

# **Review of funding arrangements for chemotherapy services**

**Discussion paper and call for submissions June 2013**

**SA Health Response**

## Term of Reference 1 and 2: How chemotherapy medicine infusions are provided, the role of each sector, and how services and funding roles have changed over time

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. .
  - Response: There are different models of care in place for patients receiving treatment in metropolitan and rural and regional sites (see Attachment 1 for response for rural and regional SA.). The model of care for metropolitan services involves:
    - A triage meeting whereby the medical team of Haematologists and Oncologists review referrals from general practitioners. The patient may then have to go through a workup whereby they get a full blood count, biopsies and CT staging.
    - Patients are then referred to the Multi-disciplinary Team (MDT) meeting for consideration of surgery, radiotherapy or chemotherapy. At the MDT meeting, oncologists, radiologists and surgeons decide on the treatment plan.
    - If a patient requires chemotherapy, the medical team liaise with the administration staff to book a patient for treatment as an inpatient or an outpatient (depending upon a range of factors including type of treatment, patient clinical factors, geographical factors etc.)
    - The medical officer then discusses the patient with other members of the health care team including Cancer Clinical Pharmacists and nurses regarding the decision to prescribe chemotherapy.
    - The chemotherapy prescription is either handwritten, pre-printed or electronic by the medical registrar or consultant.
    - The Cancer Clinical Pharmacist performs a thorough verification process of the chemotherapy prescription/orders. This may take up to 20 minutes per patient including review of the medical history and patient interview. They will determine the appropriateness of treatment including the treatment schedule, check complicated dose calculations, review drug-drug interactions, review drug-disease interactions, review PBS Streamline requirements and counsel patient on the their chemotherapy and supportive care drugs. The Cancer Clinical Pharmacist signs off all prescriptions to verify and document any follow up required.
    - The verified chemotherapy prescriptions are passed on to an internal or external pharmacy production unit and the Pharmacy Dispensary as appropriate. (Note a combination of in house and external providers are used (refer Q3 below).
    - The pharmacy production unit performs accuracy checks before and after the chemotherapy is compounded in the sterile environment. The most cost effective combination of vials is used as recommended by the Efficient Funding of Chemotherapy. Accuracy checks of chemotherapy involve a further check of calculations, volumes to be dispensed, concentrations and diluents required. The chemotherapy is labelled and dispensed and stored in house as appropriate or transferred to the unit as per local hospital policy.
    - The doctor or nurse performs a thorough toxicity assessment for each patient during treatment and before each cycle of chemotherapy. If a patient has a low blood count or has severe side effects the treatment may be delayed or the dose reduced. This means that expensive chemotherapy such as pemetrexed or rituximab treatment will

be put on hold until the results are communicated to the production unit. If a patient is on high risk chemotherapy, there is usually a Day 10 follow up by the doctor with daily blood checks.

- In many hospitals, patients are asked to complete a diary card to record any symptoms that may occur to enable consideration of treatment implications. The patient is given all the necessary contact details to contact staff with any questions or concerns during treatment.

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.

- See above and Q3.

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?

- Response: The number of complex chemotherapy regimens has increased significantly over the last 5 years with an impact on the resources required to both clinically verify prescriptions and to compound infusions.

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.

- Response : Refer below

**3. 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.**

- Response: Within SA Health, South Australia, Pharmacy services are provided either directly or under contract arrangement by SA Pharmacy, a statewide pharmacy service established in July 2012. Chemotherapy supply within SA is a mixture of in-house manufacture and outsourcing to third party compounders to meet current demand and take into account specific capacity issues.
- Therefore provision of chemotherapy infusions within public hospitals is the responsibility of SA Pharmacy, provided either directly via individual site based hospital manufacturing services where they exist or contracted from external compounding services for supply to patients. The supply to hospitals is part of an overall SLA agreement covering the totality of pharmacy services provided which is agreed between SA Pharmacy and the SA LHNs SA Pharmacy has individual agreements in place with a number of compounding services for specific product supply.

**4. 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?**

- Response: The safe supply of chemotherapy infusion services has a number of components, some of which are defined by national standards outlined by both the SHPA and COSA. Critical elements include;
  - Clinical Pharmacy Services: SHPA ratio's indicate a 1FTE Clinical Pharmacy resource per 20 patients. Overall functions include completion of a Medication Action Plan for each patient and for each cycle of treatment including safety checks as per COSA guidelines. Specific tasks include documentation of complex dose calculations, stability checks, drug-drug interactions, drug-disease interactions, drug toxicity assessments and patient counselling of chemotherapy and supportive care drugs as per protocols.
  - Pharmacy Production elements
    - Specialist facilities: Cleanroom / specialised equipment eg isolator
    - Maintenance of facilities and specialised equipment
    - Specifically Trained and appropriately competency assessed staff
    - There are four broad categories of compounding complexity which could be defined ranging from a one step process to complex manipulation
1. **One step manipulation** (no reconstitution or dilution) A straight draw up of the required dose into a bolus syringe that does not require reconstitution or dilution.
  2. **Two step manipulation (no reconstitution/dilution required)** A required dose of chemotherapy drug is drawn straight up without reconstitution and added to an infusion bag such glucose 5% or sodium chloride.
  3. **Two step manipulation (reconstitution/no dilution)**, The chemotherapy drug is provided as a powder and requires the addition of either water or saline to reconstitute or activate drug. The required volume is drawn up into a syringe as necessary.
  4. **Three step manipulation (reconstitution, draw up in syringe, dilution)**. The chemotherapy drug is reconstituted, the required dose is drawn up into a syringe and the dose is then added to an infusion bag as necessary.
  5. **Complex manipulations**. Chemotherapy drugs requiring complex manipulation, for example Infusors which require a complex dispensing process to fill elastomeric device, prime line and clear air bubbles.
- Multistep checking process to minimise errors including
    - Dose calculations
    - Stability assessments

