Consultation on applying the PHARMAC model for hospital medical devices management

Waikato Forum 15 November 2013

Key points raised by attendees

New Zealand Government

PHARMAC
Pharmaceutical Management Agency

It's essential that PHARMAC's work is informed by the views of the people who work with devices. The approach to these forums was to outline that PHARMAC is in an information gathering phase and that we wanted to hear from the sector. PHARMAC was not there to provide all the answers, but to hear what the issues were for those working in this space so they can help develop the proposed approach to management.

General question discussed:

What are the key considerations PHARMAC needs to take into account when developing its policies and processes for hospital medical devices management?

Roles, definitions & scope

> Why are we doing this? Why are PHARMAC, HBL/ hA taking over the management of medical devices?
  > There is already a struggle to get consensus, so how will this be in the future?
> HBL/ hA role: What sits where and what will remain local?
> Definition of these roles?
> HBL writing policies and processes: DHBs already have policies; will PHARMAC also impose new policies?
> There needs to be one process for all policies in order to avoid double-ups, as this will have an effect on how day-to-day activities are carried out.
> Roles need to be clearly defined
> Who will manage installations? E.g. monitoring systems, large industrial (equipment): Drawing the line between installation, procurement and on-going management.
> Responsibility for health and safety – where does criminal liability lie?

'Whole of life' costs; Associated costs

> Looking at the life cost of the device, rather than looking at the initial cost of the device alone – all indirect and direct costs should be considered.
> The laboratory information system at Waikato DHB is unique, as every device needs to "talk" to the system/ is linked to the system.
  > There is an associated cost of $40,000 - $60,00 per device because of this
> Capital purchases: Maintenance for equipment
> Will there be national agreements for maintenance/ servicing and how much will this cost?
> What opportunities are there?
> Service and maintenance cost of equipment
  > Who will provide this?
  > Consistency
  > Recommendations
  > This impacts particularly in primary healthcare + impacts on care provided and treatment received by patients in particular environments
> Cost of contract extending into private/NGO practice so they have cost benefit of product and are able to provide care in community at same cost that DHB can – some devices are cost prohibitive at present.
> Cost of parts – i.e. looking at how much parts are, on-going servicing costs will affect the price of the equipment; be aware of selecting 'cheap' products that require expensive consumables
> Overall cost effectiveness needs to be considered – does the use of one device increase or decrease use of other modalities required in the procedure?
> Capital cost plus consumables cost
> Staff training and retraining costs; implementation and change costs
> Costs of space requirements of a device – alterations needed for the setting

Education and Training

> There is a risk around lack of confidence/ competence when considering training
> There needs to be sufficient support during implementation and it needs to be on-going.
> Education of staff – lead-in time for change of products, consistency of supply of product
> Training needs required for use of a device and/or surgical techniques needed and/or if surgeon is able to use the item; major implications imposing a new/different/ unfamiliar device
> Different modes of communication may be required for the different users of devices e.g. nurses, surgeons – identify all users of a product
> Key communicators are identified in each DHB
> Time allowed for switch-over to new device – training and support for transition phase

Assessment, funding decisions and clinical input

> Focus should be on long-term gain
> Rules for exceptions
> Capitalising on national processes that we already have that work
> Assessment criteria
  > Product life-cycle in patients
  > What research/data do you base your product assessment on?
  > Must be well-researched – clinical evidence will be key
  > Evidence from overseas, TGA and Medsafe
  > Product quality – considerations other than price
  > Develop a robust testing process, trials
  > How do you measure total cost of patient life compared with cost of individual product item?
  > How is product used? Application of device – complexity, high risk or low risk?
  > Will PHARMAC take into account both cost and efficiency where efficiency relates to supply chain and the effective use of an item?
  > Different products have different features – how can you evaluate and compare them all?
  > If you limit hardware options, you are also limiting consumables

> How will sponsorship and donations be considered or managed?

> Clinical Input

> The need for medical expertise and a panel in the decision making process is essential

> Clinical integrity of representation on clinical council decisions (is a key consideration)

> Contracts

> Will contracts be long enough to ensure that skills don't have to be re-learnt too often?

> Will contracts be long enough to accommodate to the adjustment in training and the length it takes for the training to take effect? Length of contract needs to be long enough to ensure competent use

> Effects on treatments with the introduction of percentage contracts/ models: Could end up lagging if this isn't taken into consideration

> Especially for primary providers and aged care facilities – they need to be able to access contracts for the same products

> Product supply, recalls & poor product performance

> How responsive will PHARMAC be when a device does not perform to standard?

> Incident management system?

> How responsive will it be?

> Going to preferred suppliers: How will PHARMAC provide choice and how many "players" are in the market, also in terms of backup if a supplier fails to deliver?

> If there is a reduction of suppliers in the market in terms of recalls there may end up being a constraint in availability which poses a risk on quality and safety.

> There may be a reduction of supply in New Zealand through training and international standards

> Special needs and requests need to be able to be taken into consideration.

> There is a risk around supply shortage if there is only a single supplier for a certain medical device.

> E.g. Faulty devices

> Availability of parts – supply lines

> Back-ups for 'out of stocks'

> Company must have a good record of supply/quality systems/ training material

> Will there be a list of products? How to access this list?

