

# NHS Infusions and Special Medicines Programme

November 2023

Presented by:

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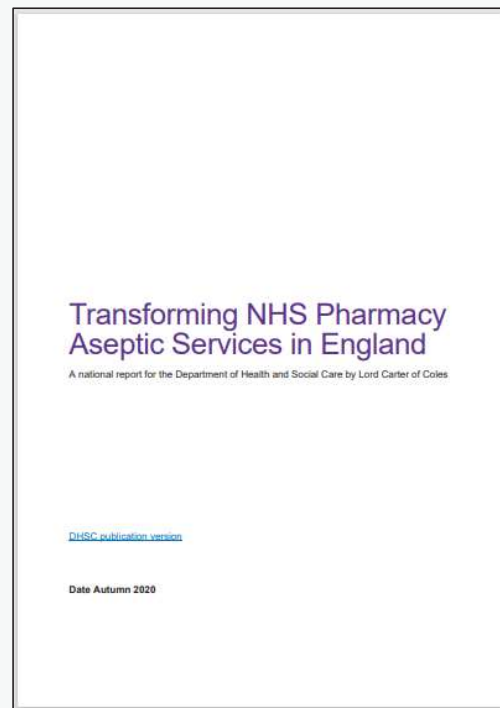
[NHS Infusions and Special Medicines Programme - FutureNHS Collaboration Platform](#)



# Aseptic Services Transformation




February 2016



Autumn 2020



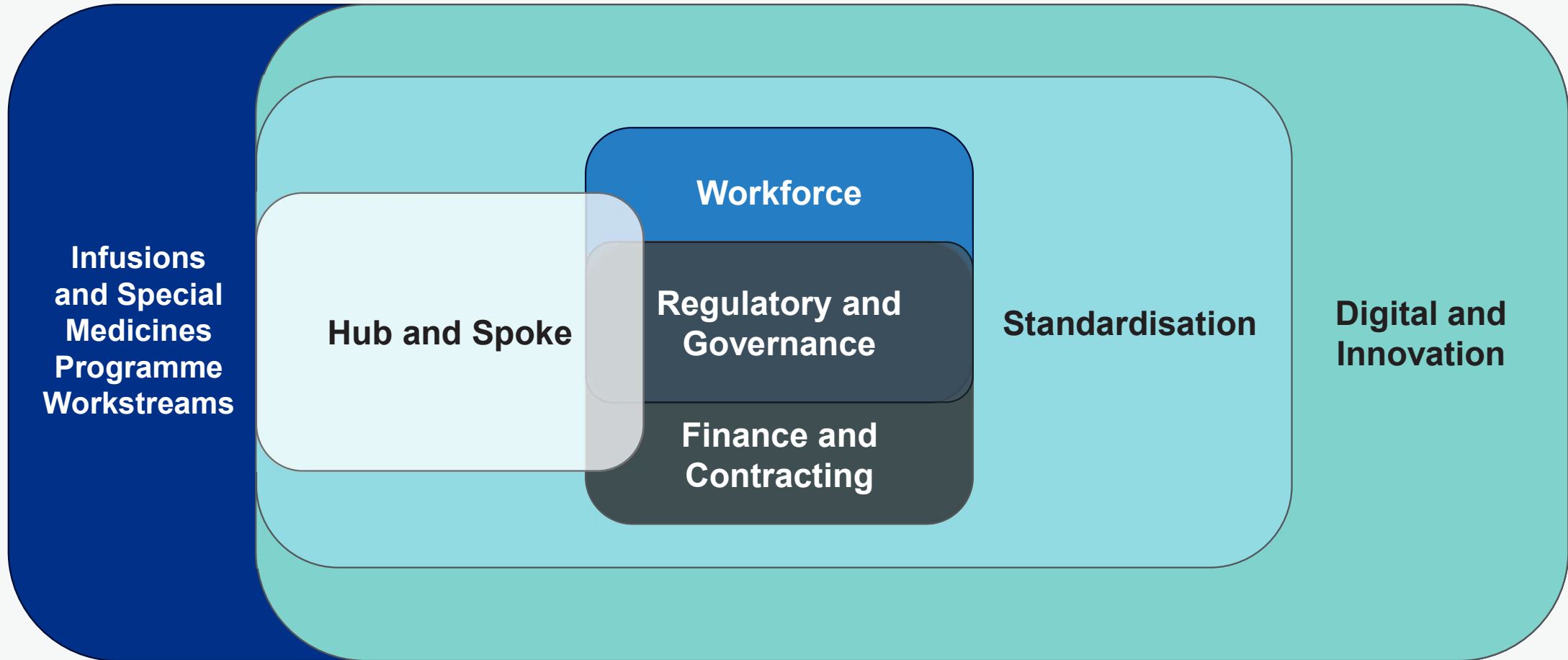
March 2022



“As a clinician, I know access to infusions and special medicines is critical for patient care. Their use will only increase as medical sciences advance and new therapies become possible. I am delighted to be taking over the Board level sponsorship for a programme that underpins so many of our ambitions for continuous improvement in patient care.”

