Dose Banded Chemotherapy Standardised Products

Background

In May 2016 NHS England published national standardised chemotherapy dose bands covering 18 drugs (see here). The next step has been to define NHS standard product specifications for each standard banded chemotherapy drug, to aid implementation of the dose bands across the NHS. Historically NHS Trusts have defined 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 and commercial compounding units. Often these differences are nuanced with little or no patient benefit, based on local decisions and preferences with little or no regard for consistency across the wider NHS, and the impact this has on costs and efficiency i.e. a large number of unwarranted variations. In turn this has placed pressure on NHS compounding units and commercial aseptic compounding companies to fulfil bespoke orders, which has impacted on the limited aseptic capacity available nationally.

Phase 2 of the NHS England Chemotherapy Dose Standardisation Improving Value Outline Business Case (Oct 2016) sought to achieve standardised chemotherapy product specifications to enable Trusts within England to reduce these unwarranted variations in the products they either compound in house or outsource externally, and thereby release compounding capacity for other activities.

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 and commercial suppliers. Historically the bespoke requirements of most Trusts have been different and precluded 'off the shelf' orders in many cases. It is expected that defined product presentations will deliver cost and 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 available (NHS and commercial).

Ultimately having a defined list of national chemotherapy product specifications should lead to licensed ready to use standard dose banded chemotherapy products becoming available from industry. One such product (Gemcitabine) is already available as licensed infusion bags covering some of the national dose banded doses. Other drugs are understood to be in the pipeline for development as licensed products.

Stakeholder Testing

Standard product specifications were produced by an expert group for all the CQUIN1 dose banded chemotherapy drugs, as well as overarching general specification requirements.

Stakeholder testing was undertaken in February 2017. The following stakeholders were invited to respond:

NHS Chief Pharmacists
NHS Pharmaceutical Quality Assurance Committee
NHS Pharmacy Production Committee
Specialised Pharmacy Services including Pharmacy Procurement Specialists
NHS Pharmaceutical Aseptic Services Group
British Oncology Pharmacy Association
UK Oncology Nursing Society
DH Commercial Medicines Unit
Commercial Aseptic Compounding Companies

Respondents were asked to comment generally on the General Specification Requirements as well as the Individual Drug Specifications for syringe, elastomeric device and infusion presentations. Respondents were also asked to comment on the following questions in more detail. Specifically:

- To rank the various infusion bag labelling options provided and how nursing staff in their organisation dealt with these different options.
- To agree/disagree with the Tall Man lettering provided for each product and suggest alternatives.
- To agree/disagree whether both available strengths of Fluorouracil raw material should be included in the device specification.
- To agree/disagree whether both 500ml & 1 litre infusion bag sizes should be included as options for Cisplatin infusions.
- To provide any further comments.

A brief summary of the responses received is provided in Appendix 1, and the review of these with decisions made to make changes to the standard product specifications in Appendix 2.

It was recognised that the various infusion bag labelling options would potentially cause the most difficulty for Trusts as several different conventions are used throughout the NHS. Nevertheless, a single labelling convention was sought and required for chemotherapy infusion bags to reduce unwarranted variations for suppliers (NHS and commercial), and to maximise efficiency gains. Inevitably this would mean a change of practice for some centres in order to comply with the national product specifications. It was also recognised that none of the options provided were perfect or absolutely accurate, but there was a need to compromise on the most acceptable/least worst option for the NHS via the stakeholder testing undertaken.

It is further recognised that the various Chemotherapy ePrescribing systems used by Trusts lack flexibility to be able to comply with the preferred (compromised) standardised product specification infusion bag labelling option selected. Engagement with the system providers is required to overcome this as a separate initiative, and is being taken forward.

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