Consultation on applying the PHARMAC model for hospital medical devices management

MidCentral Forum 30 October 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?

'Whole of life' costs; Associated costs

- > Maintenance and service components of medical devices
  - > Biomedical requirements/clinical engineering
  - > Service specifications
- > Training requirement
- > What are the total costs?
- > What are the specialised testing requirements of the equipment?
- > Servicing inhouse vs servicing externally (e.g. by supplier)
- > Associated consumables with any device
- > Associated costs of actual use of item (items being used for a different purpose than that intended)
- > Costs to the health system as a whole
  - > Clinical benefits
  - > Usability
  - > Patient use of product
  - > Prevention of wastage
  - > Ability to prevent hospital stays, continuing rehabilitation etc
- > In-house servicing costs
  - > Need to test equipment
  - > Manuals and service operator
  - > Training
  - > Diagnostic software
  - > Choice of medical devices available
  - > In-house servicing (low cost) vs no in-house servicing (high cost – provided by supplier)
  - > Biomedical engineering plays an important role via the in-house servicing of medical devices. For example, the cost per annum of servicing 'product A' can be five times more than 'product B'. The lifetime of 8 – 10 years and the number of these products yields a considerable saving by purchasing 'product A' if its failure rate is lower than 'product B'.
  - > Another advantage of in-house servicing is when clinics or theatre operations are cancelled while a device is out of action. In-house repair is always faster and does not have expensive hourly rates, airfares and accommodation.
  - > Therefore, it is necessary to ensure medical devices can be fully serviced in-house and the right product purchased. Sometimes this may require extensive consultation with many engineering departments who have quantitative evidence.

Assessment, funding decisions and clinical input

- > Clinical Input
  - > Consider clinicians' product preferences
  - > Ongoing clinician input/participation
  - > Consider usability of items when making decisions
  - > Costs need to include consideration of training - don't underestimate the costs involved in training to use a different/new device
  - > Clinicians' choice of product – preferences and training
- > Considering items on a category by category basis
- > Processes
  - > Reviewing processes as necessary
  - > Check current practise and equipment
- > Recalls
- > Indemnity
- > Where does the responsibility lie?
- > What is the role of PHARMAC in taking responsibility for an item placed on the Schedule but turns out to be faulty?
- > What is the responsibility of the industry?
- > What is the role and responsibility of the clinician?
- > MedSafe document released
- > Decisions
  - > Deciding what to fund: Ability to review decisions if something new/better comes onto the market
  - > Fair allocation of spending
  - > Not all DHBs need the same equipment – make sure the smaller DHBs get fair allocation of items on the Schedule and not all funding is poured into specialist items for big DHBs
  - > Consumer involvement in decisions
- > Especially disability groups
  - > Making sure the right people are involved in decisions from the start of the process
  - > Exceptional Circumstances
  - > What are the exceptional circumstances going to look like?
  - > Exceptional circumstances needs to take into account different users of items
- > Consider the volumes in packages – are they appropriate for the purpose intended?
- > Schedule Rules around using devices not listed
- > Audits of equipment use
  - > DHBs are often required to do spot audits at short notice
  - > Additional costs and time required to do these
  - > These need to be flexible and factored into overall work – ability to forecast when these are coming so can resource appropriately

> Need to follow best practice models

> A complaints process to manage current procurement if no longer suitable for clinical need

> A process to review new products – solicited and unsolicited processes are used currently

> Consider ramifications of patient self-management in the community

> What will happen to contracts that are already in place (and signed off for the next 5 – 10 years)?

Supply of devices

> Sole Supply

> > Consider clinical requirements

> > Patient variability

> > Competition in the market to ensure good prices: Consider small number of suppliers in NZ market, so don't want to drive out competition and make groups pull out of NZ

> > Creation of de facto monopolies – decrease competition

> Need open tenders

> Ensure supply chain

Flexibility to meet local/patient need; retaining choice

> Influence of big DHBs making recommendations that aren't suitable for smaller DHBs

> > Appropriateness of funding decisions

> Ensure that options are available to meet patient needs. For example, some patients are allergic to some dressings and need an alternative

> Maintain a variety of similar products to cater for patient variables/tolerances/allergies etc, including population variables between DHBs (age, ethnicity, gender etc)

> Freedom to move without it being considered 'exceptional circumstances'

> The wide spectrum of devices – plus/minus in each category there is a wide variation – clinicians fear imposition.