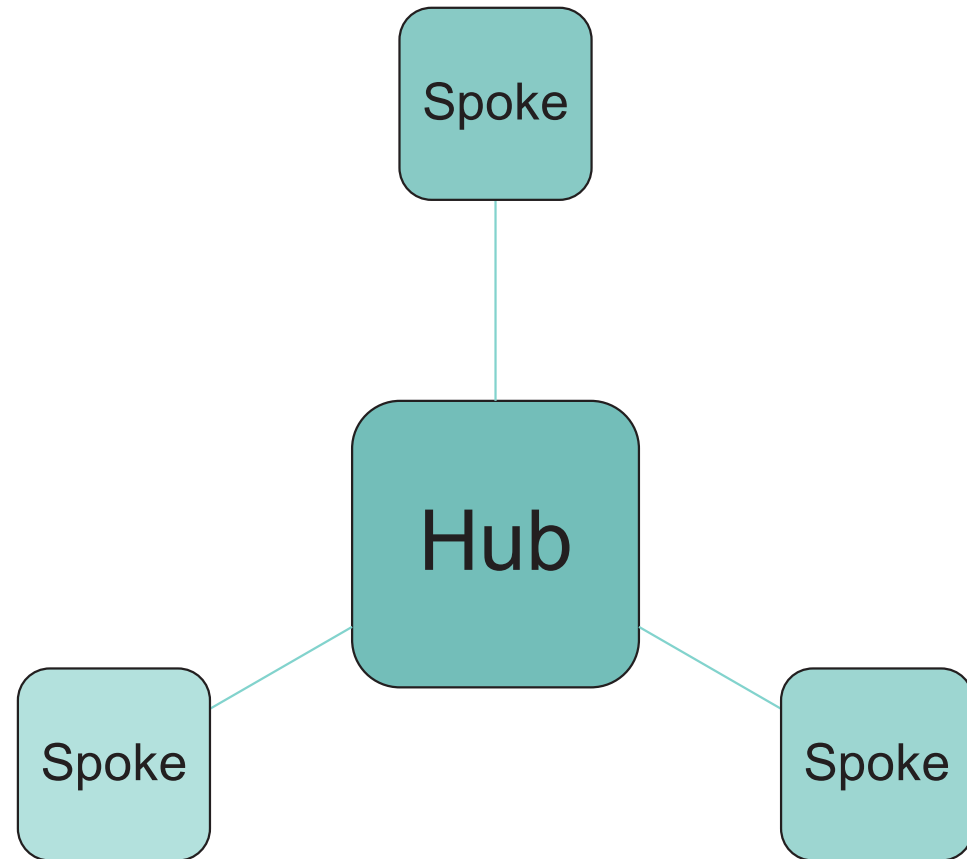
Professor Sir Stephen Powis  
**National Medical Director**  
**NHS England**

# Aseptic Services Transformation



# Hub and spoke Vision

A network of collaborative regional hub aseptic facilities to prepare large scale injectable medicines, supporting spoke facilities and ensuring safe, high quality and resilient supplies.



# Hub and spoke strategy

## National Aseptic Review recommendation:

Create a network of collaborative regional hub aseptic facilities to prepare large scale injectable medicines building on existing relationships (including with commercial providers). These hubs should support spoke facilities across England and ensure safe, high quality and resilient supplies by 2026/27.

