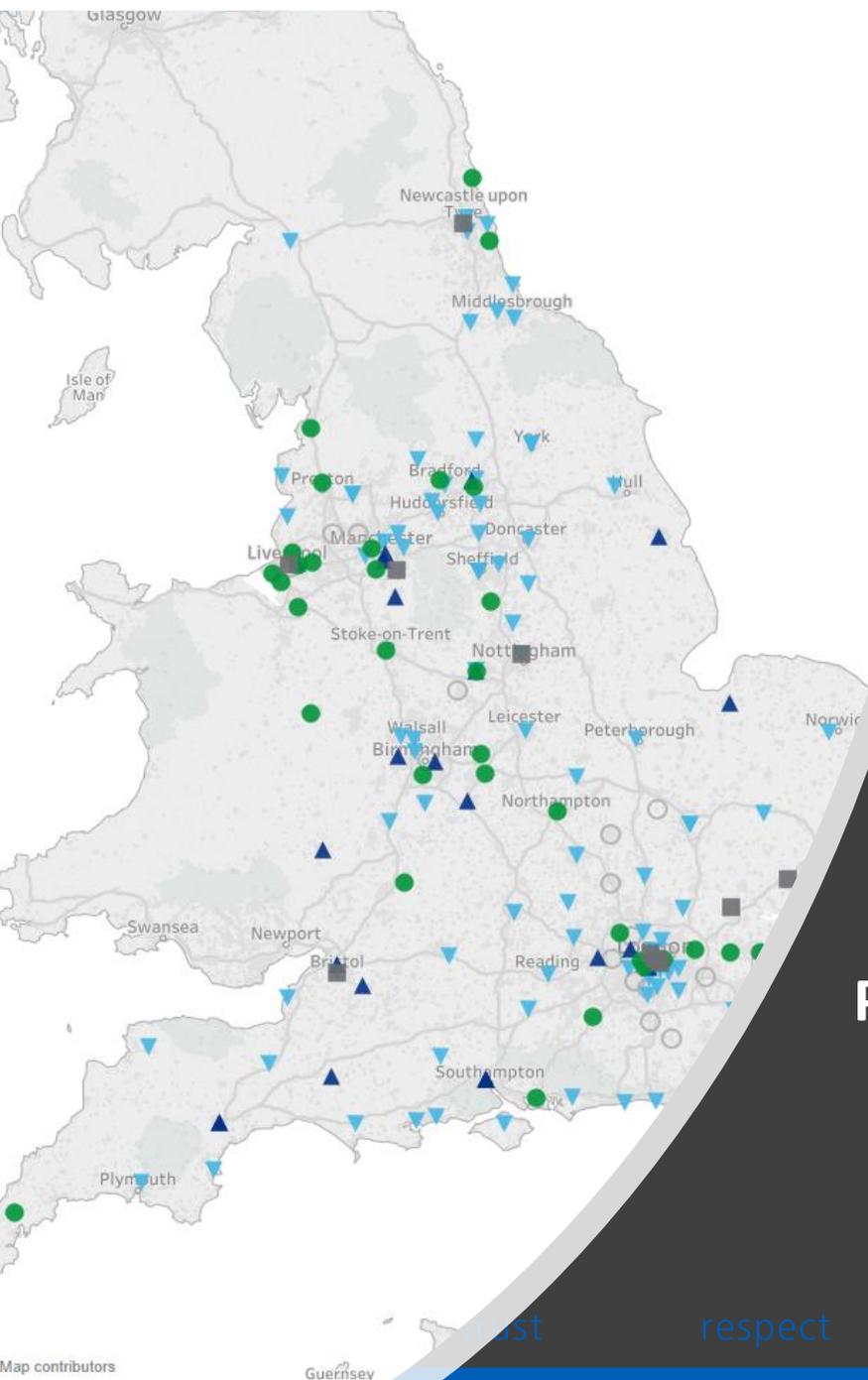


# The Future of Pharmacy Aseptic Services in England

Pharmacy & Medicines Optimisation Team

February 2019



# Introduction

## Context

A key recommendation from Lord Carter's report "Operational productivity and performance in English NHS acute hospitals: Unwarranted variations" is to shift the balance of activity in the pharmacy workforce from essential pharmacy infrastructure services to clinically facing roles.

