acquisition difficulties and promoting improvements to infrastructure and financial support.

Living related donor transplantation accounts for 10 to 12 percent of renal transplants in Australia and New Zealand. Increased use of this approach would be desirable because of the excellent results compared with cadaver transplants and the shortage of cadaver organs. In a series from a Melbourne hospital, the living related donor approach was associated with shorter waiting times for transplantation (38). Pancreas transplantation in association with renal transplantation is being undertaken on small numbers

of type 1 diabetic patients with renal failure. The service is offered at a hospital in Sydney under the Nationally Funded Centers policy, after its consideration by the Health Care Committee of NHMRC and AHTAC.

### Erythropoietin (EPO)

Recombinant EPO for management of anemia due to renal failure has been used in Australia since 1990, initially on a restricted basis because of its cost. It was suggested that treatment might need to be limited to patients in whom anemia causes serious disability unrelieved by other measures (35).

Various centers have adopted measures to reduce the EPO dose to the lowest level suitable for maintaining benefits in each patient. Experience at the Queen Elizabeth Hospital, Adelaide, has suggested that the cost per patient per year might fall to \$6,000. At the Royal Adelaide Hospital, the annual cost for EPO given subcutaneously maybe as low as \$2,000 to \$3,000 per patient (9). A study at Westmead Hospital, Sydney, reported the successful use of low-dose EPO at a yearly per-patient drug cost of \$3,681 (54).

The question of financial support for EPO was subsequently considered by HSDWP. Following its recommendations, funding was provided in the 1991 commonwealth budget to support the drug's use for treatment of anemia requiring transfusion associated with ESRD, where treatment is initiated in a hospital with a renal dialysis unit. (Any application outside these indications is not covered by the commonwealth.)

The states are responsible for meeting the drug costs of the in-hospital phase (taken to be three months from the initiation of treatment); the commonwealth meets subsequent costs. commonwealth grants to the states and territories for EPO in 1991/92 totaled just under \$7.5 million (57), and the drug is now being used by all major centers. Evaluation procedures must still be developed.

### The Impact of Technology Assessment

The impact of technology assessment in this area has been limited to date. The AHTAC guidelines

summarize current statistics, concerns, and possible future directions. Their influence will depend on how the suggested targets are viewed by state health authorities and professional groups.

### NEONATAL INTENSIVE CARE

Like many other countries, Australia has accepted the concept of regionalization for perinatal services as a means of improving access to secondary and tertiary levels of care. A paper on organization of perinatal services, which drew on Canadian experience, defined three levels of neonatal care: level 1 (suitable for uncomplicated situations), level 2 (generally located in larger or suburban hospitals with obstetric services), and level 3 (sophisticated services based in major general maternity or children's hospitals) (70).

State guidelines for the numbers of beds in level 2 units vary considerably, from 1 to 2 per 1,000 live births in Queensland to 4.25 in New South Wales. Infants admitted to a level 2 unit are generally over 32 weeks in gestation and over 1,500 g in birthweight. Most level 3 units have obstetric services and accept many high-risk pregnancies referred in from the region in which they are located; they also handle the management of normal pregnancies in their immediate area.

Guidelines for level 3 neonatal intensive care were developed by the Superspecialty Services Subcommittee in 1983 and updated in 1991 (5). Apart from an increase in the recommended number of ventilator beds from 0.6 to 0.7 per 1,000 live births, no substantial changes were made to recommendations in the guidelines during that period. Other major specifications are that level 3 units should have 10 to 20 level 3 beds (1.1 per 1,000 live births) and nurse-to-patient ratios of 1 to 1 for ventilator beds and 1 to 2 for other level 3 beds. The guidelines also outline the need for level 3 units to provide support for parents, to have a well-defined role in staff and public education, and to monitor data and outcomes on a long-term basis. The need for control of nosocomial infection is stressed, although infection is not currently a major cause of neonatal death.

In 1990, 20 hospitals in Australia had level 3 neonatal intensive care units (NICUS) and full-

time neonatologists; these had a total of 160 ventilator beds. A further 14 ventilator beds were planned for New South Wales and Victoria.

In 1983 the average cost per baby from the time of admission to the NICU to the time of discharge home, transfer to another hospital, or death was estimated at \$13,952 (based on a hospital in Sydney): the average cost per survivor was \$16,415 (61). In 1988/89 the average cost per baby had fallen to \$10,279, and the average cost per survivor to \$10,953 (62). The cost to the community of neonatal intensive care averaged \$13,857 per surviving baby, with a range of \$4,064 for a birthweight of more than 2,000 g to almost \$138,000 for those less than 750 g (62).