> Learn from mistakes

Flexibility to meet local/patient need; retaining choice and local expertise

> Will there be flexibility for local arrangements? How will they be taken into consideration?

> Some DHBs (including Waikato) are at the forefront, pioneering new procedures and innovations; how will PHARMAC's role impact on this? National consistency implies impeding innovation; discussed further below

> Will PHARMAC be proposing a one size fits all?

> Area/hospital/DHBs (needs differ) according to:

> Level of care,

> Locality,

> Population

> Urban/rural mix

> Size of hospital /community services

> Location of services and distances between, or to, urban areas

> Actual requirements of hospital / service

> Not all the same

> Ability to choose what products/devices to provide for that service

> Flexibility

> Access to education

> Accessibility of products and appropriateness for local DHBs – not having decisions made in Wellington for Rotorua

> Reduction of disadvantage according to geography, demographics

> Where is clinician/DHB choice?

> How will the local evaluation of products be managed when people are being disestablished?

> Will there be any local expertise available for rural locations?

> How will DHBs continue to be able to be responsive to the regions?

> What are the local processes for a product to be renewed? Current groups will be disestablished – how will this be achieved locally with no-one on the ground to do it?

> There are different levels of care and value within that that need to be considered.

> See additional comment under Advances/changes in technology; Innovation

> Cost effectiveness:

> Key thing from a surgeon's point of view is that the cheapest device may not be the most "effective" device.

> Clinician's preferences:

> Seems like it's going to be very difficult to get consensus with regard to which devices individual surgeons' prefer.

> Flexibility for local trials to be done if required

> Specialty services – smaller markets with specific items, e.g. neonatal, adults, paediatric

> Need to include local clinicians, procurement and other appropriate local stakeholders in decisions

Compatibility of systems and devices

> See comment under 'Whole of life' costs; Associated costs

> Compatibility – i.e. meets everyone's requirements, not just a few DHBs

> Instrumentation required needs to be compatible with device

> Material compatibility – e.g. cleaning wipes

> Compatibility with existing products

> Concerns regarding compatibility and suitability of selected models. If we can only choose equipment from a select list, we may also need to replace associated

systems/components to ensure compatibility.

> Ensure don't consider device in isolation – all associated consumables must be compatible

Advances/changes in technology; Innovation

> Innovation: Will new technology be available?

> Waikato DHB has outstanding cardiologists that have driven ground-breaking innovation. How will the expertise be taken into account especially in regard to retaining both the expertise and the experts themselves?

> Flexibility and adapting the evidence

> Things in the medical device world move/ advance incredibly fast. The worry is that the device may not be suitable after a relatively short period of time (e.g a few months) and PHARMAC would need to keep up with the development and international trends.

> Access to new and emerging products

> How will PHARMAC determine "Health Value" for one medical device over another?

> What model or mechanism will be used and how will that be factored against cost?

> How do you gain consensus on new equipment + access to improved / new technology

> Consistency

> Economic assessment

> Sustainability

> Local expertise / product evaluation available for regions

Issues for laboratories

> Is PHARMAC considering that laboratories need to meet accreditation criteria?

> Results need to be commutable and platforms need to be created for this.

> Comparisons need to be able to be made

> Policy for every platform?

> Who is responsible?

> How will the change process be managed?

> What will the process be?

Asset management; Capital Expenditure

> Is PHARMAC planning for capital expenditure?

> See comment under Whole of life' costs; Associated costs

> How will this be planned, distributed?

Issues for industry

> Are businesses likely to be locked out of the market with the introduction of PHARMAC management?

> Will preference be taken into consideration, especially with New Zealand companies?

> Preferences of working with suppliers because they can accommodate to the needs of DHBs.

> Concerns around price erosion in the market, as it is already happening.

> Is it still worth being in the New Zealand market?

> Need to ensure that standards are kept high

> Vendor changes must be well managed from a supply perspective

> Risk of having one dominant supplier

Device use between primary & secondary care

> Wound care: Funding in the future

> There is a challenge within DHBs now already to provide access to products. How will this work in terms of community access and the interaction between hospitals and community?

> Pathway between rural, primary, secondary and tertiary care environments

Relationships with other providers/entities

> How is PHARMAC intending to deal with lobbying and conflicts of interest?

> What is the role of PHARMAC compared with the role of NHC? Some Waikato clinicians have been working with NHC closely over the last couple of years; will they have to cover the same ground with PHARMAC?

> With the rotation of staff internally (in NHC) it is already difficult to get consistency in this approach.

> There is a need for sustainable and responsive engagement

> See comments under Roles, definitions & scope

> Civil Aviation standards – external providers

> Costs of meeting others' regulations – CAA, medsafe, TGA, accreditation criteria

Interim Procurement

> The Procurement Team within PHARMAC

> Will they be leveraging on existing resources and how will that look in terms of a national view?

> Savings: How will they be measured? How will DHBs benefit?

> Volumes and price – May need high investment before savings become visible

Communication with/consulting the sector

> How will information be relayed between a large community base? Proper set up communication plans so everybody is kept in the loop.

> Key stakeholders involved in decisions around change

> Need for a consistent feedback pathway to PHARMAC regarding product/supplier concerns and issues