North Cumbria University Hospitals NHS Trust

Aseptic Services

Options Appraisal 2013

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### Approved by:
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### Version History

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### List of Stakeholders who have reviewed the document

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Executive Summary

This options appraisal has been developed to assist a decision about the future manufacturing of aseptically prepared pharmaceuticals in North Cumbria, taking into consideration the fabric of existing facilities, changes in the delivery of cancer services and the requirement for a comprehensive reconstitution service for high risk or high volume intravenous medicines.

Currently, there are two aseptic units, one on each acute site. The facilities at Cumberland Infirmary are not suited to the range and volume of products prepared currently. The facility at West Cumberland will not exist in its present position the new build. Neither facility at present is equipped to deal with the volume of production entailed in a permanently centralised service. In 2000, Payne et al\(^1\) undertook a meta-analysis of the impact of travel on uptake of chemotherapy and compliance with regimens. Whilst inconclusive, this study suggests that at the very least increased travel time is inconvenient, a practical hardship and may be experienced or perceived as a barrier to treatment; thus any centralisation of manufacturing services must ensure that it is products which are transported between sites rather than patients.

Both units operate over capacity and significant changes will need to be made to fully embrace the future. A strategic decision has already been made that there will be a single unit providing aseptically prepared products to both sites. The preferred location is Cumberland Infirmary, Carlisle.

Introduction

In 2007, the NPSA Alert 20\(^2\) – promoting safer use of injectable medicines – reiterated the findings of EL(97)52\(^3\) that aseptic dispensing is “an increasing and demanding activity which should be carried out under the control of a pharmacist in suitable facilities to avoid the additional risk of microbiological contamination and medication errors associated with the preparation of parenteral medication at ward level.” As such, the amount of aseptic dispensing carried on in hospitals should increase rather than decrease.

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2. NPSA Alert #20 – Safer use of injectable medicines


3. EL (97) 52 – Aseptic dispensing in NHS Hospitals

EL_97_52.pdf
As far back as 1995, the Department of Health’s expert advisory group on cancer\(^4\) identified that the incidence of cancer was increasing with the incidence of breast, prostate and skin cancer rising faster than might be expected from an aging population. Trust FFCE data suggests that there are currently an average of 400 FFCE’s per month in oncology and haematology. Significant changes in the way that oncology clinics are operated are underway.

**Existing facilities and services**

There are currently two aseptic preparation units in the Trust, one at West Cumberland Hospital, Whitehaven and the other at the Cumberland Infirmary, Carlisle. Neither unit holds a manufacturing licence and both operate under a Section 10 exemption to the Medicines Act 1968. This requires:

- Supervision of a pharmacist for all medication prepared
- Preparation of only patient-specific doses in response to a signed prescription
- A maximum expiry of 7 days for any product
- Final release of all products by a pharmacist.

Both sites operate between Monday and Friday, excluding Bank Holidays. Current staffing with a two site model does not allow for a weekend service, or to extend the service later during the day, but the possibility of extending the service beyond the current hours requires exploration, since there is an increasing move towards 7-day working and an extension to traditional out-patient clinic hours. Both sites have staff skilled in the preparation of aseptically prepared chemotherapy, parenteral nutrition and other intravenous products including monoclonal antibodies and intraocular injections. TPN preparation differs on each site and requires review. A proposal to use pre-made bags on wards without the addition of vitamins and minerals, and without adequate remedy for electrolyte imbalance is contrary to NICE Guidance\(^5\) and should not be considered.

**Capacity**

Both sites are operating over capacity. The most recent external audits on the units have identified capacity as a potential issue and have recommended that capacity is monitored closely. Close inspection of the manufacturing figures show that the units are dealing with comparable numbers of manufactured items including cytotoxics, TPN and biologicals as a whole.

Each site uses the other unit as part of its contingency plan for emergency or planned downtime. There is a possibility that post-acquisition, the site at Wansbeck could be used either in totality or as contingency.

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\(^4\) EL (95) 51

\(^5\) NICE CG 32, Department of Health, Feb 2006

Cumberland Infirmary:

The aseptic suite is over 10 years old and is integral to the pharmacy department. An external QC inspection has identified that the air handling unit does not meet current standards\(^6\). Preparation of cytotoxic products is undertaken in a 4-glove isolator and other products are manufactured in laminar flow cabinets. Most use is made of the isolator, which operates at capacity.

West Cumberland Hospital:

The aseptic unit is adjacent to the Henderson Suite in a bespoke modular unit linked to the main out-patient department and served by a separate alarm system linked to the switchboard. The facility is 6 years old and has its own air handling plant which meets current standards. It contains a 4-glove negative pressure isolator and a 4-glove positive pressure isolator. The staff numbers do not allow either isolator to be operated at capacity at all times. The proximity of the unit to the chemotherapy out-patient unit has been exemplified as best practice.

