

Assessment and Reimbursement of Medical Devices in New Zealand

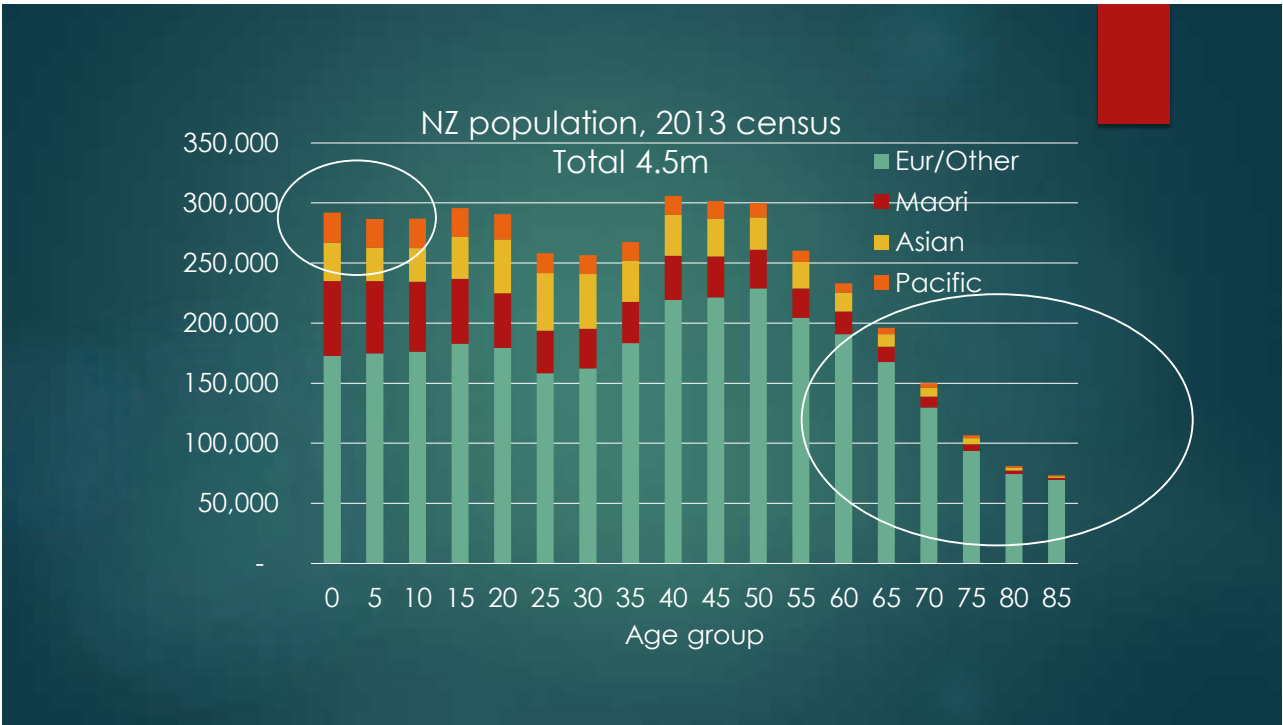
Richard Milne PhD, MRSNZ
Associate Professor
University of Auckland



ISPOR, Tokyo

September 08, 2018





New Zealand health and disability care

- ▶ Social welfare system: healthcare benefits according to need, not ability to pay
 - ▶ Moderate taxation
 - ▶ Moderate inequities (Māori, Pacifica)
- ▶ Funding: >70% of healthcare funding is from general taxation
 - ▶ Pharmaceutical Management Agency (PHARMAC) holds 5.3% of the public healthcare budget
 - ▶ Community & hospital pharmaceuticals & vaccines
 - ▶ Some hospital medical devices

New Zealand health and disability care

- ▶ Organisation:
 - ▶ Ministry of Health: policy, regulation, planning, leadership, national services, workforce issues
 - ▶ 20 District Health Boards
 - ▶ Hospitals, public health, mental health, monitoring, rehabilitation etc
 - ▶ Primary Health Organisations (capitation formula)
 - ▶ General Practice/nurses/managers (part Govt. funded, low copay)
 - ▶ Private providers
 - ▶ Labs, pharms, Trusts, disability support services, Māori health

Medical devices are sold to:

- ▶ Procurement arms of public and private hospitals
- ▶ General practitioners in primary health organisations (PHOs)
- ▶ Public and private medical clinics
- ▶ National Pharmaceutical Management Agency (PHARMAC)

PHARMAC reimburses pharmaceuticals, vaccines & some hospital medical devices

“...to secure for eligible people in need of pharmaceuticals, the **best health outcomes** that are reasonably achievable from pharmaceutical treatment and **from within the amount of funding provided.**”

▶ *New Zealand Public Health and Disability Act 2000*

PHARMAC operates within a statutory capped budget

With small inflation-linked annual increases

What's driving PHARMAC?



Assessment and Reimbursement

- ▶ Ministry of Health develops policy
 - ▶ But doesn't usually assess programmes or agents
- ▶ PHARMAC
 - ▶ Assesses and reimburses community and hospital pharmaceuticals and vaccines
 - ▶ Develops basic economic models when required
 - ▶ **Assesses and purchases some hospital medical devices by tender**
 - ▶ Has no input to sales of medical devices to General Practice

Assessment and Reimbursement (cont.)