Each non specialist acute trust in England then produced a Hospital Pharmacy Transformation Plan (HPTP) by April 2017. Many of these contained plans to **change and consolidate** aseptic services, through new service delivery models and exploitation of technology to free more clinical pharmacy time for patient facing activity. At the same time there is **constant** growth in the volume of products that need aseptic manipulation and preparation and the acknowledgement of **significant fragility** in the commercial sector.

Thus to inform decision making, NHS Improvement undertook a review of the provision pharmacy aseptic services including MHRA licensed, unlicensed and outsourced (both from NHS Providers and non-NHS commercial suppliers) activity. Product categories included in the review are chemotherapy, parenteral nutrition, clinical trials / investigational medicinal products, and pharmacy-led radiopharmacy.

Specific aspects of these services on which information was sought included: geographical location, capacity (staff and facilities), estate & equipment, management structure, staffing establishment, operational costs, service hours, range of products & services provided, and customer base.

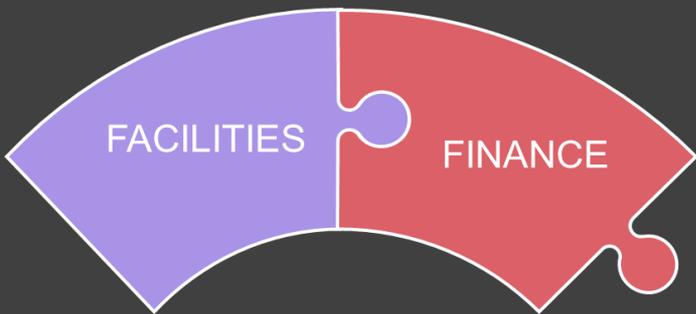
## Aim

**To deliver a safe, efficient and resilient aseptic service that is responsive to future developments**

## Medicines Value Programme Board

The MVP Board has been asked to support the proposals for phase two of the review, endorse the quick wins, including the funding of stability testing for aseptically prepared products, and fund the external consultancy to create a roadmap for implementation.

# Phase I Findings



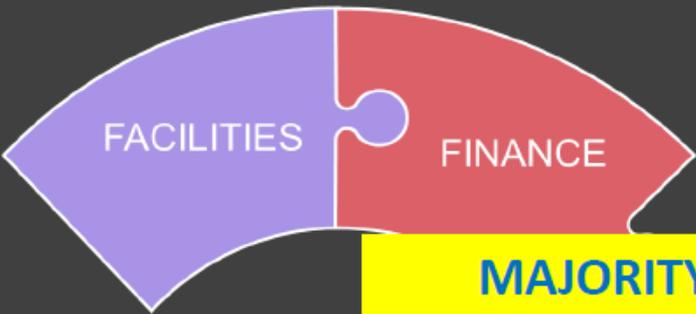
- 649 installed workstations
  - 403 workstations & equipment is near the end of its design life
- Laminar flow cabinets tend to be older and in poorer condition than isolators /AHUs
- Layout & spatial proportions of estate and poor reliability of equipment have prevented 37 Facilities from offering desired services

Product category # Trusts <sup>2</sup>	Volume growth rate <sup>3</sup>			Change in growth rate	
	2015/16 to 2016/17	2016/17 to 2017/18	2 year CAGR		
<b>Chemotherapy</b> (n = 115)	4.9%	4.8%	<b>4.8%</b>	Constant growth	
<b>Parenteral Nutrition</b> (n = 110)	4.7%	8.0%	<b>6.3%</b>	Acceleration in growth driven by increase in Adult PN	
<b>Clinical trials</b> (n = 68)	<b>Cytotoxic</b>	2.5%	0.6%	1.5%	Deceleration in growth
	<b>Overall</b>	1.7%	0.8%	<b>1.2%</b>	Deceleration in growth
<b>Antibiotics</b> (n = 22)	1.7%	0.0%	<b>0.9%</b>	Deceleration in growth	

Unless products are designed to remove the need for manipulation, it is likely that the need for aseptic manipulation will also continue to increase

There are workstations that are significantly under-utilised during current opening hours

Lack of room, too few workstations, and inability to segregate product categories are key constraints



**MAJORITY of facilities unable to provide maintenance and servicing costs – poor understanding of costs!**

**219 pieces of equipment not in use (167 in good condition)**

**On average ~ 6 Aseptic Facilities per annum are likely to need replacement or refurbishment, each costing £6.6k - £9k/m<sup>2</sup>**

