Review of funding arrangements for chemotherapy services: Response.

Joondalup Hospital Pharmacy operates an onsite chemotherapy drug infusion service supplying Joondalup Health Campus in north metropolitan Perth. Southwest Hospital Pharmacy provides a similar onsite service to St John of God Hospital Bunbury, a country location 180km south of Perth. The services operate in a similar way and are thus a useful comparison between metropolitan and regional areas.

Costs and complexities involved in the provision of chemotherapy drugs

Questions:

1. *Are there significant differences in the processes or costs of compounding certain infusible chemotherapy medicines? If so, please identify those medicines; describe the different practices or processes and evidence to support your position.*

Some medicines involve significantly different methods and take much more time to dispense than others. Some examples that we dispense are listed below.

Drug/Device	Issue	Process	Time
Paclitaxel (NAB)	Slow prep time	Slowly add saline and let sit	20-30 mins
Cyclophosphamide	Slow to dissolve	Requires a lot of shaking	15-20 mins
Trastuzumab	Avoid bubbles	NO shaking	10 mins
Elastomerics/ CADD casette	Extra steps to compound in these specialist devices	Extra labour required over syringes & PVC infusion bags	10- 15 mins

2. *If you described a different practice for certain infusible chemotherapy medicines (in response to Q1) should these be managed or funded differently to other chemotherapy medicines? If so, please describe a possible alternative funding model for these medicines.*

There is potential for a differential of funding that takes into account the time for preparation and perhaps specialist consumables. One method would be to have the PBAC and or the PBPA attach an extra payment for degree of difficulty in compounding.

This extra amount would seem to be not in line with other PBS medicines that take considerably more time to dispense. Examples such as clozapine, which requires blood monitoring and record keeping or thalidomide which has a special dispense process including patient interviews and specialist confirmations. These examples do not attract extra funding for dispensing pharmacists but take much greater time than the standard dispensing fee would seem to pay for.

Rural and regional chemotherapy provision

Questions:

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.*

Our two pharmacies are located in a Perth metropolitan hospital and a country hospital in Bunbury south of Perth. The two pharmacies have similar equipment, procedures, staffing requirements and hours of operation.

Our experience shows that major costs are more expensive in Bunbury than in Perth due to scarcity of skilled labour, delivery costs, maintenance costs and higher inventory levels.

See table 1 in Costings template

Thus the marginal cost to compound per item is higher in the country probably by as much as $10 per infusion.

The benefit for the PBS is the significant reduction in wastage that occurs with the use of 3rd party compounders. Our model is one where infusions are compounded on a daily basis after blood results and patient status is reviewed. The external supply model requires that doses are ordered 48 hours in advance meaning up to 5% are unused. It is true that unused doses may be kept for a later date but this often has required nurses adjusting doses and discarding unused portions which is wasteful and potentially unsafe.

Inventory levels are kept high at significant cost to the business. The PBS funding model assumes "just in time" supply which is ineffective in WA country areas where many drugs are delivered 3-5 days after order.

The increase in capital costs is due to equipment suppliers charging higher freight and installation costs in country areas.

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.*

Country consumers are generally shielded from extra costs by a combination of the pharmacy absorbing some costs and the hospital provider agreeing to some charges. An example is Abraxane (NAB Paclitaxel) where the product sponsor charges $30 per vial greater than the PBS agreed price. This extra cost is passed on to the hospital or patient dependent on provider billing agreements.

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 quality of the service provided by our pharmacies is identical in both country and metropolitan sites. The costs of maintaining the similar quality are outlined above. The greatest cost is that of holding higher inventory levels to enable on the day of treatment delivery. The cost of holding higher inventories in is generally offset by higher margins in other industries.

The PBS zero margin remuneration formula makes this difficult for a country pharmacy to hold extremely high cost items to the same level as more common items. Work practices are created where certain items will require a longer leadtime of 3-5 days depending on manufacturer delivery times.

Quality of infusion preparations

Questions:

- *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?*

Our facilities utilise pharmaceutical isolators to create a safe workplace for the compounding of cytotoxics. The equipment, environment, work practices and safety procedures are subject to oversight by the WA private hospital licensing unit, Licensing and Regulatory Unit (LARU). LARU has jurisdiction on pharmacies within private hospitals such as ours.

Our facilities and equipment comply with Australian standards:
AS1386 Cleanrooms and clean workstations.
AS4273 Design, installation and use of pharmaceutical isolators.
AS1807, Cleanrooms, workstations, safety cabinets and pharmaceutical isolators – methods of test.

Staff are trained externally at The Box Hill Institute in Melbourne and validated microbiologically by Pathwest testing laboratory in Perth.

Our work practices are based on Society of Hospital Pharmacists Australia (SHPA) guidelines, Worksafe published guidelines and the code of Good Manufacturing Practice (cGMP).

Adverse event recording mechanisms include in order of severity.
Pharmacy internal adverse event recording.
Hospital adverse event recording and reporting.
WA Health Department SAC code reporting system.