Asset management

> Asset management funding in DHBs – who will have control of this funding? Will DHBs still have the funding available for assets, or will this be transferred to PHARMAC?

> Standard life of equipment – how do we do manage assets, depreciation?

> Managing risk in selection criteria for new equipment – who is ultimately responsible for the device?

> Whose assets are they?

> Need to understand the capital process in DHBs

Definitions & scope

> Clarity of definitions of Pharms vs medical devices

> Do you have a 'Mission Statement' – vision + values + goals stated, so everyone knows where you are headed and what you will do?

> Where will devices be used?

> What is considered primary health sector and what is secondary?

> When does a hospital device become a community device?

> Capex Items

> > Clarity of scope of PHARMAC's role

> > Point of Care testing

> > Diagnostic vs therapeutic purpose for items – clarity around definition of what is a 'device'?

> Is this going to extend to EVERYTHING – e.g. Linear Accelerators, CT scanners, compounding isolators (Capex items), automatic cupboard storage devices?

Managing the transition phase

> Transition from current to new processes

> > Current devices being used, grandparenting in new devices as they come onstream

> > Not forcing DHBs to buy right now, when they already have something

> > Considering total costs (having to buy new when don't yet need it)

Specialist equipment vs generic; specific use

> Some groups need very specific equipment. For example, NZDF, Burns Units, Oncology – cannot make use of generic equipment

> Assurance of continuity of supply for special equipment

> Need to balance which devices can suit the needs of all vs those that suit only the needs of a few

Relationships with other providers/entities

> Alignment of Medsafe and PHARMAC

> Parties external to the health system

> > Make sure that whatever processes are developed are aligned with other groups outside of hospitals and that relationships are built with these groups

> Organisations such as Enable NZ; Access Able, ACC etc need to be involved in the listing process

> Industry

> > Industry leverage of private clinics to force public system to follow

> Force PHARMAC to fund

> > How to control supplier behaviour – pressure on clinicians?

> > What are the levers suppliers will try to use to influence decisions?

> > Consider a standard process for dealing with suppliers

> Need to consider that the workforce is across both public and private

> Need to think more about the interfaces with primary. private and ACC-funded services

Compatibility of systems and devices

> Interactions with other providers; understanding the impact of our decisions on others

> Taking into account variation between DHBs, different infrastructure of DHBs

> IT, software, other supporting equipment – understanding the interface

> Need for real time diagnostics – some are suitable for IT systems to use data, some need human intervention

> Consider the clinical requirements – how is the item used? Does it fit with other items needed for the same procedure? (e.g needle size fits into ampule)

> What is the item actually used for – consider end user

> Consideration of devices implanted in other countries and people come to NZ

  > What are the ongoing complications/costs associated with these?

  > What ramifications does it have for the items we use here – in particular if it is a device that we don't use here and what impact there is on our devices, patient care etc, if it is not compatible

> Platforms for systems – are devices going to communicate with different systems/different DHBs?

  > Costs associated with altering platforms

Advances/changes in technology

> Ability to present information about new technology to PHARMAC (or PHARMAC being able to access this)

> Clarity of processes involved to assess new technology

> Need for speed of processes

> Considering innovations regularly

> Patient safety

> Moving with new technology quickly

> Ensure access is available for new technologies and/or small 'niche' companies = innovative products

> How long before new devices can be proposed?

> Review Schedule listings when new technology becomes available

> New technology process – what are the timelines for getting this? Will it bog everything down and impede access to beneficial new technologies?

> Consider trials of new/improved products

> To include functionality

> What actual, measurable improvement it offers

> As part of evaluation process, needs to take place before funding decisions are made

> Offer a fixed number of items to choose from – involve the consumer

> Trials

  > Consider possibility of supplier reps getting patients on trials of products without these items being on the Schedule

  > What are the ongoing care implications when the reps stop providing care?

  > What happens if a decision is made not to fund it, but a few people are already using it/have it?

Communication with/consulting the sector

> When PHARMAC makes decisions, need to get support and understanding in DHBs

> How will DHB staff know when they can input?

> Communication with on-the-ground staff

> Stakeholder engagement around implementation

> Inclusiveness of consultation

> Transparency of process

> Involving people with specialist knowledge at the right time (practising clinicians not representatives of clinicians)

> A process to consult with clinical staff in DHBs prior to implementing new products

> Product equipment evaluation committee process to review and pilot medical devices currently in use and new products.