**On average ~29 isolators per annum are likely to need replacement, each costing £30k - £52k/m<sup>2</sup>**

- 649 installed
- 403 workstations & equipment end of its life
- Laminar flow cabinets tend to be older and in poorer condition than AHUs
- Layout & spatial constraints of estate and placement of equipment prevented 37 Facilities from offering desired services

Product category	Volume growth rate <sup>3</sup>	Year AGR	Change in growth rate	
		8%	Constant growth	
Parenteral Nutrition	4.7%	8.0%	6.3%	Acceleration in growth driven by increase in Adult PN
		5%		Deceleration in growth
(n = 68) Overall	1.7%	0.8%	1.2%	Deceleration in growth
		9%		Deceleration in growth

...remove the need for manipulation, it is likely that the need for aseptic increase significantly under-utilised during current opening hours

Lack of room, too few workstations, and inability to segregate product categories are key constraints



- Licensed Facilities have a greater proportion of band 2-4 staff and a lower average labour cost
- S10 Facilities use more time from band 7 to 8 Pharmacists and Technicians

- Staff turnover greater than the British average (15-20%); highest vacancies @ Band 7 level (c.14%)
- Training schedules for Assistants & Technicians varies between <2 weeks – 7 weeks

- No consistent methodology
- Overtime a weekly occurrence for 41% of facilities

- Accountable and Authorised Pharmacists are in roles on average 13 years and some near retirement
- Tenure increases for higher bands, indicating a slower pace of advancements at senior bands-

Staffing Models

Recruitment & Training

Workforce Capacity

Succession & Career Planning



- Licensed Facilities have band 2-4 staff and a low turnover
- S10 Facilities use more Pharmacists and technicians

**Across the process to make each product category, task allocation per staff band varies considerably**

Models

- Staff turnover greater than 15% (15-20%); highest vacancies (c.10%)
- Training schedules for QP's varies between <2weeks – 7 weeks

**There is no consistent methodology to calculate staff capacity**

& Training

- No consistent training schedules
- Overtime a weekly occurrence in facilities

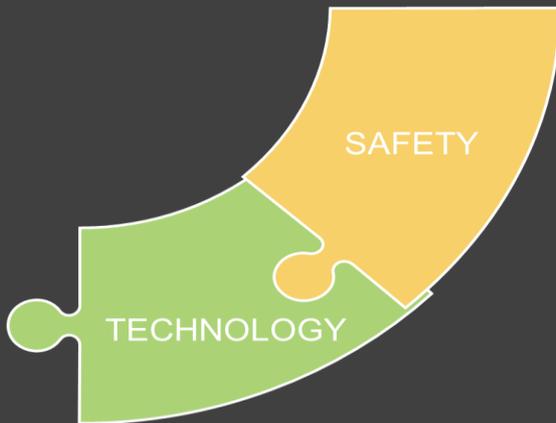
**Insufficient QP's in training to replace existing QP's**

Capacity

- Accountable and Authorised Pharmacists are in roles on average 13 years and some near retirement
- Tenure increases for higher bands, indicating a slower pace of advancements at senior bands-