- *Is further development of current standards required? If so, in which area is work needed? Is there other work, such as the development of quality programs, required? How can consumers be involved in the development of standards and programs to ensure quality services?*

Further development of standards is less important than further development of audit and review of the standards. The Pharmacy Guild Quality Care Program (QCPP) is the well established national audit for pharmacies. It would make sense to expand the QCPP program to involve audit of the sterile and cytotoxic compounding. External 3rd party compounders are already regulated by the TGA which is appropriate. The link between the compounder and pharmacy via service level agreements and contracts could be reviewed by the QCPP program.

- *Should meeting any of these standards be a mandatory requirement for Commonwealth funding? If so, which? How would this be managed or enforced? Are there different standards that should be met depending on the circumstances under which the infusion is prepared? What would the effect of any changes be for consumers, in terms of access to and quality of chemotherapy services?*

Some standards are applicable for some situations and not for others. For instance our facilities utilise pharmaceutical isolator technology which differs from the industry standard laminar flow safety cabinets#. Standards therefore differ depending on the method of manufacture. Third party TGA compounders are unlikely to use the isolator method.

Should TGA approval be required for all compounding this would eliminate small compounders that are not able to create sufficient volume in regional communities such as Bunbury. Consumers who currently receive a bespoke on the day of treatment infusion would be delayed by up to three days to receive an infusion. The distances travelled by our country patients can be as much as 400km. Onsite compounding is imperative for these patients.

There is little or no evidence of non compliance with standards by pharmacies and 3rd party compounders. The introduction of greater audit power should bear this in mind.

#The laminar flow cabinets use air flow as a barrier and are very effective but must be within a high class clean room with interlocking doors. The isolator is an all in one clean room and anteroom in one with a barrier between the operator and the cytotoxics. The isolator is inherently safer for the operator due to the barrier but less efficient than the laminar flow cabinet.

Other matters pertinent to funding for chemotherapy infusion preparation

Questions:

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

The administration of the PBS in the hospital environment is difficult and this is especially so in the area of chemotherapy. The disconnect between the drug chart, as a method of ordering and administration, and the PBS prescription as a method of remuneration is time consuming to administer. We have invested considerable effort and time to develop

IT systems to link the drug chart to the compounding and the PBS prescription. Much has been written about the use of the medication chart to bill PBS instead of an extra prescription. This would be an excellent help.

The claiming of PBS chemotherapy infusions requires coding of the exact disease state by the pharmacist. This is not a requirement in any other area of PBS claiming. This coding is often quite intricate and takes time for our pharmacists to ensure congruence with the treatment given.

The data available from the PBS on the calculation of what is paid for each infusion is limited. So audit and review of payments to ensure correct remuneration is difficult. There is no method to document the payment of an individual claimed infusion direct from a PBS website for instance. The data collected by the PBS claiming software is little help in this regard.

The supply of trastuzumab (Herceptin®) for metastatic breast cancer is delivered to the pharmacy free after application from the oncologist. The PBS pays the drug company for the drug. No claiming is made by the pharmacist. The pharmacy is expected to compound and deliver the drug for the patient but no reimbursement is paid for this dispensing and compounding whatsoever. The administrative burden of managing this system is onerous but again no remuneration is offered for this effort.

2. *What if anything should be addressed in relation to these matters?*

The administrative burden of PBS rules continues to increase with little consideration of the potential for efficiencies on the pharmacy side. Particularly the use of interactive website tools that allow checking of reimbursement, delivery of trastuzumab and calculations of funding expected for a particular drug dose combination. Utilising medication charts as prescriptions would relieve a major burden.

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?*

Our submission to the prior senate enquiry described concerns of application of the accelerated price disclosure arrangements. One of the reasons for concern in chemotherapy funding is that reimbursement reductions from PBS for chemotherapy medicines have been larger and faster than would have happened if data had been collected at the price pharmacy pays. See Senate Commitee Report CRShenton

We have concerns that there is an incomplete mechanism for controlling the price to pharmacy of PBS drugs. The basis of PBS reimbursement calculation of chemotherapy drugs is the Agreed Manufacturer Price. Our concern is that if a PBS drug sponsor chooses to charge above this price that there is no clear method for that manufacturer to be held to account. The cost then may be passed on to the consumer or may mean lack of access to the drug. Our experience is with Abraxane (NAB Paclitaxel) where the product sponsor charges $431.67 a 100mg vial in excess of the agreed manufacturer price of $401.48. We believe there are other examples of this practice with drugs that we do not currently dispense.

Conclusion

This reponse to the Review of funding arrangements for chemotherapy services is intentionally a concise answering of questions raised in the discussion paper. The primary value of this submission is the comparison between similar services in metropolitan and country Western Australia. We welcome any further enquiries or requests for clarification from the review committee.

Christopher Shenton MPS MACPP Bpharm, GradDipHealthEc

chris@jhpharmacy.com.au

Joondalup Hospital Pharmacy
Joondalup Health Campus WA

Southwest Hospital Pharmacy
St John Of God Hospital Bunbury WA

29 July 2013