Review of funding arrangements for chemotherapy services

APHS Pharmacy Group
29 July 2013
1. Describe the model of care for the provision of chemotherapy medicine infusions that apply in your healthcare sector or the institution in which you practice. Please consider all components from the clinical decision to order an infusion to follow-up after the course or cycle has been completed.

The supply of chemotherapy is a vastly complex process. Dealing with highly toxic drugs requires numerous steps and highly trained staff to ensure supply supports optimum patient safety and outcomes. The following flowchart outlines the pharmacy model of care employed in the provision of chemotherapy infusions as part of the overall model of care.

Oncology pharmacy model of care

Referral form received by the Oncology Clinic (first contact Oncology Clinical Nurse Consultant, then referral given to Pharmacist).

Pharmacist assesses whether additional pathology tests are required prior to the patient commencing treatment.

Collect and assess current and past patient clinical and drug history and family information necessary to design a pharmacotherapeutic plan.

Pharmacist participates in a Multidisciplinary Team Meeting to establish therapeutic goals in collaboration with patient.

Pre-treatment chart revision. Pharmacist checks the body surface area, dosages, pre and take home medications.

Pharmacist attends Chemotherapy drug/chart write ups with treating specialists to optimise patient outcomes.

Assessment of the financial impact of the selected treatment on the hospital as well as for the patient. This careful assessment by the Pharmacist ensures reduction in unnecessary financial burden for either party.

Compounded chemotherapy products are checked upon arrival for dose, container, compatibility and safety. Labels printed.

Pharmacist orders drugs as per the checked chart. This includes all medications including take home drugs.

Assessment of patient outcomes.

For all Patients
Pharmacist visits them in the clinic for assessment of physical signs of drug-related effects.

For New Patients
During first visit to clinic: provide: a Patient Care Kit, Cancer Council Kit and information from EVIQ.

For all Patients
Pharmacist in conjunction with the chemotherapy nurse conduct a holistic assessment of patients’ wellbeing and any non-drug related side effects that may require further referral.

For all Patients
Monitor compliance with medications, diet, sleeping, nausea, constipation, affect of treatment on lifestyle, medication interactions. Liaise with family members.

For all Patients
Respond to drug information requests; liaise with nursing staff about drug issues.

For all Patients
Liaison with doctors to recommend newly available drugs, extra therapeutic drug monitoring or suggested management techniques to improve patient outcomes.
2. Describe the professional and administrative practices for the provision of chemotherapy medicine infusions within the healthcare sector/s in which you participate and the business model/s which support them.
3. **Can you identify and describe any changes to the provision of chemotherapy medicine infusion services over recent years? Have these changes (if relevant) affected consumer access to services and, if so, how?**

Over recent years, patient access to chemotherapy has increased via new therapies, expanded indications and new PBS listings. As a result, initial and subsequent treatments have remained or become in most cases affordable and accessible for patients. Combine this with significant investment in cancer treatment settings and a growing number of cancer diagnoses, & the number of Australian patients receiving chemotherapy continues to grow each year.

This has seen chemotherapy treatment become available in more hospitals, with more frequency, making it a more significant component of hospital pharmacy activity.

4. **If third party compounders of chemotherapy medicines are used within your sector or institution, please describe where and how they are incorporated within the practice and business model. Also discuss the reasoning for the decision to involve a third party compounder in preparing the chemotherapy infusions.**

APHS have differing proportions of in-house versus third party compounding to meet the requirements of the hospital and pharmacy location.

Third party compounding orders are placed after revision of the pre-treatment chart is complete, and go through the same checking and labelling process as in-house compounded items.