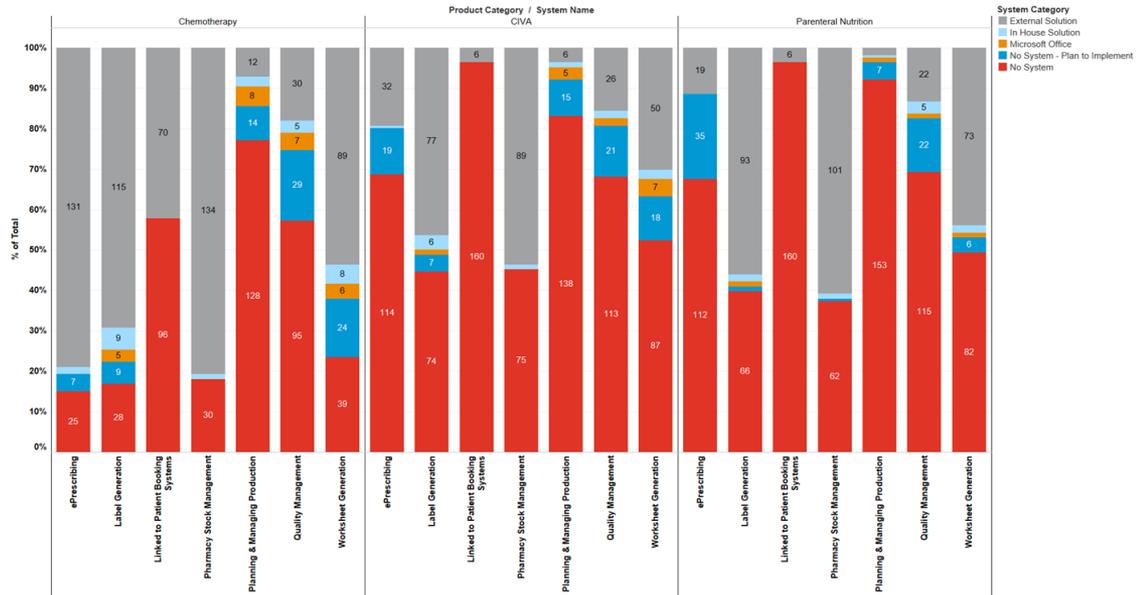
**Succession & Career Planning**





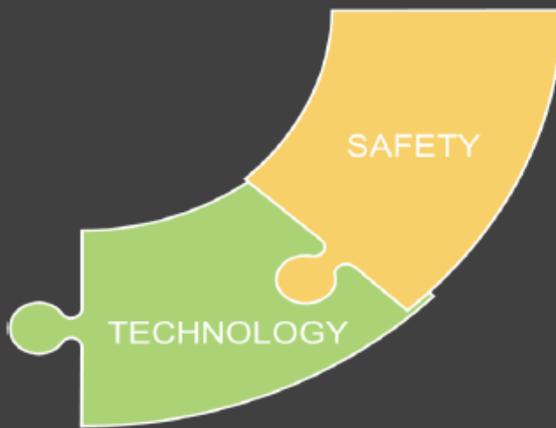
33% Facilities have EPMA in key clinical areas, and this rises to 85% for cancer care

- There are many points in the supply chain for waste to occur and it is inconsistently and poorly tracked
- Wasted stock is not reimbursed so Trusts are losing money
- 12 NHS Aseptic Facilities (10%) have deployed 28 basic volumetric filling pump automation solutions for PN and CIVAs preparation.



A small number of Facilities have developed their own in-house solutions for label generation, quality management, and production management

There is significant fragmentation of software vendors used by product category and system type



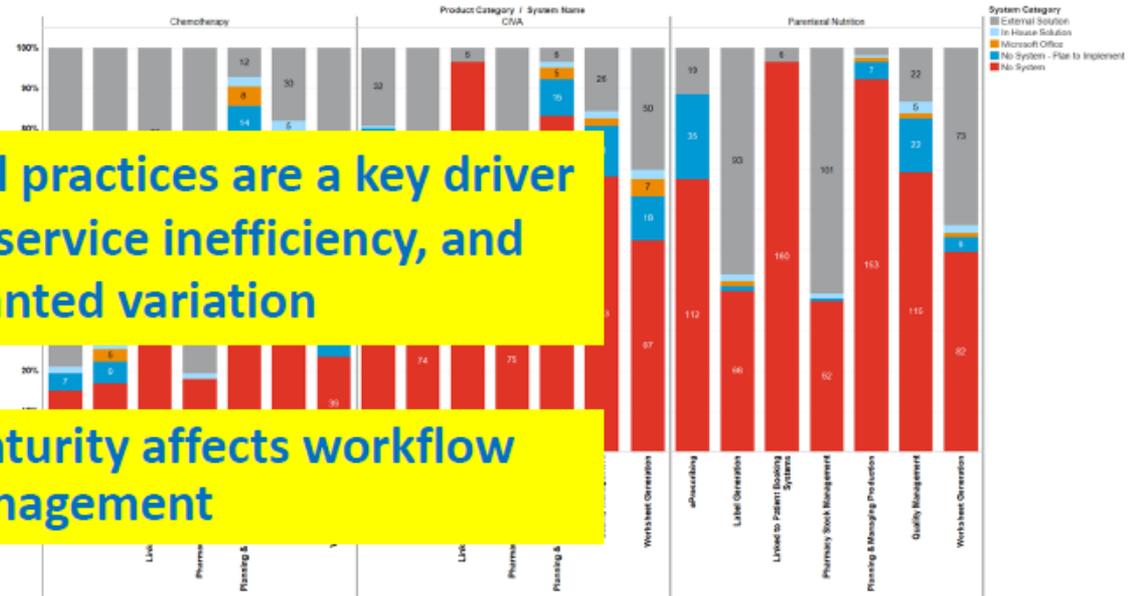
33% Facilities have EPMA in key clinical areas, and this rises to 85% for cancer care