- ▶ Medical device suppliers
 - ▶ Provide submissions to procurement arms of hospitals
 - ▶ Some have a formal assessment but very few have economic models
 - ▶ Some tender to PHARMAC
- ▶ District Health Boards
 - ▶ Assess some and purchase all hospital equipment and devices, mostly through hospitals

Healthcare budget 2018/19

▶ Vote Health (\$NZ)	\$18 Bn (\$US12 Bn)
▶ District Health Boards	\$13 Bn
▶ Disability Support Services	\$1.3 Bn
▶ Primary Care	\$0.3 Bn
▶ Maternity/child/mental health etc	\$0.5 Bn
▶ Governance/training	\$0.7 Bn
▶ Accident Compensation (est.)	\$4.0 Bn
▶ Pharmaceuticals & vaccines	\$0.9 Bn
▶ Medical devices	\$0.2 Bn (0.8%)

Medical devices

- ▶ Annual expenditure: about \$0.2 Bn (<1% of Vote Health)
- ▶ Very little formal clinical or economic assessment
- ▶ Bulk purchase of some high volume items, by PHARMAC, by tender
- ▶ PHARMAC is progressively taking control of reimbursement
- ▶ In 2019 PHARMAC will hold the budget for all medical devices
- ▶ Economic evaluation will be required for reimbursement (where possible)

Medical devices progression to PHARMAC's budget

Devices progression – complete



- Interventional cardiology (stents etc)
- Sutures and glues
- Wound care
- Sterilisation wrap
- Surgical gloves
- Negative pressure wound therapy
- Hand hygiene
- VTE Prevention

Devices progression – underway



- Thermometers
- Surgical tools
- Orthopaedics
- Anaesthesia consumables
- Respiratory consumables & equipment
- Interventional radiology
- Needles and syringes
- Endomechanical & electrosurgical
- Renal dialysis
- Non-invasive ventilation
- IV consumables and equipment
- Urology, ostomy & continence
- Patient warming

Devices progression – what's next



- Enteral nutrition
- Ophthalmology consumables
- Surgical implants
- Surgical suction and chest drainage
- Examination gloves
- Rhythm devices and electrophysiology
- Cardiothoracic surgery
- Laboratory equipment

Devices progression – remaining



- Patient monitoring including ECG
- Rehab equipment
- Audiology
- Theatre equipment & furniture
- PPE, Drapes and gowns/procedure packs
- Dental equipment
- Sterilisation, maceration and cleaning
- Ward equipment
- Diagnostic imaging
- Scope/gastro equipment
- Sterile solution
- Other

Progress so far



Medical devices in hospitals

- ▶ Medical devices are not required to be evaluated by a regulator for safety, efficacy or cost-effectiveness
- ▶ No tracking requirements for implantable devices
- ▶ Distributors and manufacturers market directly to hospital doctors
- ▶ Decisions about the use of diagnostic equipment and test kits and new medical and surgical services are:
 - ▶ made by hospital managers on the basis of affordability and/or the ability to cost-shift
 - ▶ OR approved by hospital procurement units without evaluation.



Northern Region Clinical Practice Committee

- ▶ Hospital-based HTA committee evaluating a wide variety of new health technologies
- ▶ Purpose: to assist senior management by giving evidence-based advice on investment and disinvestment decisions on new and existing health technologies
 - ▶ Medical devices, diagnostics, services
- ▶ 4 District Health Boards
 - ▶ Auckland, Waitemata, Counties Manukau and Northland
 - ▶ 12 clinicians chosen for their clinical expertise and ability to analyse evidence dispassionately and apolitically
 - ▶ Supported by analytical, economic and administrative staff.

Submission process

- ▶ Comparative evaluation of one health technology (usually a new one) against another (usually the existing one)
 - ▶ Safety - no more adverse events than with current management
 - ▶ Effectiveness - adds QALYs when compared to current management
 - ▶ Cost utility and budget – the Incremental Cost-Effectiveness Ratio (ICER) is acceptable in terms of affordability
 - ▶ Organisational implications - need to consider practical matters such as training, capital outlay, space, ability to recruit practitioners etc

Northern region clinical practice scoring tool

Budget focussed

Patient outcomes	Procedure costs		Quality of Evidence			
			A	B	C	D
Outcomes improve or remain unchanged	Procedure costs will be reduced	Cost neutrality expected within 12 months	100	90	40	30
		Cost neutrality expected within 1–2 years	90	80	35	25
		Cost neutrality expected within 2 – 5 years	60	50	30	20
Outcomes improve	Procedure costs remain unchanged		60	50	30	20
Significantly improved survival	Procedure costs will increase		40	30	20	10
Significantly reduced morbidity			20	15	10	5

Summary

- ▶ HTA for medical devices is rudimentary in NZ but improving
- ▶ PHARMAC holds the budget for many devices and will reimburse or purchase most hospital devices by 2019
- ▶ Budget holding by PHARMAC:
 - ▶ Cost savings to Government (bulk purchasing; negotiation)
 - ▶ Lower profitability for import devices industry
- ▶ Some District Health Boards have local evaluating committees
 - ▶ Hospital devices only
 - ▶ No HTA or reimbursement for devices in general practice