*'To deliver the necessary increase in capacity to over 40 million units per annum to release nursing time for care and enable more out of hospital care will require standardisation and automation, which can only be achieved by consolidating services in new hubs. It is proposed that a small number of regional hubs would be developed across England to create industrialised, automated facilities able to produce the 10- fold plus increase in capacity needed. The hubs may be NHS, commercial or joint ventures.'*

*'The importance of continued ability to manufacture bespoke medicines for patients at short notice or use of products with limited stability (less than 12 hours) highlighted the need for continued expertise and facilities in spoke organisations, able to support individual patient needs and clinical trials. Spoke NHS organisations would be required to obtain their high-volume products from their network's licensed hub.'*

[Transforming NHS pharmacy aseptic services in England - GOV.UK \(www.gov.uk\)](https://www.gov.uk)

# Innovation Vision

Use of advanced technologies such as aseptic compounding robots and patient safety systems including barcode technology, decision support and workflow management systems linked to electronic prescribing and medicines administration





# Sustainability in Technical Services



## Net Zero Tech Services

- John Landers
- Laura Stevenson
- Mark Jackson
- Linda Hardy
- Anne Black
- Matt Greening



## Sustainability in Technical Services

Sustainable  
by design


Embedded  
in processes

Balanced  
with quality  
and safety

Minimising  
waste

Resource  
use

# Sustainability – call for evidence



The NHS has committed to deliver the world's first net zero health service and respond to climate change, improving health now and for future generations.

Aseptic Services teams provide a critical service, ensuring patients receive safe, efficacious prepared injectable medication; but this service is inherently high resource and energy intensive. The pathway to a more sustainable service also aligns with wider initiatives like reduction in waste, cheaper operating costs and improved staff engagement.

This call for evidence seeks to understand work already being undertaken or planned within the system to reduce the environmental impacts of aseptic services, the level of understanding and engagement in Net Zero and any blockers to progress.

A joint call from: NHE England, PASG and Regional Quality Assurance.



# Workforce Vision

New roles and skill mix in technical services and new routes of entry.

Policy and structures to support training and development for the technical service workforce.

[Workforce - NHS Infusions and Special Medicines Programme - FutureNHS Collaboration Platform](#)



Infusions and Special Medicines Programme - Workforce - call for evidence



# Quality Vision

Strengthen the accountability and responsibility around the unlicensed preparation of aseptic medicines and the role of the Chief Pharmacist

## Assurance of aseptic preparation of medicines

### Publication

#### Content

- [1. Purpose](#)
- [2. Introduction](#)
- [3. Definitions](#)
- [4. Scope of guidance](#)
- [5. Restrictions for aseptic preparation](#)
- [6. Roles and responsibilities](#)
- [7. Revised assessment process](#)
- [8. Assurance and performance management](#)
- [9. Compliance management and escalation](#)
- [10. Improvement process](#)
- [11. Reporting](#)
- [12. Glossary](#)
- [Appendix 1: iQAAPS](#)
- [Appendix 2: Explanatory notes regarding definitions](#)
- [Appendix 3: Roles and responsibilities](#)
- [Appendix 4: iQAAPS quality indicators](#)
- [Appendix 5: EL\(97\)52 Review Working Group](#)

NHS Infusions and Special Medicines Programme: Guidance to replace EL(97)52 in England

This [video](#) summarises the guidance and explains why it is important for acute trusts and integrated care boards

### 1. Purpose

This guidance sets out the governance and regulatory arrangements for aseptic preparation of medicines for NHS patients in England and replaces the 1997 NHS Executive letter EL(97)52, Aseptic dispensing in NHS hospitals.

It defines the roles and responsibilities for:

- NHS organisations in meeting quality standards, responding to audits and inspections, and reporting quality indicators when performing aseptic preparation activities. This includes the statutory responsibilities of chief pharmacists as established by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022.
- The NHS Specialist Pharmacy Service Quality Assurance service (SPS QA) in providing regulatory oversight and inspection of aseptic preparation activity, auditing services against quality standards.
- NHS England as responsible for commissioning the overarching governance and assurance process, providing oversight and ensuring the delivery of enforcement where necessary.

It also describes the oversight provided by the Care Quality Commission (CQC) and the inter-relationships between the regulatory bodies, primarily the CQC, Medicines and Healthcare products Regulatory Agency (MHRA) and General Pharmaceutical Council (GPhC).

### 2. Introduction

Since 1997 the NHS has operated within an assurance process for the aseptic preparation of injectable medicines issued under a Department of Health Executive letter – EL(97)52. This requires audits every 12 to 18 months of NHS sites in England that perform any aseptic preparation not covered by an MHRA manufacturer's 'specials' (MS) authorisation. SPS QA officers undertake the audits and reported. There have been concerns about the transparency of the results of these audits and the lack of understanding at NHS trust board level of the board's responsibility and accountability, particularly the importance of implementing required remedial actions and the need to prioritise associated works.

