Working towards improved access to and quality use of palliative medicines in the community

Heath P, Mitchell G, Rowett D, Aloizos J, Currow D,
(On behalf of the Palliative Medicines Working Group, Prof Peter Ravenscroft Chair)

1 Mercy Health Service Albury NSW
2 Discipline of General Practice University of Queensland
3 Drugs and Therapeutics Information Service, Repatriation General Hospital, Adelaide
4 Chair Australian Pharmaceutical Advisory Council
5 Department of Palliative and Supportive Services Flinders University, Adelaide.
The policy context

Not all palliative care medicines are available or affordable to people who want to stay in the community or at home – this is a major barrier!

A key aim under the National Palliative Care Strategy and National Palliative Care Program is to increase options and support for people to receive care at home.

The slide defines the problem. The policy position of the Commonwealth that led to this initiative is that access to palliative care should be based on need, and that patients should have a choice of care - that is - they should be able to be in the place they want, and not have impediments to that. The cost of some essential medications constituted an impediment for some people. Some medications were not on the Pharmaceutical Benefits Scheme (PBS) - if they were essential to the patient’s wellbeing, the only source of those drugs for those not able to pay full price was the public hospital system. For some that may have meant forced inpatient stays, for others it may have meant personal visits to outpatient departments. Creating access to these drugs was an important issue.
The Palliative Care Medicines Working Group (PCMWG)

Is working with the Therapeutic Goods Administration (TGA). The Pharmaceutical Benefits Advisory Committee (PBAC) and Sponsors to support the listing of as many priority palliative care medicines as possible on the Pharmaceutical Benefits Scheme (PBS).

Backs up previous slide
PCMWG

• Committee chairman: Prof. Peter Ravenscroft
• Representatives from the Department of Health and Ageing
• Representatives from peak industry and organisation bodies
  Palliative Care Australia
  Medicines Australia
  Cancer Council of Australia
  Consumer Health Forum

The committee represents a wide range of professional, government and community interest and expertise.
Tasks of the PCMWG

Raise awareness of existing palliative care medicines listed on the PBS.

Improve rational use of palliative medicines

Improve access to medicines used in palliative care through the framework of the PBS.

The issue of access to appropriate drugs has two elements. Firstly there are several drugs already available in the normal PBS that can be used by palliative care patients. Practitioners need to be made aware that they exist. Secondly, those drugs not available need to be placed on the PBS if possible.
Application for a new drug or new indication for an old drug

TGA receives application
Application approved

Australian Drug Evaluation Committee
(safety and efficacy checked)

PBAC receives application
Evidence for application assessed and approved
Pricing Authority reaches agreement with company on price
Listing approved

Listed in PBS book

Getting a new drug listed on the PBS

TGA- Therapeutic Drug Administration
PBAC - Pharmaceutical Benefits Advisory Committee
## Requirements for PBS listing

For each drug:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a sponsor?</td>
<td>✓</td>
</tr>
<tr>
<td>TGA Indication approved?</td>
<td>✓</td>
</tr>
<tr>
<td>Form of drug approved?</td>
<td>✓</td>
</tr>
<tr>
<td>Route of drug approved?</td>
<td>✓</td>
</tr>
<tr>
<td>PBAC Is the drug listed in any form?</td>
<td>✓</td>
</tr>
<tr>
<td>Is the indication appropriate OR Is there a very similar indication?</td>
<td>✓</td>
</tr>
<tr>
<td>If the evidence of efficacy is present, can agreement be reached on price?</td>
<td>✓</td>
</tr>
<tr>
<td>Is a new listing required and feasible?</td>
<td>✓</td>
</tr>
</tbody>
</table>
Results

- **Results** A new section was introduced into the *Schedule of Pharmaceutical Benefits* dedicated to palliative care medicines on the PBS on 1 February 2004. All authority only.
Initial supply 4 months

Mandated review by a palliative care service.
Can be by phone, can be specialist Dr or Nurse

Subsequent supply
How were the medicines required in the community identified?

• National survey of over 200 clinicians

• Conducted by the Joint Therapeutics Committee of Palliative Care Australia, the Clinical Oncology Society of Australia and the Australian New Zealand Society of Palliative Medicine

• Priority list of approximately 25 essential medicines were identified for possible listing within the Pharmaceutical Benefits scheme.

• The list of medicines identified were assessed to work out which medicines could be listed through the PBS.

• There is a need to remember that only medicines that have been approved by TGA can be listed through the PBS – This process is a rigorous scientific assessment of data that makes sure that medicines that are made available through this system are safe and effective. The TGA registers not only the indication but the formulation, and mode of administration.
Medications in PBS Palliative care list.