**Disorganised clinical practices are a key driver of waste, aseptic service inefficiency, and unwarranted variation**

**Lack of digital maturity affects workflow management**

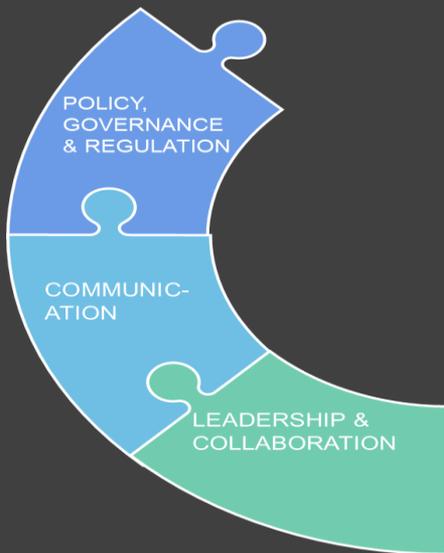
**No instances in England of high volume efficient batch production of aseptic medicines with robots**

- There are gaps in the supply chain to occur and it is inconsistently and poorly tracked
- Wasted services not reimbursed so Trusts are losing money
- 12 NHS A&E (10%) have deployed 28 basic volumetric filling pump automation solutions for PN and CIVAs preparation.



... have developed their own generation, quality management, and production management

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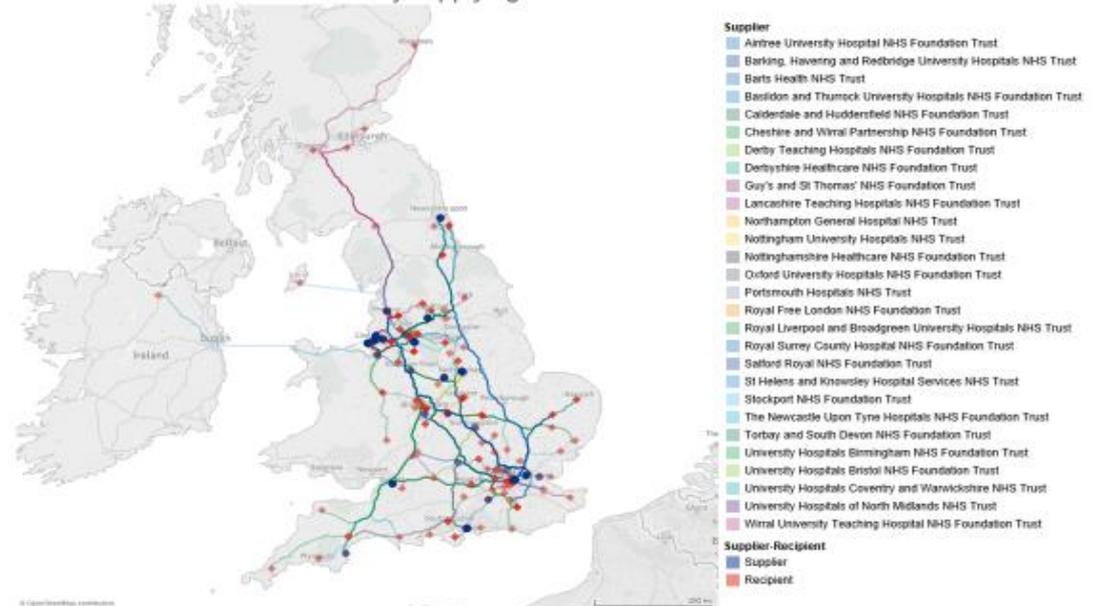
## Current barriers to progression of services:

- lack of data, significant time and goodwill needed to harmonise differing methodologies, and a lack of pre-existing frameworks to guide development
- lack of infrastructure to support sharing and adoption of best practice, culture of resistance to change, lack of central procurement resource
- scale of engagement needed, organisational sovereignty and commercial interests, and lack of role model governance structures

Who supplies and from where?

