Dose Banded Chemotherapy Standardised Products Specifications Stakeholder Testing Briefing

Background

In May 2016 NHS England published national standardised chemotherapy dose bands covering 18 drugs. The next step has been to define NHS standard product specifications for each standard banded dose of chemotherapy drug, to aid implementation of the dose bands across the NHS. Currently NHS Trusts have different requirements for their own product presentations and hence those they outsource. This has led to a large number of similar, but not identical, products being requested from NHS & commercial compounding units. Often these differences are nuanced with little or no patient benefit, based on local decisions & preferences with little or no regard for consistency across the wider NHS, and the impact this has on costs & efficiency i.e. a large number of unwarranted variations. In turn this has placed pressure on compounding units and companies to fulfil bespoke orders, and has impacted on the limited aseptic capacity nationally.

Benefits of Standardised Product Specifications for the NHS

The availability of NHS standardised chemotherapy product presentations will enable Trusts to more readily be able to outsource 'off the shelf' products from both NHS & commercial suppliers. Currently the bespoke requirements of most Trusts are different and preclude 'off the shelf' orders in many cases. It is expected that defined product presentations will deliver cost & efficiency savings through economies of scale, as well as improved order turnaround times from suppliers through not needing to compound bespoke products to order and the ability to predict regular usage for each national standard product line. This will lead to better utilisation of the nationally limited aseptic compounding capacity (NHS & commercial).

Ultimately having a defined list of national chemotherapy product specifications may lead to licensed ready to use standard dose banded chemotherapy products becoming available from industry.

Stakeholder Testing

Standard product specifications have now been produced for all the CQUIN1 dose banded chemotherapy drugs (*link to specification spreadsheet*). The specifications are laid out in the following order - syringes, devices, infusion bags and then alphabetically within each group. Respondents are asked to comment generally on the following aspects (i.e. whether in agreement with the criteria or not, and whether anything has been overlooked?) using the comments form *(link)*:-

1) General Specification Requirements
2) Individual Drug Specifications for syringe, elastomeric device and infusion presentations

Respondents are asked to comment on the following in more detail using the comments form *(link)*:-

3) To complete the scoring/ranking system for the various infusion bag labelling options (see below). N.B. It is recognised that this will potentially cause the most difficulty for Trusts as several different conventions are used throughout the NHS. Nevertheless, a single labelling convention is sought for chemotherapy infusion bags to reduce unwarranted variations for suppliers (NHS & commercial), and to maximise efficiency gains. Inevitably this will mean a change of practice for some centres in order to comply with the national product specifications. It is also recognised that none of the options listed below are perfect or absolutely accurate, but there is a need to compromise on the most acceptable option for the NHS via this stakeholder testing.

   Consideration needs to be given to the perceived benefit of accuracy for each option weighed against any disadvantages and risks in achieving it. With most options there will be a discrepancy between the volume infused and the volume or infusion rate stated on the electronic prescription (system dependent). In these circumstances nursing staff will need to be covered to make this amendment to the infusion rate, or allow the infusion to run for longer. It is assumed that this is already practice in many Trusts, and it would be helpful to indicate this on the comments form.

4) Do you agree with the Tallman lettering provided for each product, if not please suggest alternatives?
5) Should both strengths of Fluorouracil be included in the device specification?
   N.B. It will be necessary to include both in the syringe & infusion bag specifications.
6) Should both 500ml & 1litre bag sizes be included as options for Cisplatin infusions due to non-standardised hydration regimens used by different Trusts (which is out of scope at this stage)?
7) Any other comments?

Infusion Bag Labelling Options

A) Label as the nominal bag volume plus addition volume. Where it is necessary to remove some volume from the bag in order to add the total dose, the label shall state the nominal bag volume plus the net addition volume. The nominal bag overage should not be included within the volume stated on the label.
   Commentary – For Drug X labelled as 100mg in 270ml the electronic prescription (system dependent) may read Drug X 100mg in 250ml, which can cause problems for nursing staff. In some Trusts nursing staff use the volume stated on the label to set the infusion rate rather than from the prescription in this example 270ml rather than 250ml.
B) Label as nominal bag volume only with the added instruction stating to give the whole contents of the bag including overage.
   Commentary - In this case the addition volume is unknown and hence the total length of the infusion is also unknown which can be significantly longer than expected if just

based on a nominal volume of e.g. 250ml. This may also impact the capacity on chemotherapy units with longer chair times.

C) Label in approximately xxxml (being the total of the bag nominal volume, the nominal overage and the net additions), with the added instruction stating to give the whole contents of the bag including overage.
   Commentary – as in B above, the total length of the infusion is unknown which can be significantly longer than expected and may also impact the capacity on chemotherapy units with longer chair times.

D) Remove an equal volume to the addition volume from the bag before making the addition, and label as the nominal bag volume e.g. 250ml.
   Commentary – Unless required for concentration dependent stability this is an unnecessary extra aseptic manipulation which potentially can compromise sterility of the end product. It is also less efficient in terms of time, capacity and cost, and also increases error potential for confusion between the removed diluent and the drug solution. On the face of it this provides an accurate final volume, but as the bag overage can vary it is no more accurate than the other options.

E) In addition to D above remove the nominal or measured overage from the bag and label as the nominal bag volume e.g. 250ml.
   Commentary – The bag overage varies from manufacturer to manufacturer and batch to batch, therefore bags have to be weighed and knowledge is required of the specific gravity of the infusion solution and the weight of an empty bag in order to calculate the overage. As in D above this is an unnecessary extra aseptic manipulation which potentially can compromise sterility of the end product. It is also less efficient in terms of time, capacity and cost, and increases potential for errors as in D above.

F) Nursing staff disregard the volume stated on the label and infuse the volume stated on the prescription.
   Commentary – This potentially can lead to under dosing if the addition volume isn't taken into account. See A above for an alternative approach.

G) Nursing staff disregard the volume stated on the label and weigh the infusion bag to determine the total volume to infuse. Or aseptic services weigh the final bag and calculate the 'accurate' volume and add an additional label (as the actual label has already been printed by then).
   Commentary – Whilst this is practice in some Trusts, it would require chemotherapy units to be trained to use weighing balances. As in E above knowledge is required of the specific gravity of the infusion solution and the weight of an empty bag in order to calculate the total volume in the bag. It is also less efficient in terms of nursing time, unit capacity and cost, including regular maintenance & calibration of the balance equipment. However, this does give the opportunity for a final QC check on bag weight if performed in Pharmacy.

H) Please provide any other labelling options not listed above.

The stakeholder testing will be open until - *date TBC*