The survival rate for very immature infants rose from 20 to 61 percent, associated with the introduction of positive pressure-assisted ventilation. Between the 1977-83 and 1984-86 periods, survival increased by 9 percent while the cost per additional survivor rose by 60 percent.

Both outcomes and costs for each individual baby are variable and difficult to predict (4). Those making decisions about withholding intensive care for individual babies are essential in making value judgments. Cost and economic data can only be one component of these judgments. The Subcommittee's guidelines point to statements on ethical issues in intensive care and to other guidelines for very low-birthweight babies developed at consensus conferences at Westmead Hospital, Sydney.

Concern has been expressed about the increased need for NICU services that may result from births following in-vitro fertilization (IVF) and gamete intrafallopian transfer (GIFT) techniques. Assisted conception by IVF and GIFT in 1991 resulted in 2,009 live births up to September 1992, with overall totals of 6,932 and 3,794, respectively, since these techniques were introduced (86). About 1 in 200 births in Australia now result from these new reproductive technologies. These births are more likely to result in low birthweights, to be multiple, and to require neonatal intensive care. Over one-third of IVF/GIFT babies are of low birthweight, and about 23 percent of these births are multiple. Some NICUS report that

the IVF/GIFT cases consume up to 7 percent of bed days.

### **Extracorporeal Membrane Oxygenation (ECMO)**

ECMO was introduced in Australia in mid-1988 at the Royal Children's Hospital, Melbourne, and about a year later at the Prince of Wales Children Hospital, Sydney (51). The decision to develop an ECMO program was made by the hospitals, and costs were met from their own budgets. Early results for neonates and other children were excellent. Different approaches were adopted at the two Australian centers. In Melbourne ECMO was offered to all neonates who met specified entry criteria. In Sydney high-frequency ventilation was tried first and ECMO was used only when it failed.

Following the units' initial experience, a consensus conference organized by the Australian Association of Pediatric Teaching Centres and NHMRC was held to define the role of ECMO as well as resource and research requirements. It was apparent that local clinical and cost data were limited and that a strong minority opinion held that satisfactory results were obtainable using conventional treatment.

The improvement in conventional treatment over recent years suggested the need for a critical comparison of ECMO with alternative approaches. Local evaluation was seen as necessary because of differences between Australia and other countries both in patient population and in standards of obstetric and neonatal care. For example, perhaps 40 percent of neonatal cases treated with ECMO in the U.S. have a primary diagnosis of meconium aspiration syndrome, which is comparatively rare in Australia. Also, the small national caseload would make it difficult to design and conduct a randomized controlled trial that could produce definitive results.

It was recommended that a panel be set up to explore the feasibility of a trial and that AHMAC be approached for funding and agreement to restrict ECMO units to two centers (1,92). AHMAC in turn referred to NHTAP the question of the costs and financial benefits of limiting ECMO to

not more than two centers. NHMRC was to give further consideration to the feasibility of conducting a controlled trial of the technology.

The assessment of costs and financial benefits drew on information from the consensus conference, further opinions from the hospitals concerned, and relevant literature (81). It emerged that the marginal costs of ECMO were relatively modest (\$5,800 to \$8,400 per patient). Although NHTAP found that there was little difference in cost terms between the different options for numbers of ECMO centers, there appeared to be compelling reasons to limit the number of centers. The technology was still evolving and was in some senses experimental, and an appropriate minimum caseload was seen as necessary to maintain expertise and achieve efficiencies of scale.

Various issues needed to be considered by health authorities with regard to the future use of the technology. ECMO appeared to be a useful method of last resort in treating neonates and older children with severe respiratory distress; however, the data on its efficacy were limited, and pediatric use data were not conclusive. Future selection criteria used by ECMO centers would strongly influence caseload, cost per case, and the rate and quality of survival. The efficacy of ECMO in comparison with conventional therapy was deemed to need further critical review given the apparent shifts in practice, possible improvements in conventional therapy, and the perceived low sensitivity and specificity of selection criteria. NHTAP suggested that it would be wise for any future research on ECMO in Australia to include appraisal of alternative therapies.

AHMAC subsequently accepted the recommendation that there be not more than two ECMO centers but did not consider additional support under the Nationally Funded Center policy appropriate, in light of the limited impact of the specialized service on hospital budgets when marginal costs were taken into account. The issue of the controlled trial remains unresolved. The NHMRC has considered the question, but the fact is that many clinicians and nurses using ECMO have become convinced of its usefulness and will not accept al-

location of at-risk neonates to a control group. Efforts are being made to include one of the Australian centers in the British randomized trial of this technology.