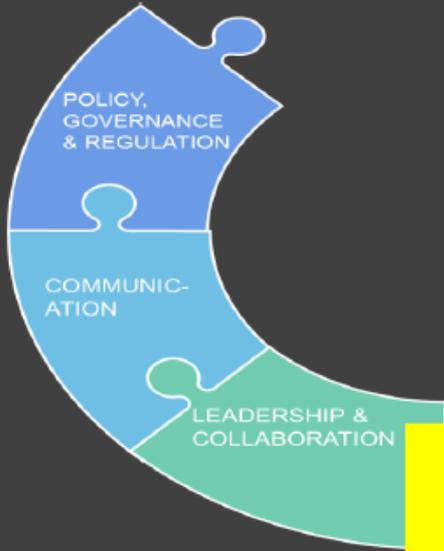
## There is a significant flow of products between NHS sites in and around the major metropolitan cities

There are 28 NHS Trusts currently supplying other NHS Trusts



Source: Aseptic Facility data collection JAN 2018

Parts of the South, Midlands and East regions do not have any supply relationships between NHS Trusts  
Currently there is a lack of licensed Facilities in these geographical areas, but several Facilities do have plans to apply for a Specials Licence



Who supplies and from where?

**There is a significant flow of products between NHS sites in and around the major metropolitan cities**

There are 28 NHS Trusts currently supplying other NHS Trusts



**Commercial suppliers currently tend to outperform licensed NHS suppliers in flexibility, responsive customer service, and economies of scale**

**Low operating margins restrict the ability to fund future capital investment and prompt suppliers to divest unprofitable product lines**

**Throughout the supply chain, transparent collaborative relationships, customer service metrics, and physical proximity are important**

Current barriers to product services:

- lack of data, significant goodwill needed to harmonise differing methodologies
- lack of pre-existing guide development
- lack of infrastructure sharing and adoption of best practice, culture of change, lack of central procurement resources
- scale of engagement, organisational sovereignty and commercial interests, and lack of role model governance structures

Parts of the South, Midlands and East regions do not have NHS Trusts facilities in these cities do have

# Aseptic Review 2017 : QUICK WINS

Demand		<ul style="list-style-type: none"> <li>• Fund national stability testing, especially for antibiotics</li> </ul>
What is supplied?		<ul style="list-style-type: none"> <li>• Maximise uptake of dose-banded chemo framework contracts</li> <li>• Incentivise uptake of standardised PN for adult, paed, and neonatal and standardise approach to manipulation</li> </ul>
Who supplies and from where?		<ul style="list-style-type: none"> <li>• Adopt/customise the capacity calculation and product complexity standards developed in Scotland</li> <li>• Develop/use a sample business case that lists all sources of cost to consider when thinking about outsourcing</li> </ul>
How is supply managed?		<ul style="list-style-type: none"> <li>• Share staff around a community</li> </ul>
		<ul style="list-style-type: none"> <li>• Track unused equipment and facilitate transfer between Trusts e.g. leasing agreements</li> </ul>
		<ul style="list-style-type: none"> <li>• Share clinical collaboration and logistics good practices</li> </ul>

# Aseptic Review 20



Demand



- Fund national

What is supplied?



- Maximise
- Incentivise neonatal a

Who supplies and from where?



- Adopt/customise standards
- Develop/upgrade to consider

How is supply managed?



- Share staff



- Track unused e.g. leasing



- Share clinical

National Pharmaceutical Supply Group (NPSG) Communication:  
Making best use of restricted aseptic compounding capacity

In order to assure patient safety, the MHRA has recently taken regulatory actions against some commercial aseptic compounders placing limitations on their aseptic compounding activity. This is in addition to the constraints supplier's planned and unplanned maintenance is placing on the system. This has led to restrictions on their capacity to accept new business and extended lead times for some existing business.

It is essential that NHS customers of these services review their local activity and practices to ensure that the available services can support as many NHS patients as possible across the country. All pharmacy teams under the leadership of Chief Pharmacists should consider how best to manage the continued challenges to services for supply of aseptically prepared injectable medicines.

The NHS Improvement review of aseptic services which reported to Keith Ridge in April 2018 is being progressed through the Medicines Value Programme Board and the strategic actions are expected in the autumn. This review will not provide a "quick fix" to the current challenges however it will be critical to identifying and securing essential medium to long term system-wide changes to facilities, services & service efficiency together with staffing and associated logistics.

