Aseptic Compounding Services, Past, Present & Future: The English National Health Service Experience

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Objectives

• Outline the recent history of pharmacy aseptic compounding services to the NHS in England

• The current status and the challenges facing aseptic services

• An overview of the findings and recommendations of an ongoing national programme of work to develop and implement a national strategy for service development

The National Health Service

Development of aseptic services in England

1994 April: Death of 2 children following administration of contaminated TPN - 2 more “very seriously ill”

“A very seriously ill” Baby died at Chase Farm Hospital Apr 2006

• Bag made at G & St T’s

• “40% glucose instead of 4% after the wrong number was entered into a mixing machine”

1995 Aug: “Farwell” Aseptic Dispensing for NHS Patients

1996: MCA audit of a sample (10%) of unlicensed services in 6 ELN:PS1: Aseptic Dispensing

1997: Internal audit of all unlicensed aseptic preparation units in NHS Hospitals

1997: EL(97)52: Aseptic Dispensing in NHS Hospitals

2006: UK – Death of baby in London – too much glucose

2014: UK – 3 babies die – 22 infected with Bacillus cereus

2018: UK – Lady dies – suspected overdose – picking error

Licensed vs unlicensed

Aseptic preparation of medicines is an important part of the service provision by pharmacy departments to facilitate accurate and timely administration of injectable medicines for patients.

MHRA Special Licenses

A licensed unit holds a ‘Specials’ License granted by the MHRA. This allows the unit to manufacture products without a product license or marketing authorisation.

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<th>MHRA Special Licenses</th>
<th>Unlicensed—Section 10 exemption</th>
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<td>A licensed unit holds a ‘Specials’ License granted by the MHRA.</td>
<td>Aseptic preparations in the UK are only exempt from the licensing requirements of the Medicines Act 1968 and subsequent amendments provided all of the following conditions are met (MCA 1992):</td>
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<td>Licensed units can:</td>
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<td>• Manufacture products and sell them to external customers</td>
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<td>• Assign extended expiry dates to products provided they’re supported with stability data</td>
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<td>As aseptic preparations in the UK are only exempt from the licensing requirements of the Medicines Act 1968 and subsequent amendments provided all of the following conditions are met (MCA 1992):</td>
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<td>The preparation is done by or under the supervision of a pharmacist who takes full responsibility for the quality of the product</td>
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<td>The preparation is done in closed systems</td>
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<td>The components or ingredients used to prepare the products are manufactured under aseptic conditions</td>
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<td>Products will be allocated a shelf life of no more than one week. The shelf life should be supported by stability data</td>
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<td>All activities should be in accordance with defined NHS guidelines</td>
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NHS Improvement
Long term ambition for NHS aseptic services

The findings highlight a need for the long-term ambition for NHS Aseptic Services to focus on the following principles, aligned with the NHS Long Term Plan:

- Enhance network collaboration between clinical and non-clinical teams to increase the scope of services (e.g. non-grown products) and enhance the focus on NHS organizations working with high-locally procured products.
- Support more efficient and effective use of the operational workforce to improve services and reduce unnecessary patient costs and opportunities for improvement. Improved labor standards and time and motion analysis are required.
- Invest in an evidence-based strategy and support the long-term sustainability and resilience of NHS aseptic services.
- Invest in a national framework for innovation, which would develop and implement the next generation of technology and bioprocesses.

Now – Optimisation opportunities

To provide the current cost position of facilities representing all 5 archetypes identified in phase I, which will be used to model the cost optimisation model.

Costed models
- Draft model for key variables of cost
- Cost optimisation model

Best practice framework
- Business case & strategies
- Long-term financial model

Implementation plans
- Transition roadmap & guidance

Model Hospital Integration
- Minimum dataset & metrics

Cost position of facilities based on the different archetype supply models

Key findings from the data:
- Average cost per dose decreases as the proportion of total products that are outsourced increases. However, majority in house supply also have relatively lower costs per unit.
- Pay costs and service & maintenance costs are the main drivers of variable costs.
- Economies of scale are related to product complexity, the greater the complexity of a product the greater the savings that can be made.
- On average, supplying other trusts and carrying out clinical trials are not profitable.
- Facilities do not appear to be using their MS licence or using it to hire lower bands of staff.
- The cost of wasted products has an immaterial effect on the overall cost per unit.

Strategic Goals and Transformation Levers

NHS Improvement recognises the opportunity to transform Aseptic Services in order to:
1. Improve quality, productivity and resilience towards more sustainable NHS services.
2. Ensure patient access and safety to the medicines provided by these services.
3. Optimise the use of capital to upgrade, automate and future-proof Aseptic Services.

In phase II, we have identified 4 strategic levers to enable transformation and improve sustainability, resilience and productivity in NHS Aseptic Services: PLUS one overarching principle.

Business Approach for Transformation

- Standardisation: Standardising practices, reducing manual work, and increasing the use of technology.
- Automation: Automating processes, reducing variability, and increasing efficiency.
- Outsourcing: Outsourcing non-core activities, reducing costs, and increasing focus on core services.
- Resilience: Enhancing resilience, ensuring continuity of supply, and increasing the focus on patient safety.
Adopting a business-like approach for transformation

Business Approach for Transformation
Adoption of enabling business capabilities to manage aseptic services to drive well-governed services and insight-driven decision making.

2 potential stages in transforming aseptic services:

1. Apply a business-like approach to understand resources, portfolios, demand, and performance.
2. Define the conditions for successful proactive collaboration.
3. Learn, improve, and optimise collective scale and expertise.

Objectives

‘To confirm the NHS strategic direction for pharmacy aseptic services’

- Provide the Target Operating Model for pharmacy aseptic services
- Review legislative, regulatory, and commissioning frameworks
- Strategic investment options for alternative futures

English Pharmacy Aseptic Services Transformation Board

Chaired by Lord Carter of Coles
To confirm the NHS strategic direction for pharmacy aseptic services in England

CALL FOR EVIDENCE
nhsi.asepticmedicines@nhs.net

English Pharmacy Aseptic Services Transformation Board

Call for Evidence

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Outline Timeline 2019/20 for review:

- Prospects published: Call for evidence open
- Invitations to give oral evidence: From November 2019
- Report to Ministers: February 2020

English Pharmacy Aseptic Services Transformation Board

Call for Evidence

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