There are a number of reasons APHS uses a third party compounder at certain pharmacies. In-house chemotherapy preparation requires investment in infrastructure, processes, training and highly specialised staff due to the nature of the drugs involved. In situations where a third party is used there may be:

- An inability to recruit specialist oncology pharmacists to the area
- The cost of staff required to compound in-house may outweigh the margin paid to a third party compounder because of the required drug mix/volume
- The cost of infrastructure and space required for in-house compounding is prohibitive at a particular pharmacy or simply unavailable
- The size of the hospital’s cancer ward, or pharmacy contract length, makes investment in a compounding unit unviable for both the hospital and pharmacy operator

5. **Preparation and provision of chemotherapy medicine infusions undertaken by individual pharmacy businesses or business units within a larger institution. Describe the contractual or business arrangements in place with other upstream and/or downstream parts of the same healthcare sector.**

Pricing, ordering and delivery arrangements are negotiated and contracted with third party compounders where applicable.

Pharmacy contracts are negotiated directly with the hospital operator, including the pricing arrangements for professional services, KPI measurements and other aspects of the hospital/pharmacy relationship. The financial contribution to a pharmacy business in a private hospital is highly variable depending on the case mix and occupancy rates. In addition to this, doctors’ careers and referral volumes can vary significantly during the course of a pharmacy contract, which is typically entered into an initial term of 3-5 years.
6. Please describe the components of dispensing and clinical services provided in relation to infusible chemotherapy medicines? It may be useful to provide a comparison with dispensing practice for non-infusible medicines, such as tablets. Please consider the differences in relation to costs, time involved, skills required, outcomes achieved and activities undertaken?

The flowcharts below demonstrate the pharmacy model of care required for infusible chemotherapy versus an ordinary medicine, such as antibiotics. It is clear from the charts below that there is a significant difference in process.

<table>
<thead>
<tr>
<th>Infusible Chemotherapy Medicines</th>
<th>Other Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time to complete prescription</strong></td>
<td></td>
</tr>
<tr>
<td>• Multiple interactions that can occur across several days</td>
<td>• Single interaction</td>
</tr>
<tr>
<td>• “Pick up / put down” approach to process, due to third party ordering or internal compounding activity</td>
<td>• Prescription is typically the “order,” although, in a hospital setting, the medication chart may be the order</td>
</tr>
<tr>
<td>• High authority prescription requirements, triggering increased administration activities and interactions</td>
<td>• In the majority of cases the prescription is for a pre-packaged drug that is on the shelf in a ready to administer form</td>
</tr>
<tr>
<td>• The prescription is not the supply order, rather an additional administrative component required for pharmacy to receive payment</td>
<td></td>
</tr>
<tr>
<td><strong>Costs</strong></td>
<td></td>
</tr>
<tr>
<td>Dispensing and administration costs to ensure safe chemotherapy supply, including pharmacy operation overheads, average $70 in APHS pharmacies.</td>
<td>Significantly lower cost per prescription.</td>
</tr>
<tr>
<td><strong>Drug cost</strong></td>
<td></td>
</tr>
<tr>
<td>The cost of preparing a ready to infuse product approximates $100 per infusion, excluding the underlying drug cost. This may be a cost paid to a third party compounder or the fully allocated costs of in-house compounding activities including direct labour, consumables and facility costs. In an “ideal” setting with a high and consistent volume of compounding activity, a slightly lower average cost per infusion may be achieved via in-house compounding. However, in APHS’ experience there are more frequently settings that result in an equivalent or higher cost.</td>
<td>Drug cost is usually fully reimbursed under the PBS with no additional costs incurred. Where drugs are unavailable through CSO wholesalers, additional costs may be incurred for delivery or minimum order volumes. However, the strength of the CSO system means this occur infrequently.</td>
</tr>
</tbody>
</table>
Oncology pharmacy delivering infusible chemotherapy medicines

Referral form received by the oncology clinic (first contact oncology clinical nurse consultant, then referral given to pharmacist).

Pharmacist manually transcribes that these values/data are correct or makes changes in consultation with specialist if they are incorrect.

A patient chart is created in the pharmacy to store all correspondence and scripts regarding the patient's treatment. Each patient has their own dedicated folder.