[NHS England » Assurance of aseptic preparation of medicines](#)



# Data

- 2019 extensive data collection as part of the national review
- Repeat data collection in 2021 – lower response rate (COVID pandemic, onerous data collection)
- iQAAPS – new quality monitoring system used by SPS.
  - Mandatory monthly submission of quality indicators from section 10 units from July 23
  - To include regular submissions on simple activity and workforce data
  - Exploring potential for data capture from MHRA authorised NHS production units too
- SHAPE - online, interactive, data mapping, analysis and insight tool that supports service planning and estates strategy development
  - Being used to map aseptic units



Attribute overlay

Aseptics review

Products Equipment Hours Workforce MMR

Units prepared or produced in aseptic facility

Units produced under an MHRA Licence or IMP Authorisation

Units produced for own Trust

Units routinely produced for other Trusts

Products Equipment Hours Workforce MMR

WTE

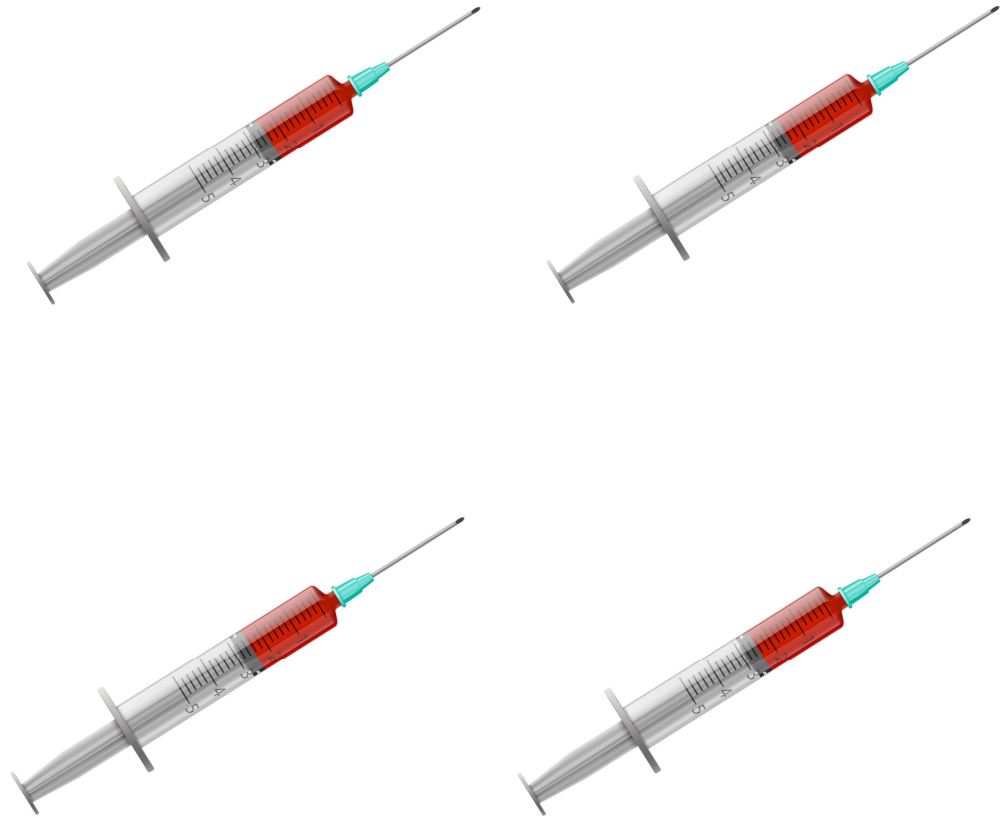
Bank WTE

WTE Vacancies

WTE Rotational

# Standard products Vision

National standard injectable medicines specifications (concentrations, presentation, volume, expiry time, labelling and dm+d coding)





# Standard Product Specifications – the benefits

## NHS

- Single uniform product available to purchase and produce
- Opens doors to quantity-based contracting, with accurate data enabling forecasting, mutual aid and more
- Off the shelf solutions, regional stores, supply resilience
- Value for money medicines procurement
- Closed loop administration
- Smart pump libraries

## Industry

- Single uniform product available to purchase and produce
- Ability to plan business growth and development as a result of predictable workload
- New ways of working – manufacture to stock
- Novel logistics solutions – able to plan drops based on location rather than order date
- Large scale batch production providing economies of scale

