Assessment and Reimbursement of Medical Devices in New Zealand

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New Zealand health and disability care

- Social welfare system: healthcare benefits according to need, not ability to pay
  - Moderate taxation
  - Moderate inequities (Māori, Pacifika)

- 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?

- All decisions informed by consultation and clinical input
- Consistent national access with appropriate regional variation
- Sustainable expenditure growth
- Balancing health gain and cost
- Investment in new technology
- Best population health outcomes

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 though 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.
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
Budget focussed

<table>
<thead>
<tr>
<th>Patient outcomes</th>
<th>Procedure costs</th>
<th>Quality of Evidence</th>
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<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Outcomes improve or remain unchanged</td>
<td>100</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>90</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>60</td>
<td>50</td>
</tr>
<tr>
<td>Outcomes improve</td>
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<td>50</td>
</tr>
<tr>
<td>Significantly improved survival</td>
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<td>30</td>
</tr>
<tr>
<td>Significantly reduced morbidity</td>
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<td>15</td>
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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