All of the medications used for the treatment of the patient are dispensed into the pharmacy's dispensing program (APHS uses Fred).

The prescription is reconciled in the dispensing system. New prescription requests made for continuing treatments.

Individualised patient medication kits are packed. These kits include treatment, pre and post medication and supportive care medications.

On their first visit the patient is provided with a Patient Care Kit, Cancer Council Kit and information from EvQ2.

A daily log is filled out of the room temperatures, ridge temperatures and the pressures in the mixing suite if applicable.

Mixing suite daily clean and decontamination, including a log of processes undertaken and batch and expiration of products used. Also occurs weekly and monthly.

Waste management and disposal maintenance are performed every second day to ensure a safe work place and adhere to environmental guidelines.

A weekly consumables order is completed to stock the correct equipment and devices for reconstitution. This is done in addition to the usual weekly stock ordering.

Constant and thorough stocktakes are undertaken to support the way the PBS now works on per mg not nearest vial base.

Collect and assess current and past patient clinical and drug history, as well as the family information necessary to design a pharmacotherapy plan.

Chemotherapy drug/chart is received via hard copy or electronic communication from the treating specialist and their clinic.

The patient's disease state, medication history, doctors' orders, dosages and ancillary medications are entered into a cancer management program (APHS uses CHARM).

Compounded chemotherapy products are checked for dose, container compatibility and safety. Labels are printed and placed on the product.

The patient chart is used to produce the pre and take home medications. Labels are attached to the applicable medication boxes.

The patient's next treatment is scheduled in the cancer management program. Pharmacist requests a new order for the next cycle of treatment.

Pharmacist assesses whether additional pathology tests are required prior to the patient commencing treatment.

Pharmacist checks the body surface area, dosages, pre and take home medications, as well as existing medications.

Assessment of the financial impact of selected treatment on the hospital and patient. This ensures reduction in unnecessary financial burden for either party.

Pharmacist attends Chemotherapy drug/chart write-ups with treating specialist to optimise patient outcomes. Prescription requirements discussed.

Pharmacist monitors patient's compliance with medications, diet, sleeping, nausea, constipation, effect on lifestyle and medication interactions. They also liaise with family.

Pharmacist liaises with pharmacist to recommend newly available drugs, therapeutic drug monitoring or management techniques to improve patient's outcome.

Pharmacist visits the patient in the clinic to assess physical signs of drug-related effects.

Third party compounding

A cytotoxic drug order is created via the cancer management program and faxed to our manufacturer. A fax confirmation is required to ensure the order has been received.

Once the order is received unsigned, it is checked off against the invoice to cross check charges and stock levels.

Once order is received, it is checked off against the invoice to cross check charges and stock levels.

In-house compounding

A manufacturing worksheet is created in the cancer management program. Once the worksheet has been generated, it is printed and checked by another oncology pharmacist.

The chemotherapy product along with necessary equipment are set up for manufacture. This is undertaken by a qualified reconstitution technician.

The reconstitution technician enters the compounding episode into a daily log. This is filled out for every product that was manufactured in order to record exposure times.

Optimised patient outcome
7. Describe in detail one or more possible options for:

- The appropriate level and source of funding for each component of practice (described in response to Q6).

Across APHS pharmacies, which have differing proportions of in-house versus third party compounding to meet the requirements of the location, the true cost of compounding averages approximately $100. Dispensing, administration and overhead costs average around $70. The EFC model currently provides $40 to cover the cost of compounding, $4.83 for diluent and a $6.52 dispensing fee.

We believe the compounding fee should be increased by $60 from $40 to $100, which matches the interim funding provided from July to December 2013. An increased dispensing fee is also necessary to support the administrative aspects required in this complex care setting. Our analysis suggests an increase of $25 to the dispensing fee for EFC items and a separately claimable $15 per infusion clinical services fee is appropriate. A correction to the flawed mark-up calculation could contribute, or significantly reduce, the $25 dispensing fee shortfall.