<table>
<thead>
<tr>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carmellose sodium</td>
</tr>
<tr>
<td>Hyoscine butylbromide</td>
</tr>
<tr>
<td>Promethazine</td>
</tr>
<tr>
<td>Paracetamol and suppositories</td>
</tr>
<tr>
<td>Clonazepam</td>
</tr>
<tr>
<td>Laxatives</td>
</tr>
<tr>
<td>Bisacodyl</td>
</tr>
<tr>
<td>Docusate with bisacodyl</td>
</tr>
<tr>
<td>Sterculia with Frangula bark</td>
</tr>
<tr>
<td>Bisacodyl enemas</td>
</tr>
<tr>
<td>Microlax enemas</td>
</tr>
<tr>
<td>Glycerol suppositories</td>
</tr>
<tr>
<td>Diazepam</td>
</tr>
<tr>
<td>Macrogol</td>
</tr>
<tr>
<td>Methadone</td>
</tr>
<tr>
<td>Paracetamol Tablet 665 mg (SR 4 months supply)</td>
</tr>
<tr>
<td>Naproxen (oral suspension)</td>
</tr>
<tr>
<td>Oxazepam</td>
</tr>
<tr>
<td>Nitrazepam</td>
</tr>
<tr>
<td>Temazepam</td>
</tr>
<tr>
<td>Diclofenac</td>
</tr>
<tr>
<td>Ibuprofen</td>
</tr>
<tr>
<td>Indomethacin</td>
</tr>
<tr>
<td>Naproxen</td>
</tr>
<tr>
<td>Sulindac</td>
</tr>
<tr>
<td>Naproxen sodium</td>
</tr>
<tr>
<td>Morphine Sulfate tablet (10 mg and 20 mg)</td>
</tr>
<tr>
<td>Morphine sulphate SR 200 mg</td>
</tr>
<tr>
<td>Benzydamine Hydrochloride</td>
</tr>
<tr>
<td>Lactulose</td>
</tr>
</tbody>
</table>
Matching the priority list to PBS list

For each medicine:
Is the medicine ALREADY listed on PBS?
If YES-
• Is the listing for the right indication?
• Is the listing for the preferred route of administration and formulation?

Note that TGA is for a given drug, a particular formulation (eg capsule, injection), a given indication and a particular route of administration.
If there is NO PBS listing

• Is there a TGA approval for:
  – the drug?
  – the indication?
  – the preferred route of administration and formulation for palliative care?

TGA only approves if there is robust evidence to support the quality, safety and effectiveness of the medicine for ALL of these factors
Only medicines that are appropriately listed by TGA can be listed on the PBS.

Only the sponsor (pharmaceutical company) can list a medicine or change a listed indication on the Australian Register of Therapeutic Goods (ARTG).

The key is that the manufacturing company must be willing to sponsor the drug through this process. Some medications required minimal extra submissions to allow listing as a palliative care medication. Other medications require full TGA approval, and subsequent PBS approval.

The company must make a commercial decision that the expense required to complete the process will be recouped. Many companies have perceived this as a public good gesture and have proceeded even though the numbers of patients is relatively small, others have decided the effort is not worth the return.
What has been achieved to date?

- A framework to support the listing of palliative medicines through the PBS
- A palliative care section (mauve) within the PBS Schedule
- Medicines not previously listed now available through the PBS

The framework is a grid to identify the status of each drug, so that it is made clear what each drug requires to achieve registration.
Other changes to the PBS effecting opioid management

- Simplification of prescribing requirements for GPs for narcotic analgesics
  
- Increased quantities and repeats for narcotic analgesics for patients with chronic, severe, disabling, non-malignant pain without having to hospitalise the person
  
- Improves capacity of GPs to provide adequate pain management

This is a very important advance. Previously the patient was either required to have terminal cancer, or to have non-,malignant pain where the patient had to have the drug started by a specialist while in hospital, to get access to increased quantities. Now any doctor can prescribe increased quantities for up to 12 months, for any condition. As a quality control mechanism, persons requiring medication for more than 12 months needs to have the case reviewed by another doctor.
Gathering new evidence

• PaCCSC- Palliative Care Clinical Studies Collaborative
  – Multi-site trials to gather new evidence to support TGA submissions
  – Basis for ongoing clinical studies of palliative care treatment

Flinders University- Prof David Currow
Dissemination Plan

Targets:
- Professionals- primary/ community care
- Professionals-  
  • Palliative care  
  • Non palliative specialists
- Consumers
- Pharmaceutical manufacturers
Professional strategies

1. Mass communication through professional media
   
   – Medicare Australia Forum (42000 recipients)
   – Australian Doctor Weekly – every GP – news article, How to treat
   – Australian and New Zealand Society of Palliative Medicine newsletter – all PC doctors
   – Newsletter of the Royal Australian College of Nursing
   – Repatriation General Hospital Newsletter in Adelaide
2. Train the trainer

Workshop in early 2006

Training kit

Trained staff disseminated to professional meetings across Australia

Network of trainers - newsletters
Promoting access to consumers

1. Inform consumers of the availability of palliative medicines.

2. Empower consumers to seek access to appropriate medicines
Promoting access to Consumers

3. Different strategies required than for Health Professionals
   – Patchy public knowledge of pc and presence of the PC medicines scheme
   – Caregivers and patients
     • short term contact with pc
     • High stress
   – PC medicines scheme not of “general interest”
Conclusion

The strategy has enabled clinicians to prescribe a broader range of medications outside of hospitals, and to provide greater patient choice about place of care.