- Additional Dispensary elements: With intravenous chemotherapy protocols, additional supportive care medicines are often required. This includes small quantities of tablets and liquids etc. used to prevent adverse effects associated with chemotherapy. Dispensary staff may require additional safe handling training for the dispensing of these medications.

**5. Describe in detail one or more possible options for:**

- the model of care for your institution (Described in response to Q1);
- the professional practices for the provision of chemotherapy medicine infusions (described in response to Q2);
- possible funding models for the preparation and supply of chemotherapy medicine infusions;
- the appropriate level and source of funding for each component of practice (described in response to Q6).

### **Term of Reference 1e: costs and complexities involved in the provision of chemotherapy drugs**

The Department has received information throughout the process of examining the evidence relating to chemotherapy services that there are some differences in the processes and costs for compounding certain chemotherapy drugs.

For example, the submission to the Senate Inquiry by the Australian Private Hospitals Association (APHA) highlighted certain drugs that the APHA asserted were incurring a loss per infusion. It has also been suggested that the processes involved in preparing infusions for certain drugs, such as monoclonal antibodies or proteasome inhibitors, may differ from that of preparing other drug infusions and incur different costs. Some suggestions have also been made that the relatively higher cost of some chemotherapy drugs for providers may be due to the charging practices of manufacturers or third party compounders of 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.**

- Response: There are four broad categories of compounding process complexity which could be defined ranging from a one step process to complex manipulation.

- Broad Categories

**One step manipulation** (no reconstitution or dilution) A straight draw up of the required dose into a bolus syringe that does not require reconstitution or dilution.

**Two step manipulation (no reconstitution/dilution required)** A required dose of chemotherapy drug is drawn straight up without reconstitution and added to an infusion bag such glucose 5% or sodium chloride.

**Two step manipulation (reconstitution/no dilution)**, The chemotherapy drug is provided as a powder and requires the addition of either water or saline to reconstitute or activate drug. The required volume is drawn up into a syringe as necessary.

**Three step manipulation (reconstitution, draw up in syringe, dilution)**. The chemotherapy drug is reconstituted, the required dose is drawn up into a syringe and the dose is then added to an infusion bag as necessary.

**Complex manipulations.** Chemotherapy drugs requiring complex manipulation, for example infusors which require a complex dispensing process to fill elastomeric device, prime line and clear air bubbles

- **Administration Devices:** Elastomeric infusors are devices that provide continuous chemotherapy over a number of days. A patient is connected to treatment in the outpatient department and is then disconnected by returning to the unit or having the Homecare Nurse disconnect treatment. There are 2 types of container that can be used.
- One that administers chemotherapy via a mechanical mechanism similar to balloon and another that is battery operated called a CADD cassette (both have a financial implication). The infusors contain chemotherapy such as fluorouracil and are provided in a number of different ways. Compounding of this type of preparation may take up to 20 minutes to dispense in a sterile environment.

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.**

- Response: An alternative funding model for chemotherapy services may include consideration of the complexity of manipulation required in the compounding process. There are four broad categories of compounding complexity which could be defined ranging from a one step process to complex manipulation. Remuneration could be scaled depending on the complexity of the process involved
- Broad Categories could include;

**One step manipulation (no reconstitution or dilution)** A straight draw up of the required dose into a bolus syringe that does not require reconstitution or dilution.

**Two step manipulation (no reconstitution/dilution required)** A required dose of chemotherapy drug is drawn straight up without reconstitution and added to an infusion bag such glucose 5% or sodium chloride.

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### **Term of Reference 3: Rural and regional chemotherapy provision**

#### **Questions:**

- 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.
- 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.
- 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?
- 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?
- Response: Please refer to the attachment for response regarding rural and regional chemotherapy models.

### **Term of Reference 3: 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?**

#### Approval processes

- HER2 Metastatic program – requires excessive coordination to ensure continuing supply

- Timeliness of approval of applications

Day to day operations elements:

- Unavailability of most efficient vial combination due to supply constraints. Assurances that if larger strength vials have to be utilised that these are appropriately re-imbursed.
- Process of dealing with changes mid cycle when a prescription contains repeats

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

- A consistent approach should be implemented to deal with Herceptin supply
- Item codes should be consistent to allow for interchange of vials
- Remuneration for specialised containers e.g. baxter infusors or rate limiting devices should be considered