**Impact of dose-banding**

Guidelines for dose banding in chemotherapy have been written by Williamson\(^7\) on behalf of the North of England Cancer Network and it is apparent that NHS England and the Specialist Commissioners will, in future, expect a proportion of chemotherapy to be delivered as a dose banded product. The number of products identified as being suitable for dose banding represents 40% of the chemotherapy products prepared between the two units at present. Significantly increased storage capacity will be required, particularly fridge space. More administrative support will be required to implement dose banding, and an increase in Band 3 staff as a combination of ATO and clerical positions is suggested.

A reduction in aseptic manufacture of chemotherapy products will increase the available capacity of the unit(s) to deal with either high risk or frequently used intravenous additives for in-patients, bringing the Trust towards some degree of compliance with the NPSA Alert Number 20.\(^8\)

**Homecare provision**

Delivery of medicines to patients in their own homes, with or without nurse administration, has increased in the last 12 months. There are significant savings to be made on some products (mainly oral chemotherapy) but those products

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\(^6\) External audit review, A. Beaney 2012


\(^8\) NPSA Alert #20 – Safer use of injectable medicines
requiring nursing administration generally cost the same as the purchase of the product within the hospital. It does have the advantage, however, of releasing capacity both in clinic and in the pharmacy aseptic units, although there is a significantly increased administrative burden placed on ordering and invoicing staff. Previous arrangements for sharing cost savings with the CCG ended in July 2013 and have not been re-negotiated. The staffing and administrative requirements for the increased use of homecare with appropriate funding and a gainshare model is part of a separate business case.

In the last 12 months, there have been increased numbers of patients in gastroenterology and rheumatology who have been able to use this service and discussions have been held regarding the potential for out-patient IV antibiotic administration which will considerably reduce the pressure on community services.

**Clinical services**

Clinic capacity has increased over the last few years and the cytotoxic preparation workload has increased for the pharmacy department both in terms of actual numbers and complexity of preparation. Staffing numbers, however, have not increased overall and the increasing demands of areas other than oncology and haematology have put additional pressure on each unit. Phase III trial data show that there is likely to be an increasing number of preparations on the market, some of which are timetabled to be considered by NICE\(^9\). Planning of various clinics requiring manufacturing services needs to be co-ordinated by the aseptic unit(s) since the preparation of products is the rate-limiting factor. The introduction of e-prescribing for chemotherapy may go some way towards more efficient planning of chemotherapy clinics, but control of chair times must be held by pharmacy to some extent since there are clinics other than oncology and haematology to consider and in the future, preparation of cytotoxic chemotherapy will not, therefore, form the majority of the business of any aseptic preparation unit.

There is a significant body of evidence to suggest that glutamine-supplemented parenteral nutrition improves outcomes and reduces costs in ICU patients\(^10\), there appears to be a paucity of evidence suggesting that it can be infused separately and thus requires addition to the TPN bag in aseptics. Addition of vitamins and

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9. Phase III aug11.doc

minerals is also required, along with the scope to amend nutritional requirements and correct electrolyte balance. Additions to parenteral nutrition should be made in a pharmacy aseptic unit.\textsuperscript{11}

Increasing the ability to prepare high risk or high volume intravenous additives in the aseptic unit(s) has the support of the Medical Director and is urgently required to minimize the number of errors made when high risk IV’s are prepared at ward level in compliance with NPSA Alert 20.

Staffing levels within the WCH new build are based on existing services and there are no plans for additional staffing funding to provide additional pharmacy services. There is a requirement for the pharmacy to be registered with the General Pharmaceutical Council and the presence of a Responsible Pharmacist is therefore a legal requirement. This will mean that of approximately 6 WTE pharmacists (2.0WTE of whom have cross-site roles), 1.0WTE will always be required in the pharmacy department. Plans have been proposed that the Accountable Pharmacist in aseptics will also assume the Responsible Pharmacist role for a significant part of the day to comply with legal requirements, allowing the clinical pharmacists to provide near-patient care.

Current staffing structures are based on running two separate units and will therefore require a complete review. It is unfortunate that the NCN capacity planning tool is not suited to providing an indication of staffing required on an annual basis, but there are centralised aseptic services in Durham and Darlington, Blackburn and Burnley, Northumbria and Lancashire Teaching Hospitals. Once the degree to which the use of homecare and dose banding have been properly established, a benchmarking exercise can be undertaken to review staffing and management structures to provide a staffing model for a centralised service.