# Standard products – the ambition

## Carboplatin

- Doses regularly used in dose banding tables **13**
- Expected variation in naming/presentation **13-39**
- Actual variation in naming/presentation **1000+**

## Ready to use Vs Ready to administer

Ready to use

Ready to administer

## Batch production of aseptically prepared products

### Currently

- Large amounts of hospital-to-hospital variation
- Limits batch sizes
- Product specifications non-descript
- No contracting emphasis on providing standardised focus



### The Future

- Standardised product specifications
- Build contracts around maximizing batch production
- Bulk starting goods
- Commission stability studies where needed
- Enable automation/semi-automation uptake
- Develop standardised nursing and prescribing practices

[Standardisation - Core messages \(NHSFuture\)](#)



# Standard products- Key Messages

- Specifications for standardised products are being developed by an expert panel through a robust governance process, including wider stakeholder consultation
- Starting with chemotherapy, and applying to as many injection/infusion products as possible
- Large-scale change programme involving changes in ways of working to bring uniformity across the NHS – prescribing and production
- Operationally challenging implementation
- Shows NHS commitment to using standard products – enabling the wider industry to develop them as licensed products where possible
- Uptake of national standard products will be tracked as one of the [NHS England 16 national medicines optimisation opportunities 2023/24](#) metrics and in the Model Health System
- Supportive research being commissioned for ready-to-administer standard products to provide evidence for value and recommendations for implementation.

# Standardisation products - Stability Work

- SPS commissioned to review existing stability data
- Methodology developed with standards for assessors
- Phase one complete – initial review process underway
- Guided by standardisation expert panel
- Monographs to be published on SPS website
- Phase 2 to involve commissioning stability studies to cover gaps in available data
- On-going conversations with industry partners around data sharing

Stability studies						
Diluent	Container	Conc. range (mg/mL)	Storage conditions (°C)	Evidence confidence rating	Maximum shelf-life from study	Reference
NS	PVC bag	5, 10 and 20	5	Low	28 days	1
NS	Freeflex container	10	2-8	Medium	14 days	2
NS	Freeflex container	10	25	Medium	4 days	2
WFI	Polypropylene syringe	140	4-8	Low	9 days	3
WFI	Polypropylene syringe	50	2-8	Medium	10 days	4
WFI	Polypropylene syringe	5	2-8	Medium	28 days	4
Buffered NS	PVC bag	10-20	2-8	Medium	3 months	5
NS	PVC bag	20	2-8	Medium	9 days	5
WFI	Polypropylene syringe	5	2-8	Medium	21 days	6
NS	IV bag	10	2-8	Low	21 days	7
NS	Freeflex container	20	2-8	Low	21 days	7
NS + 5.25%*	Barter infusors	4.44-53.33	2-8	High	14 days, plus 6 hours at 25°C, followed by an infusion period of 24 hours at 37°C	8
NS + 0.9%*	Accufuser and Infusor LV	10 and 50	2-8	High	13 days, followed by a body-worn infusion period of up to 24 hours at 32°C	9
Buffered NS	Polypropylene syringe	100	2-8	Medium	11 days	10

## Product-specific stability assessments

Our assessments are based on expert opinion and validated data to help assign a proposed shelf-life to your aseptically prepared product(s).

### IV infusion

Diluted in 100ml sodium chloride 0.9% or glucose 5%, smaller or larger infusions volumes can be used if necessary.

[Flucloxacillin 2 g in 100 mL stability assessment](#)

## Flucloxacillin: understanding physico-chemical stability

Published 1 August 2023

Understanding the physico-chemical stability of flucloxacillin enables you to assign a shelf-life to aseptically-prepared products.

### Contents

- Drug characteristics
  - Pharmacopoeia Monograph
  - Empirical Formula
  - Molecular weight
  - Chemical structure
  - Possible routes of degradation
  - Solubility
  - pH
  - Physical compatibility
- Literature review of preparations
  - Stability Profile
  - Stability studies
- Licensed products and brands
  - Bowmed
  - Esteve
  - Panpharma
  - Wockhardt
- Product-specific stability assessments
  - IV infusion

### Drug characteristics

Flucloxacillin's pharmaceutical properties will affect the mechanism and rate of degradation in an aseptically-prepared preparation.