### **The Impact of Technology Assessment**

The impact of technology assessment on neonatal intensive care has been variable. The original guidelines produced by the Superspecialty Services Subcommittee were probably influential because of the consultation process that took place during their preparation. When they were updated, much of the material prepared some six years earlier was considered still current. Policy on support for ECMO was clearly influenced by a consensus conference and subsequent assessment by an advisory body, although the effect on patterns of practice probably was more limited.

### **SCREENING FOR BREAST CANCER**

Breast cancer is the most common cancer and the most common cause of death from cancer among Australian women (4). Small-scale breast cancer screening services were established in the mid- 1980s but fell well short of a national program. They were limited in coverage, not subject to accreditation or other controls, and not designed to recruit and screen those women most likely to benefit from screening.

Use of mammography services increased in all age groups between 1984 and 1988, but women over 65 made least use of them, although the death rate associated with the disease was highest in that group (4). Data from the 1988-90 National Health Survey conducted by the Australia Bureau of Statistics indicated that only 22 percent of women aged 40 to 64 had had a mammogram in the previous three years, with the highest proportion (25 percent) in the 45-to 49-year age group (2). Poor awareness appeared to be a contributing factor, influenced by education level, family income, place of residence, and whether women spoke English at home.

### **■ Evaluation of Breast Cancer Screening**

Two of the targets set in 1987 by an AHMAC committee were to reduce the death rate from breast cancer by 25 percent or more by the year 2000 and to increase participation in breast cancer screening to 70 percent or more of eligible women by 1995 (56).

In 1988, Australian health authorities established a National Breast Cancer Screening Evaluation. The evaluation, coordinated by a unit at AIH, reported in mid-1990 (4). It drew on a number of pilot projects based on some of the already established screening services and included a detailed economic assessment. Technical aspects of screening mammography were considered by NHTAP as input to the national evaluation (79). The Panel supported proposals by RACR to accredit clinics for mammography screening and summarized specifications for mammography units, film processing and quality control. Brief consideration was also given to personnel requirements, the need for follow-up facilities, and a national database.

The NHTAP report was followed up by AIH at the request of the AHMAC Steering Committee (11 ). The AIH report confirmed that mammography was the only proven technique suitable for breast cancer screening, gave detailed specifications for mammography units, and recommended adoption of quality control guidelines prepared by the Australasian College of Physical Scientists and Engineers in Medicine. According to a survey by the Australian Radiation Laboratory, there were about 300 mammography units in Australia in 1989, but it was not known how many of these would be available for screening work.

The Steering Committee's report supported introduction of a national screening program for all eligible women on both scientific and economic grounds. Cost per life year gained was estimated to be in the range of \$6,600 to \$11,000 (4). It was recommended that the program select women on the basis of age alone. The Committee also urged that mammographic screening be made available and publicized for women aged 40 years and older but that recruitment strategies should be targeted at women from 50 to 69 years old.

Screening should be made available as widely as possible to all eligible women in the target group with the intent of rescreening every two years.

Important practical and ethical issues arise in addition to cost-effectiveness considerations. The introduction of a mammography screening program that excluded women from 40 to 49 years old would encounter a practical difficulty: women in this age group would obtain mammography outside the screening program. Because such mammography would lack many of the features required of a national program, it would be likely to be less effective, with variable quality control, and seriously undermine the conduct of a national screening program.

Economic aspects of breast cancer screening have subsequently been considered by Carter and co-workers (23), whose analysis suggested that screening all women aged 50 to 69 every two to three years is reasonable value for money. For women from 40 to 49 mortality benefits and cost-effectiveness are less clear. It was suggested that screening in this age group be allowed but not actively pursued until further evidence is available.

This series of assessments addressed major issues in screening mammography, including the degree of benefit of the technology compared with other approaches, expected gains in quality of life, and problems caused by false positive results. These matters were taken into account during the development of a national program.

### **Establishment of a National Program**

In March 1990 the commonwealth announced that it would contribute \$64 million over three years toward the establishment of a National Program for the Detection of Breast Cancer. The earlier AHMAC report formed the basis for this program's development. By 1993 all states and territories had made commitments to population-based screening programs for eligible women.

The national program fully funds the provision of screening and assessment services through to confirmed diagnosis of breast cancer. Funding is independent of the Medical Benefits Schedule. Services funded under the program must be accredited.