**Cost of refurbishment and new build**

Refurbishment of the CIC facility would need to be undertaken whilst there is still a unit available at WCH to ensure continuation of a service to patients. Building a new unit within the new build at WCH could be undertaken before the current unit is demolished and would be commissioned prior to the move in to the new build, ensuring that there would be service continuation across both sites and enabling production in the new unit to begin for both sites whilst the current units are decommissioned.

Quotes based on the URS for the new build at WCH have been received. The specification for either a partial or complete refurbishment of the facilities at CIC has been based on the URS for WCH. Costs are based on an average of 3 quotes.

\textsuperscript{11} Patients who need parenteral nutrition should have their nutritional requirements determined by healthcare professionals with the relevant skills and training in the prescription of nutrition support. Before using most parenteral nutrition products, micronutrients and trace elements should be added and additional electrolytes and other nutrients may also be needed. Additions should be made under appropriate pharmaceutically controlled environmental conditions before administration.\textsuperscript{,} NICE Clinical Guideline 32, 2006, Department of Health [http://www.nice.org.uk/nicemedia/live/10978/29978/29978.pdf](http://www.nice.org.uk/nicemedia/live/10978/29978/29978.pdf)
New build at WCH:

Within the confines of the department itself, an aseptic unit housing 4 isolators would cost approximately £340,000.

Refurbishment of CIC:

To provide a 3-isolator fit-for-purpose unit at CIC, including reprovision of ducting to ensure it meets current standards, is approximately £500,000 (£390,000 for the work on the unit and upwards of £100,000 for reprovision of the duct work).\(^{12}\)

On either site, adequate fridge storage for dose-banded products, approximately £9000; for storage of prepared items prior to administration, £2500-4000.

Overheads

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Opinions of existing staff.

Following a consultation exercise with all staff in Aseptic Services in June 2013, the majority opinion was that a new build at WCH would provide an environment.

\(^{12}\) “From the drawings of the ventilation scheme... the ductwork ris[es] to Level 3 where the air handling plant is... [T]he Cyto Isolator and the Class 2 exhaust system are linked into the room extract system. I have never seen this done before anywhere else, and we would certainly not recommend this approach. There is a significant risk of contamination of ductwork and the air handling extract unit all the way to the Plant Room, especially from the Cyto Isolator...Looking at the risers through the building it is apparent that there is absolutely no space for additional ductwork, so this is a significant issue if the air handling plant is found not to be large enough. I think there will be a problem with the plant, from the filter sizes and layout of the grilles in the rooms and the lack of low level return air ducts, particularly in the Isolator Room, the Laminar Flow Room and the Class 2 Room.” E-mail correspondence, R Phillips, Mach-Aire 22/08/2013.
that was fit for purpose, and facilitate productivity. In addition, it was felt that this
option would be the most likely option to optimise pharmacy staff engagement
with patients and other clinical staff.

**Options**

The proposed options assume that there will be an increase in homecare
provision for both cancer chemotherapy and biologicals, together with the use of
dose-banding for chemotherapy. In turn, these create capacity to manage the
manufacture of high risk or high volume intravenous medicines.

Option 1 – maintain 2 units
Option 2 – close WCH unit and centralise service at CIC
Option 3 – close CIC unit and centralise service at WCH
Option 4 – close both units and purchase service from a third party

Following a request from the Shadow Board in October, further options were put
forward following input from Estates experts.

Option 1 Refurbish Existing Department at CIC
Option 2 Refurbish and Extend Existing Department at CIC
Option 3 New Stand Alone Unit at CIC.
Option 4 Fit out of New Build at WCH.
Option 5 New Stand Alone Unit at WCH.
Option 6 New Stand Alone Unit Off Site (Off Site Construction).
Option 7 New Stand Alone Unit Off Site (Rented Industrial Unit).

The advantages, disadvantages and risks of each option have been considered
previously. The increased use of appropriate homecare and the introduction of
dose banding for cytotoxic chemotherapy are without question. It is the opinion of
the Trust that a single aseptic production unit is required, although the opinion of
external QC is that maintenance of a unit on each site is the most sensible option
given the geography involved and the poor road infrastructure between the two
sites. Cumbria Overview and Scrutiny Committee were assured in January 2012
that an aseptic preparation facility did form part of the plans for the new WCH
build.\(^\text{13}\)

**Conclusion**

Closing one or other unit will not make staff savings or efficiency savings. The
Shadow Board recommend Option 2 – to centralise the Aseptic Unit at Carlisle
and refurbish and extend the existing department at CIC.

\(^\text{13}\) [http://councilportal.cumbria.gov.uk/documents/g6969/Public\%20reports\%20pack\%2031st-Jan-