Suggested immediate actions:

1. **Prioritise local aseptic pharmacy capacity** for short shelf-life, very expensive and genuinely clinically urgent items ahead of long shelf life, less urgent items which could be batch manufactured.
2. **Ensure continuing engagement and effective communication between teams (medical, pharmacy & nursing).**
  - This is vital to manage the current situation safely, efficiently and maximising the quality of care. The wider healthcare team should be aware that aseptic compounding capacity available to the NHS is a finite resource that is directly influenced by their practice. Local clinical engagement is critical to maximising the opportunity to use batch-manufactured products in preference to patient specific products which represent least efficient use of capacity.
  - Recognise that for non-NHS suppliers to work efficiently and minimize costs, they must be able to plan their workload **just as our own units do**. This places the onus on NHS customers to plan the care processes that generate the demand for these products.
3. **Ensure that priorities for use of aseptic compounding be they outsourced or local within the NHS are focused on continuity of care and patient safety** and are considerate of the wider NHS needs.
4. **Minimise reliance on patient specific (bespoke) products.** Bespoke and short turnaround time product demand reduces commercial supply capability to deliver batch produced products. Trusts should be aware that short turnaround services will carry a disproportionate cost and contribute to reduced efficiency and supply capacity.
5. **Use licensed ready to administer products wherever possible.** Examples of where immediate efficiencies might be gained include methotrexate sc – one manufacturer is preparing 8000 doses per year when this is available as a licensed medicine. Gemcitabine is available as a licensed ready to administer infusion.

Contracts

and

complexity

of cost

Trusts

# Long Term Ideas

Demand		<ul style="list-style-type: none"> <li>• Develop national approach to “unmet need”</li> <li>• Develop national strategy for ATMP supply chain</li> <li>• Develop standardised clinical protocols for PN</li> </ul>
What is supplied?		<ul style="list-style-type: none"> <li>• Develop a national product catalogue</li> <li>• Develop framework contracts for standardised PN base bags</li> <li>• Regulate radiopharmacy charging</li> </ul>
Who supplies and from where?		<ul style="list-style-type: none"> <li>• Develop standardised capacity calculation, product complexity, and templates for SOPs and worksheets</li> <li>• Invest in national relationship between the NHS and commercial suppliers and understand how to develop the market for sustainability</li> <li>• Consider which aspects of outsource management and procurement to centralise</li> <li>• Have dialogue with the MHRA to seek guidance for IMPs</li> </ul>
How is supply managed?		<ul style="list-style-type: none"> <li>• Develop a career plan to tackle recruitment and retention</li> <li>• Develop regional aseptic service governance structures for strategic issues that are broader than QA</li> <li>• Scale up scientific apprenticeships (e.g. Barts) and maximise uptake of PTQA* for band 7s</li> </ul>
		<ul style="list-style-type: none"> <li>• Investigate potential for a national aseptic service ownership structure and/or capital budget</li> <li>• Incentivise / fund technology for workflow productivity</li> <li>• Develop guidance for new-build aseptic Facilities</li> </ul>
		<ul style="list-style-type: none"> <li>• Appraise options and develop a stock control &amp; logistics strategy for collaborative NHS supply networks</li> </ul>

# Long Term Ideas

Demand

- Develop national approach to “unmet need”
- Develop national strategy for ATMP supply chain

What is supplied?

## Aseptic services: PHASE 2

Who supplies and from where?

1. Develop fully costed options for a national aseptic service based on clinical networks or hubs

2. Identify logistics and synergies with other key programmes e.g. life sciences

3. Develop road map setting out the route to fully developed networks

4. Work with commercial & NHS providers to deliver resilient services

5. Address unmet needs (Time for clinical staff to prepare, OPAT, complex medicines)

How is supply managed?



- Appraise options and develop a stock control & logistics strategy for collaborative NHS supply networks

OPs and  
erstand

broader  
and 7s

al budget

# Aseptic Review-Phase II

# Aseptic review - Phase II

## Objectives:

- To deliver a **safe** and **resilient** aseptic service that can meet **growth in demand** for these services over the next 10 years and beyond.
- Work on mapping existing aseptic services in England has demonstrated a lack of capacity in both workforce and equipment.
- Phase II work will deliver a range of **costed models (Archetypes)**, suggestions for **networks** across STPs and drive the **implementation** of the quick wins from the initial mapping work.
- However, to **transform** the aseptic medicines manufacturing in England to a world leader in aseptic services will require **strategic vision** building on the best international practice and innovation in technology.
- The **English Pharmacy Aseptic Services Transformation Board will** make recommendations for the NHS and others outside NHSI/E pharmacy direct control including the Department of Health & Social Care and Medicines and Healthcare products Regulator Agency to reform the legislative and regulatory framework to support different models of automation, supply and quality systems.