Proposals in the AIH report regarding machine specifications and quality control were adopted in the National Accreditation Guidelines issued as part of the national program (87). The guidelines cover recruitment, services, and facilities for screening and assessment, data collection, training activities, and program management. Other topics covered include performance objectives and acceptable process, the timeframe for the national program, technical items to be evaluated in a quality assurance program, and suggested specifications for mammography units.

Under the national program, each screening unit will be linked to an assessment center. The assessment center will function with multidisciplinary teams and have primary responsibility for quality control and for management of screening and assessment procedures, including counseling and diagnostic workups.

Coordination units in each state or territory will have primary responsibility for liaison and negotiation with the commonwealth and implementation of the national program. This responsibility includes making recommendations on the location, type, and number of screening units and assessment centers; recruitment; accreditation; monitoring and evaluation; financial management; and data management. The national coordination unit (located within DSHS) is responsible for data collection and analysis and program monitoring and evaluation.

The national program has given detailed consideration to the role of general practitioners in the primary health care of women who are eligible for screening. General practitioners should be kept informed of the results of screening and any further workups required unless a woman directs otherwise. However, a doctor's referral is not a prerequisite for attendance at a screening service.

The current intention is to rescreen women every two years subject to revision as new data become available. Screening will be made available at minimal or no cost and will be free to eligible women who would not attend if there was a charge. Comprehensive and easily understood information, emotional support, and counseling will be provided. Women will be advised on the

effectiveness and risks of mammography and on the maintenance of a regime of breast care, such as breast self-examination, to reinforce the message that a negative mammographic screen does not preclude the diagnosis of breast cancer prior to the next screening.

The program follows earlier recommendations of the AH MAC Steering Committee in specifying requirements for screening services. Film-screen mammography alone is the principal screening method, using two-view mammography with one view at rescreening if previous mammograms have indicated that two views are not required. All mammograms will be taken by a radiographer appropriately trained in screening mammography, and read and reported independently by two or more specially trained readers, at least one of whom is a radiologist. Reports will be combined into a single recommendation and results provided to patients promptly and directly.

In 1990, 10 screening and assessment services were offered in five states that had been pilot projects in the National Screening Evaluation. Screening services under the national policy are now established in all states and the Australian Capital Territory (with the Northern Territory to follow in shortly), for a total of 21 centers in place. Areas where coverage is poor are being reached by mobile mammography units in order to increase acceptance of the technology before establishing permanent facilities. Participation rates are rising,

although they remain considerably below target.

Current NHMRC policy on mammography screening for women under 50 years of age is that there is insufficient evidence to advise women under 50 years to have routine mammography (72). Women from 40 to 49 should not be excluded from screening programs if they request it but should be counseled on current evidence of benefits; women at higher-than-average risk should have the option of attending a screening program. There is no evidence of benefits from screening women under 40 years old.

Now that substantial resources have been committed by governments to the national program, concerns are to ensure an appropriately high rate of recruitment, adequate minimum technical standards, and effective reporting and follow-up procedures. The program will be subject to ongoing evaluation coordinated by a national advisory committee. It is hoped that this concerted effort will lead in the medium term to a significant improvement in one aspect of women's health.

Technology assessment has strongly influenced the development of screening mammography services. The substantial evaluation program funded by AHMAC set directions for the current national program, and the brief assessments by NHTAP and AIH assisted this process. Assessment will continue with formal reviews of the performance and impacts of the program.

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## CHAPTER SUMMARY

Substantial changes in approaches taken to health care technologies in Australia have occurred in the past two decades. Medical benefits remain an important factor in the funding and use of health care technologies: however, other mechanisms, such as government grants and the Nationally Funded Centers program, have become significant. Health care technology mechanisms has been put in place, and quality assurance programs have been developed. The availability and quality of data have improved. Debate continues on how

much should be spent on high-technology medicine as opposed to preventive and community programs.

Overall, the Australian population's access to a wide and appropriate range of health care technologies is good, and an effective level of support has been delivered within expenditures that have remained at or below 8 percent of GDP for a number of years. Concerns typically arise regarding whether some technologies (notably diagnostic techniques) are overused, delays in providing services to some patients, appropriate levels of reim-

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bursement for use of technologies, and whether both superspecialty and more routine services are consistently provided cost-effectively and to appropriate standards.

In Australia significant segments of the population will always be geographically remote from some technologies and services. Most specialist medical practitioners with expertise in new health care technologies are based close to metropolitan areas or to university teaching hospitals, not easily accessible for many Australians. The inconvenience and expense to some patients is unlikely to change in the short term. Certain health care technologies will continue to be sited in large population centers because of high costs and limited demand.