There has been much discussion with the Government and wider sector regarding the ‘final mile’ of clinical services delivered to the patient by a multi-disciplinary team (oncologist, nurses, surgeons, allied health professionals). Led by an oncology pharmacist, these services are vital to the safe supply of chemotherapy and essential for a positive patient outcome. Due to the different settings in which APHS operates pharmacies across Australia, we have the opportunity to comment on the true cost that clinical services incur. In this context, ‘final mile’ clinical services are the direct interactions between patient and pharmacist at the bedside or in the chair. APHS fulfils a number of pharmacy contracts where the hospital provides their own clinical service and our pharmacy dispenses and supplies the compounded items. From evaluating the performance of these contracts, APHS believes our dispensing,
administration and overhead costs are in the range of $10-15 lower per infusion when the ‘final mile’ service is not provided.

Making clinical services a separate $15 reimbursement, as outlined above, would ensure pharmacy is not inadvertently remunerated for services that are not provided by the pharmacy in every setting of care. For example, in public hospital settings where a community pharmacy has been engaged, the hospital may be delivering clinical services & only outsourcing the dispensing & supply functions. However, APHS would contend that in many cases the reduced cost structure for pharmacy not providing the final mile clinical service is currently transferred to the public hospital authority via lower service pricing for the dispensing and supply function. Thus, the potential ‘double dip’ may be more theoretical than actual.

Based on learnings from previous chemotherapy funding models, APHS proposes that hospital executives are required to confirm service delivery of ‘final mile’ clinical services, based on eligible infusions provided for a period, before payment is made for this fee. If not, we may find ourselves with a similar issue to the per prescription model (where payment was received at the start of a treatment cycle to cover multiple infusions even when a patient may not ultimately complete the full cycle of treatments) which was changed to a per infusion model under the EFC. Upfront payments could be an inefficient option for government, leading to overpayment when the full treatment cycle is not completed or, potential underfunding when patients do complete their full cycle.

• **Possible funding models for the preparation and supply of chemotherapy medicine infusions**

A great deal of discussion has occurred regarding where the cost of chemotherapy infusion should sit. We view costs and services as so integral to the safe supply of chemotherapy, that it is vital to accommodate the full supply arrangement in the PBS remuneration. No element of this process can be removed from the provision of chemotherapy without compromising patient safety.

The cost of “final mile” clinical services could be considered for introduction as a newly funded, new 5CPA professional program. In the same way that medication review services are funded under 5CPA, we believe equivalent arrangements should be put in place to fund clinical services provided by pharmacy. This funding should be subject to signoff by hospital operators and eligible to both s.90 and s.94 pharmacy operators. While clinical services could be assessed as a health fund obligation in private hospital settings, ensuring that this service remained appropriately funded and not eroded over time may be challenging. On a practical level, implementing this change across hundreds of existing hospital/pharmacy contracts would require unprecedented coordination and unilateral change for all private health funds, hospital operators and pharmacy providers.
Term of Reference 3: Rural and regional chemotherapy provision

1. Are there significant differences in the costs or processes for providing chemotherapy services in rural and regional areas? How do arrangements vary between public and private sectors, and what is the effect on accessibility of services? Please provide any data or evidence you have to support your position.

Access to specialised staff and volume of activity due to population density are the key issues for pharmacy providers in rural and regional areas. Hospital operators also experience similar challenges in availability of medical oncologists and haematologists, as well as experienced oncology nurses.

For pharmacy, the most practical and common approach to dealing with these issues is to increase reliance on third party compounding. This enables the pharmacy to manage their fixed cost base and reduce their exposure to risk around service continuity where it otherwise relies on 1 or 2 critical employees delivering the service.

These steps will usually achieve a cost of supply that is similar to that achieved in more concentrated settings where greater in-house compounding activity may occur, with the exception of the very high volume centres where scale may deliver greater efficiencies of cost per infusion.

2. Do consumers or providers have extra additional costs or other factors that limit access to services in these areas? Please provide any data or evidence to indicate the difference in costs or other factors for consumers.