**This work will ensure the maintenance and growth of NHS aseptic services to support patient care including improvements to cancer survival rates, introduction of advance therapies, optimal clinical workforce productivity, innovation and care transformation supported with a pathway for strategic capital investment.**

# PHASE II TIMELINE, KEY ACTIVITIES & DELIVERABLES



Improvement

- Development of costing models
- Collecting relevant data
- Identify & scrutinise best practice

- Develop Change Management Strategies
- Develop long term financial models
- Transition roadmap & guidance
- Minimum dataset & metrics

Provide future strategic direction

DELOITTE CONSULTANCY WORK

ENGLISH PHARMACY ASEPTIC SERVICES TRANSFORMATION BOARD

Jan

Feb

Mar

Apr

May

Jun

Jul

Aug



## DELIVERABLES

### Costed Models & Business Cases

- For current and future aseptic requirements
- Informed by existing global models

### Best practice framework

- To aid sharing of knowledge across organisations
- Develop change management strategies

### Strategic direction

- A roadmap outlining move from current state to recommended models
- Development of a toolkit of guidance materials
- Identify any potential or capital costs

### On-going Benchmarking & KPI data

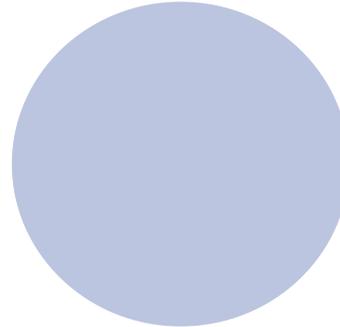
Proposals for data collection help to track delivery of efficiencies that do not place unnecessary burdens on the NHS

# KEY DELIVERABLES EXPLAINED

Costed models	Draft model for key variables of cost	<p><b>A framework for the typical cost structure</b> of each of the archetypes and provide example costings from data collected with pilot sites</p> <p><b>An indicative assessment of how well each archetype performs</b> currently (cost efficiency, resilience, sustainability) based on pilot site data</p>
	Cost optimisation model	<p><b>A cost optimisation model</b>, based on discrete scenarios for future service options for that facility. Produces an output of net impact on operational cost and an estimate of future capital investment required</p> <p><b>Guidance describing the key strategic levers per archetype</b> to manage cost, efficiency, and sustainability</p>
Best practice framework	Consolidation business case & strategies	<p><b>An outline consolidation business case template</b> enabling robust comparison, prioritisation, and selection of archetypes for a group of trusts (e.g. STP). It helps the STP explore risk, net operational cost impact, resilience, and sustainability.</p>
	Long-term financial model	<p>At STP level, a framework identifying indicative potential <b>transition costs and capital investment</b> needed for consolidation implementation</p> <p>A national view of indicative <b>capital investment</b> needed over 5 to 10 years for the NHS in England (e.g. to meet unmet need for CIVAs with robots)</p>
Implementation plans	Transition roadmap & guidance	<p><b>Documentation to guide trusts and STPs</b>, covering how to:</p> <ul style="list-style-type: none"> <li>• Use the optimisation tool and plan implementation of a consolidation programme</li> <li>• Share knowledge / best practice, and</li> <li>• Manage change</li> </ul>
Model Hospital integration	Minimum dataset & metrics	<p><b>KPIs for Model Hospital</b> to enable trusts and regulators to:</p> <ul style="list-style-type: none"> <li>• Understand trends e.g. number of each archetype</li> <li>• Assess efficiency versus other sites with the similar archetype</li> <li>• Flag resilience / sustainability risks</li> </ul>

# ENGLISH PHARMACY ASEPTIC SERVICES TRANSFORMATION BOARD

Purpose: To confirm the NHS strategic direction for pharmacy aseptic services in England



Chair  
To be confirmed – non  
pharmacy lead

## Core members



Keith Ridge- Chief Pharmaceutical  
Officer for England



Department  
of Health &  
Social Care



Andrew Davies – Director of Hospital  
Pharmacy & Medicines Optimisation, NHS  
Improvement



TBC – external to  
NHS Pharmacy



Chief Pharmacist  
representation

**Informed by evidence from system-wide expert groups**

*Methodology : Invite submissions from interested parties & Oral evidence from subject matter experts*

For all queries please contact [khola.khan1@nhs.net](mailto:khola.khan1@nhs.net)