Although there are areas of dissatisfaction, including pressure on public hospitals and the level of out-of-pocket expenses for some services under current insurance arrangements, the level of public acceptance of the health care system seems quite high. Notably, the Medicare insurance scheme continues to be popular. In early 1994 only 38.4 percent of Australians had hospital insurance coverage through private funds.

Australia's relative success in controlling technologies—taking account of introduction, diffusion, level of use, societal costs and benefits, and equity of access—has been mixed. As described earlier, legislative provisions to control most types of health technology are limited. Both health authorities and health professionals have to live with the realities of operating within a system with a complex mix of government responsibilities and political and professional imperatives. The control and use of health technologies in Australia will be strongly influenced by intergovernmental relationships, the size and distribution of budgets for health care, and funding mechanisms. Major programs that have been put in place in recent years, such as the casemix development and cancer screening initiatives, are likely to significantly affect government and professional relationships and patterns of provision of health services.

The control of pharmaceuticals with regard to safety and efficacy has been generally successful, with changes seen as necessary to ensure that evaluation is timely. Close consideration of cost-effectiveness is a recent development. Control of medical devices has been less certain, and even less direct influence has been possible with regard to procedures.

The Nationally Funded Centers policy has provided defined mechanisms for support of very specialized technologies in their early stages of use and review to determine when this type of intergovernmental support is no longer justifiable. Linking government grants conditionally to assessment of new types of medical devices has been a useful approach. The shortcomings of such initiatives have been the limited assessment and monitoring of technologies after diffusion. Accreditation procedures for pathology services have worked effectively, although they provide only a narrow focus of control, and the Superspecialty Services Subcommittee and AHTAC guidelines have been successful in providing a framework for discussion and planning of health care services.

The Australian experiment of linking the introduction and support of health care technologies to assessment is now in its second decade. There have been some significant successes in informing policy through appropriately targeted, well-timed assessments. Recommendations and data from the assessments have influenced policy on whether to fund technologies, levels of funding, indications for use, and placement of services, but only in a minority of cases. Practice, too, has been influenced, but the data here are more limited.

Despite "islands" of assessment and fully informed policy, the mainstream of health technology has been deployed through less formal mechanisms (42). This is perhaps inevitable until assessment is linked more systematically to decisions on resource allocation and is undertaken more widely within hospitals and other institu-

(ions. Further progress is likely though more systematic linking of funding decisions with formal assessment, application of practice guidelines, and longer term educational initiatives.

Reports from Australia's national advisory bodies have been influential and well regarded and have contributed to policy formulation and to the wider education of health technology providers and purchasers. A major factor in the success of these assessments has been the expertise and continuity provided by a permanent group of evaluators who have supported the national committees.

Some assessments, notably those involving collection of primary data, have to some extent been opportunistic, depending on the level of support obtainable from staff in hospitals and other institutions. The emerging databases and assessments undertaken by AIHW (some in support of AHTAC) have also worked well.

The involvement of professional bodies and industry in the work of the national health technology assessment groups, and the practices of inviting comment and being willing to update reports and recommendations in the light of experience and new data, have helped considerably in broadening the base of assessments and their acceptance. One possibly undervalued aspect of the assessments has been the provision of general descriptions of technologies to policy makers, administrators, and the media, which have helped to demystify technical terms and concepts.

Information from agencies in other countries has been a valuable input to many assessments. However, local appraisal of a health technology is often highly desirable because of limitations in the data from other countries and the need to take into account local characteristics (98).

Conducting primary research locally is often desirable, even if studies are not entirely definitive: counsels of perfection need not impede clinical trials of new technologies. Several Australian trials have provided rich information on costs, effectiveness, and process even though pragmatic decisions had to be made on limiting the power of particular studies.

Health authorities and professional groups face constraints in controlling technologies and ensuring their appropriate use. The timing of assessments and the prompt provision of results remain major issues, and evaluators need to be aware of the pressures on policymaking areas. Mechanisms are needed to link the introduction and diffusion of new services and procedures to the assurance of efficacy and to the collection and provision of data by the new methods' sponsors. This will not be easily achieved without legislative changes and close cooperation between Australian governments and professional groups.

Australia has achieved a realistic balance between the coverage of technologies, rigor and depth of evaluation, speed of assessment and available resources. However, changes in the administrative arrangements for national advisory bodies in recent years have caused some loss of momentum. A period of stability would be desirable to permit consolidation of achievements and stronger links between different evaluation groups—all of which seek increases in funding. It must be said that assessment output has probably reached its limits with the current level of resources.

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