In rural and regional settings choice of hospital and doctor is generally much more limited, with travelling time one of the key issues. To the best of our knowledge there has not been a direct “pharmacy cost” passed on to patients as a result of being in a rural or regional area. In the private setting, health fund agreements dictate equal treatment for all insured patients.

3. Does the quality of services vary in rural and regional and remote areas compared to more urban areas? What, if anything, should be changed about current funding arrangements to address?

The aim and intent is to have no differential in the quality of services. In the same way that attracting pharmacists or other medical and allied health professionals can be more challenging in certain rural, regional and remote areas, attracting and retaining experienced, specialised, oncology pharmacy staff may be more challenging due to some locations.

It is important that the remuneration model provides sufficient margin to operate a quality chemotherapy service, regardless of location. Expanding cancer care has been a clear direction of the current Government. To maintain sustainable regional cancer centres patients, hospital operators and pharmacies must be able to afford the treatment that is required.

If financial incentives or similar arrangements are required to attract staff to work in rural settings, whether this be for doctors, nurses or pharmacists, the incentives will be specific to the location. We believe any employment incentives should be treated very separately to the funding of chemotherapy infusions that is the subject of this review.
4. **Do the current funding arrangements help to support consumer access to chemotherapy services?**
   What changes, if any, need to be made to current pharmacy funding arrangements to address rural and regional access issues? What is the most appropriate mechanism for making any changes and/or how should the funding be managed under any such change?

   The current funding arrangements do not support consumer access to chemotherapy services, with funding currently below cost of supply. The temporary funding introduced from 1 July 2013 provides an improved position, but would not yet support long term investment in infrastructure and quality programs for a safe and sustainable supply.

   Putting in place the appropriate funding arrangements, and delivering certainty to pharmacy operators and hospital operators alike, will ensure that consumer access is supported in all locations across Australia.

**Term of Reference 3: Quality of infusion preparations**

1. **What are the range of relevant guidelines and standards that apply to chemotherapy services across States and Territories?** How are these standards enforced – i.e. regulations, on-site audits? Which if any of these standards should apply where drugs are being compounded on-site, or purchased from a third party, or prepared days before the infusion is delivered? How are adverse events monitored and reported?

   A separate review of compounding arrangements in pharmacy, including but not limited to chemotherapy infusions, is running concurrently to this review. In considering Term of Reference 3, we believe this review must take cognisance of the alternate review’s activities and outcomes.

   It should be noted that the outcome of that review may alter the costs incurred by pharmacies using in-house compounding models. Quality and safety must be paramount, irrespective of the source of compounding.

**Term of Reference 3: other matters pertinent to funding for chemotherapy infusion preparation**

1. **Are there any concerns in relation to current administrative processes surrounding the provision and claiming of PBS chemotherapy medicines and infusions?**

   Management of prescriptions in the chemotherapy sector is a complex and unnecessary administrative burden for doctors and pharmacy. Due to the setting in which chemotherapy treatment occurs, the prescription is a duplication of information the doctor has already recorded on the patient’s medication chart. Requiring secondary duplication of this data introduces risk of error and consumes specialist practitioner time that could be better spent on patient care or research. Further to this, not all items are available for prescribing under the streamlined authority system. This causes significant interruption to a doctor’s ability to prescribe treatment for a patient when an authority code must be obtained, as well as the workload and cost that the authority process places on Medicare.
2. **What if anything should be addressed in relation to these matters?**

Knowing ‘trial sites’ in Victorian private hospitals have operated using the medication chart as the prescription for more than a decade, a wider adoption is well overdue. APHS believe Medicare, doctors and pharmacy would all benefit from removal of the current authority system, as well as adopting the medication chart as the script. This would deliver financial savings to Medicare, while doctors and pharmacy would benefit from an increase in their availability for patient care from reduced paper chasing.

