promoting excellence in medicines management

ABN 54 004 553 806

28 April 2015

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Development of a table of standard costs for conducting clinical trials in Australia

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 3,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a core base of members practising in public and private hospitals and other health service facilities.

SHPA supports the approach of compiling the list of standard items for clinical trials and presenting the activities in three categories linked to the life-cycle of a typical clinical trial.

SHPA would like to highlight that some activities are not inherently homogenous. Considerable variations linked to the type of medicine involved, along with the complexity of services required to ensure the safe and effective delivery of these medicines, should be anticipated. As an example item 2.4.3 will have a wide variation in cost (at least a 10 fold difference) which will depend on how the medicine must be prepared to be ready to administer to the patient, any consumables that must be used and, if the trial includes the need for randomisation, whether the patient would typically be randomised during or outside 'normal' business hours.

SHPA makes the following specific comments in response to the consultation questions.

Are the principles for developing the Table of standard costs reasonable?
Are there any principles that should be modified or deleted? Should additional principles be adopted?
Please suggest wording changes and / or additional principles where necessary.

SHPA believes that the data may suggest that some activities require the identification for more than one 'standard cost'. For example should a second protocol review, that might be required in response to the Ethics review, be costed at the same cost as the initial protocol review? Principles guiding if and how more than one standard cost should be identified could be added to the current list.

Is the proposed method for deriving the standard cost for each item on the NHMRC sub-list for site authorisation reasonable?
Are there any items for which the costing approach should be modified?
Please suggest alternative costing approaches where appropriate?

Table 3.1
Yes. As noted above consideration should be given to how an activity that is repeated or requires review is costed.

Table 3.2
Item number 2.4.1. SHPA notes that the cost of this activity will be linked to the total number of staff that require training as well as the cost of delivering the training.

Item number 2.4.2. SHPA notes that in addition to labour costs the cost of this item also needs to allow for the cost of specific storage conditions e.g. refrigeration, lockable safes etc.

We also note that this activity would be required multiple times throughout the trial; therefore it may be that the standard cost reflects each batch of stock received, monitored, stored etc. (irrespective of the volume of stock) or the total cost of this activity per clinical trial (irrespective of the number of times stock is processed and managed).

Item 2.4.3. SHPA notes that in addition to labour the cost of this item also needs to include the cost of specific preparation facilities such as clean rooms, costs associated with disposing of waste (e.g. cytotoxic waste) and all consumables required to prepare the medicine for use.

As noted earlier this activity will have a wide variation in cost (at least a 10 fold difference) which will depend on how the medicine must be prepared to be ready to administer to the patient, any consumables that must be used. In addition, if the trial includes the need for randomisation, whether the patient would typically be randomised during or outside 'normal' business hours which will result in additional labour costs.

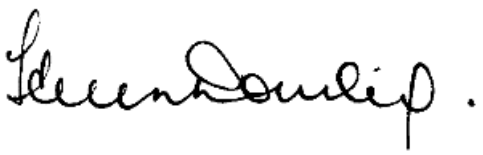
Table 3.3
Item 3.3.1. SHPA notes that this activity may be required multiple times throughout the trial; therefore it may be that the standard cost reflects each batch of stock returned or destroyed (irrespective of the volume of stock) or the total cost of this activity per clinical trial (irrespective of the amount of stock returned or destroyed).

Is there a need to provide for adjustments to the standard cost based for the identified factors? Are there other factors that should be considered for potential adjustments to the standard costs?
Please suggest methods for adjusting standard cost to account for the factors where considered necessary?

SHPA believes that the data may suggest that some types of clinical trials are inherently more expensive and an adjustment may be warranted; for example clinical trials involving chemotherapy medicines.

If you would like to discuss the contents of SHPA's submission or require further information, please do not hesitate to contact Karen O'Leary (koleary@shpa.org.au or 03 9486 0177).

Yours sincerely,



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