### Pharmacopoeia Monograph

Flucloxacillin Injection Monograph: Ph. Eur. Monograph 0668  
Parenteral Preparations Monograph: Ph. Eur. Monograph 0520

### Empirical Formula

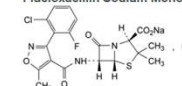
$C_{19}H_{16}ClFN_3NaO_5S \cdot H_2O$

### Molecular weight

493.9

### Chemical structure

Flucloxacillin Sodium Monohydrate



# Standard products - Timeline

Milestone	Timeframe
Governance process final draft	11 Nov 2023
System consultation	01 Dec 2023 – 22 Dec 2023
First specifications published	31 Jan 2024
Work begins on non-chemo products	01 Mar 2024
Implementation of initial specifications	01 Apr 2024 – 31 Mar 2025

# Contracting vision

Contracts for outpatient antimicrobial therapy to care for people closer to home or at home.

Contracting approach that supplies patients the medicines they need and supports planning and development of services



# Infusions and Special Medicines – Finance and Contracting

## Background/Achievements

- Review of OPAT services in England:  
[The Provision of Outpatient Parenteral Antimicrobial Therapy \(OPAT\) Services in NHS Trusts in England - NHS Infusions and Special Medicines Programme - FutureNHS Collaboration Platform](#)
- Recommendations to develop a commissioning model are being taken forward by the national antimicrobial prescribing team
- Standard ready-to-administer products will be essential

## Progress

- Reviewing how to ensure commercial contracts support NHS uptake of standardised products and reduce the level of bespoke ordering which is exacerbating supply issues.
- Workshops with commercial suppliers in 2023.
- Standardising NHS framework terms and conditions.
- Planned review of aseptic on-cost reimbursement to trusts by Specialised Commissioning



# Independent Aseptic Compounder workshops

## Phase 1 – chemotherapy suppliers

### Format

- Series of workshops involving IAC and NHS stakeholders (pharmacy, procurement, policy, clinical)
- Exploring each focus area in detail
- Identifying themes
- Developing aligned vision and strategy and recommendations for change

### Focus areas

- Purchasing behaviour of NHS customers and impact on commercial strategy and operation.
- NHS-wide contracting approaches and strategies and impact on commercial strategy and operation.
- Ongoing supplier engagement including Key Performance Indicator (KPI) and data reporting complexities.

# Commercial strategy

The overarching vision is for a commercial strategy that:


- supplies patients the medicines they need
- provides the NHS value for money
- improves and encourages standardisation by the NHS
- is operationally and commercially attractive for suppliers to encourage growth and demand continuous quality improvements in the sector



# Key themes

1. **Agility** – in award criteria and tenders, sourcing raw materials, distribution, feedback loops
2. **Collaboration** – between the NHS and independent aseptic suppliers on services, resources and facilities, with a variety of business and risk sharing models. Sharing information and changing behaviours
3. **Data** – commitment to safe and efficient sharing of meaningful data
4. **Standardisation** – tendering and contract management and products - consolidating and reducing duplication
5. **Transparency** – clarity on policy, process and strategic direction, ability to ask questions, standard KPIs, consequences and escalation routes
6. **Planning** – collectively understanding future supply and demand, horizon scanning, use of data, engagement and readiness preparation, consistency





“In this service, I found an unsung hero – one that is critical to our plans for the NHS – but that is little understood or lauded.”

“By transforming these services, we have the chance to deliver better clinical outcomes, an improved patient experience and deliver considerable productivity gains in product costs, clinical staff time and in-patient bed days. It presents one of the best opportunities I have seen in a long time to invest to improve patient care and deliver significant savings, with the added benefit of enhancing our international status as an innovator in new medicines.”

Lord Carter of Coles

**Former chair of the English Pharmacy Aseptic Transformation Board**

## Chief Pharmaceutical Officer / Specialist Pharmacy Services Pharmacy Technician Fellowship



Applications are open for the first national Chief Pharmaceutical Officer Pharmacy Technician Fellowship, hosted by NHS Specialist Pharmacy Service (NHS SPS).

We are looking for an experienced pharmacy technician from **any sector of healthcare**, an individual who is ready to work in a new way, providing professional leadership and advice where pharmacy technicians can add value to national healthcare priorities aligned to the SPS's areas of expertise.

The successful applicant will be supported with new opportunities and to develop themselves as a strategic leader.

More information about the role and application process can be found here: [Jobs at Liverpool University Hospitals NHS Foundation Trust \(liverpoolft.nhs.uk\)](https://liverpoolft.nhs.uk/jobs).

**Applications close at 9am on 9 November.**

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## Thank You

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