3. **Are there other matters not mentioned in other areas of the paper that should be considered in developing a sustainable, transparent funding model for chemotherapy infusion services? Are there consumer issues that may not have been considered that should be taken into account in developing a sustainable funding model for chemotherapy infusion services?**

**s.90 mark-up algorithm**

There were unintended consequences in the application of the mark-up algorithm for s.90 pharmacies when EFC was implemented. The concept of maximum prescribable dose (in mg) was introduced as an internal administrative concept by DOHA and the regular s.90 pharmacy mark-up became pro-rated against the maximum dose. Instead of receiving the capped $70 mark-up on a chemotherapy item costing more than $1750, as had historically been the case, the mark-up now varies for different drugs and doses where drug cost exceeds $1750. However, it rarely approaches $70. For s.90 pharmacies, the introduction of the maximum dose concept reduced the mark-up component of their remuneration by approximately $20 per infusion.

This creates a margin on some high cost drugs that is well below the cost of production and service delivery; it is inconsistent with general PBS remuneration principles and non-commercial. Not only is the algorithm potentially providing remuneration below the cost of supply, there is no financial recognition for the risks associated with high cost inventory and the compounding of items ready for supply. This includes costs associated with holding inventory, such as insurance premiums, and compounding risks such as errors in process or split bags that become contaminated products and must be disposed of. With the current remuneration arrangements 25 or more infusions are required to offset the loss arising from a single compounding error, that is before any of the costs of compounding, supply or administrative processes are considered.

Restoring an s.90 mark-up algorithm based on the cost of the product being provided (minimum vial combination) provides some recognition of the financial risk absorbed by pharmacies and re-establishes an equity between products and doses that is more commercial and appropriate.

Put simply, the required adjustment is for the pharmacy mark-up payment to be based on the cost of the infusion.

**S.94 pharmacy remuneration**

The 2010-11 Federal Budget introduced changes to s.94 private hospital remuneration, which were intended to better align remuneration arrangements with operational requirements. The core tenets of this change were to replace the wholesale mark-up of 7.52% with an 11.1% storage and handling mark-up, and the tiered pharmacy mark-ups (6 levels of mark-up with a maximum $70) became a flat 1.4% private hospital mark-up.
Fact sheet 4368.09.10 issued by Medicare Australia provided further information in relation to these changes, specifically noting that medicines supplied under the Intravenous Chemotherapy Supply Program (ISCP) would not be affected by these changes.

When ICSP was subsequently replaced by the adoption of EFC, there was no indication that the communicated exclusion of ICSP from the changed mark-up arrangements would alter under EFC.

In the final implementation of EFC this exclusion was not carried forward and s.94 pharmacies in private hospitals had the 11.1% storage and handling mark-up replaced by the $24 distribution fee contained in the EFC model, while continuing with a flat 1.4% mark-up. In essence, s.94 pharmacies lost the compensation of a higher storage and handling mark-up that had offset a lower product mark-up and were left worse off.

As the services provided to cancer patients are not dictated by the type of pharmacy approval for PBS claiming and hospitals may outsource their pharmacy services while still utilising s.94 arrangements for reimbursement, there is no logical reason for this differential in remuneration under EFC. We believe this should be corrected to match the s.90 remuneration arrangements.

Due to the “underpayment” of mark-up to s.90 pharmacies, the additional shortfall for s.94 pharmacies has been lower than it would normally be. But, while we advocate strongly for the correction of the mark-up, the s.94 issue is also one that must be addressed.

We believe it is important to note in the development of the Alternate Proposal, neither of these additional savings to the Government was factored into modelling or forward estimates of savings by either the Government or the CPCSG, to the best of our knowledge. When the industry realised these changes, the Government was notified of the additional reductions to remuneration with an expectation that they were an unintended outcome. However, they have continued to exist since 1 December 2011.

Submitted by Andrew Reid, APHS CEO, in conjunction with Stuart Giles and Cathie Reid - owners of pharmacies in the APHS Pharmacy Group.