

# NHS Infusions and Special Medicines Programme

September 2023

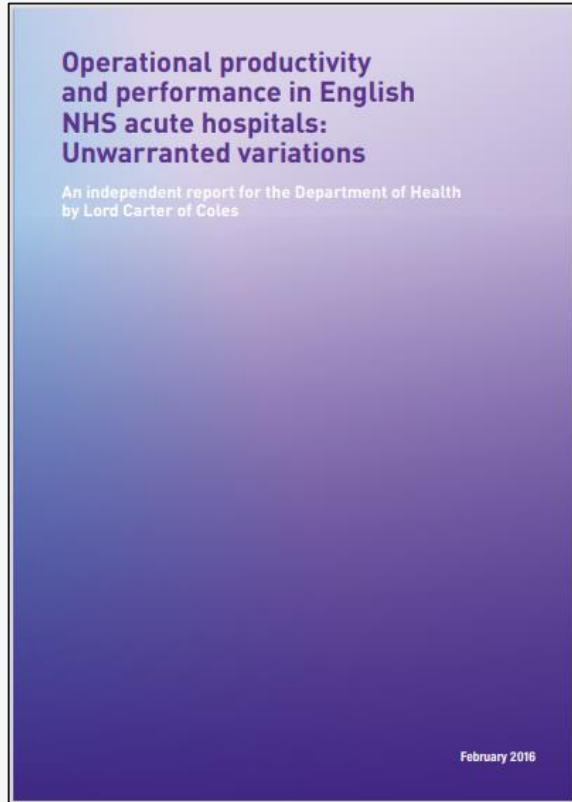


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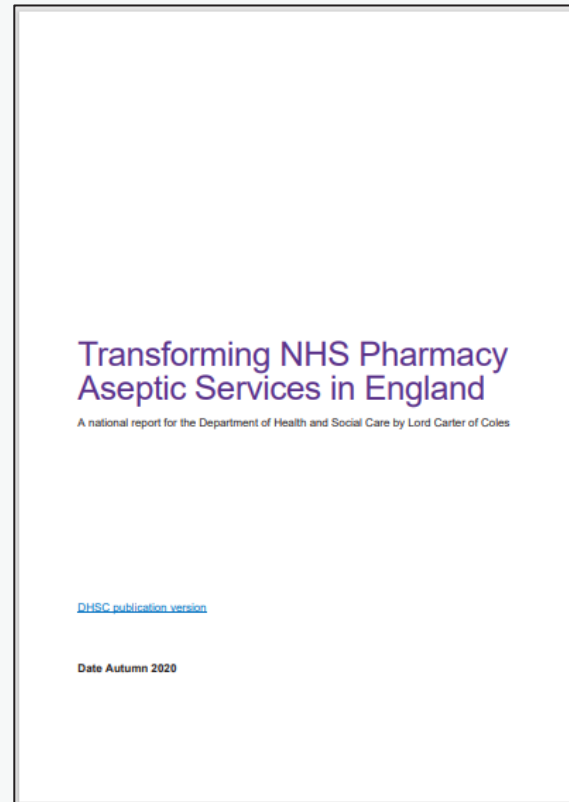
Presented by:

**Sue Ladds - Hospital Pharmacy Modernisation Lead**

# Aseptic Services Transformation




February 2016



Autumn 2020



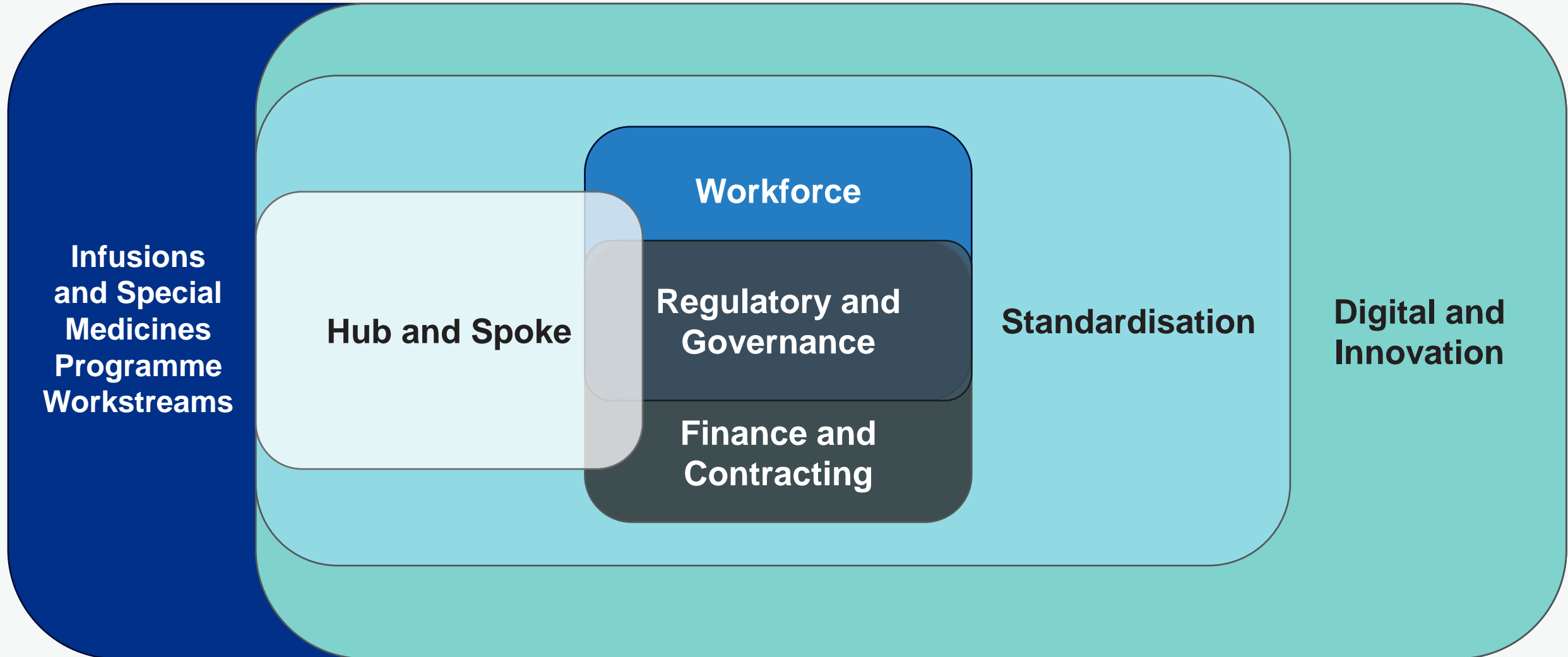
March 2022



“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.”

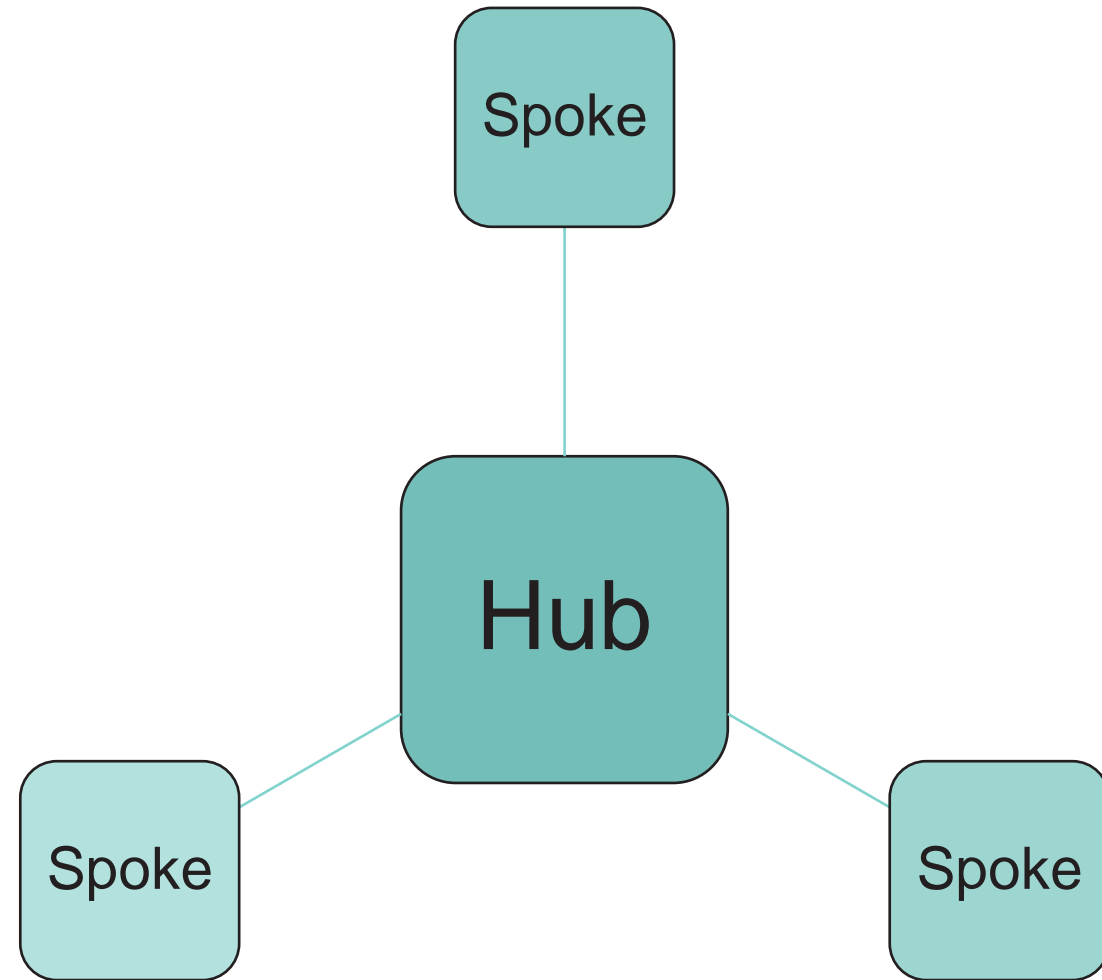
Professor Sir Stephen Powis  
**National Medical Director**  
**NHS England**

# 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.



# Infusions and Special Medicines – Hub and Spoke

## Background

### Hubs

- Licensed to supply several ICS areas and can be NHS, commercial or joint ventures.
- Making high volume standardised products to enable increased OPAT, chemotherapy closer to home and release nurse time at ward level.
- Creating capacity in spokes for complex bespoke medicines and clinical trials
- Enabling the NHS to keep pace with increasing use of aseptically produced medicines.
- Delivering the ambition to move from 4m doses annually to 40m.
- I&SMP is providing funding for path finder hub sites, then will develop a further national business case for 2026.

### Spokes

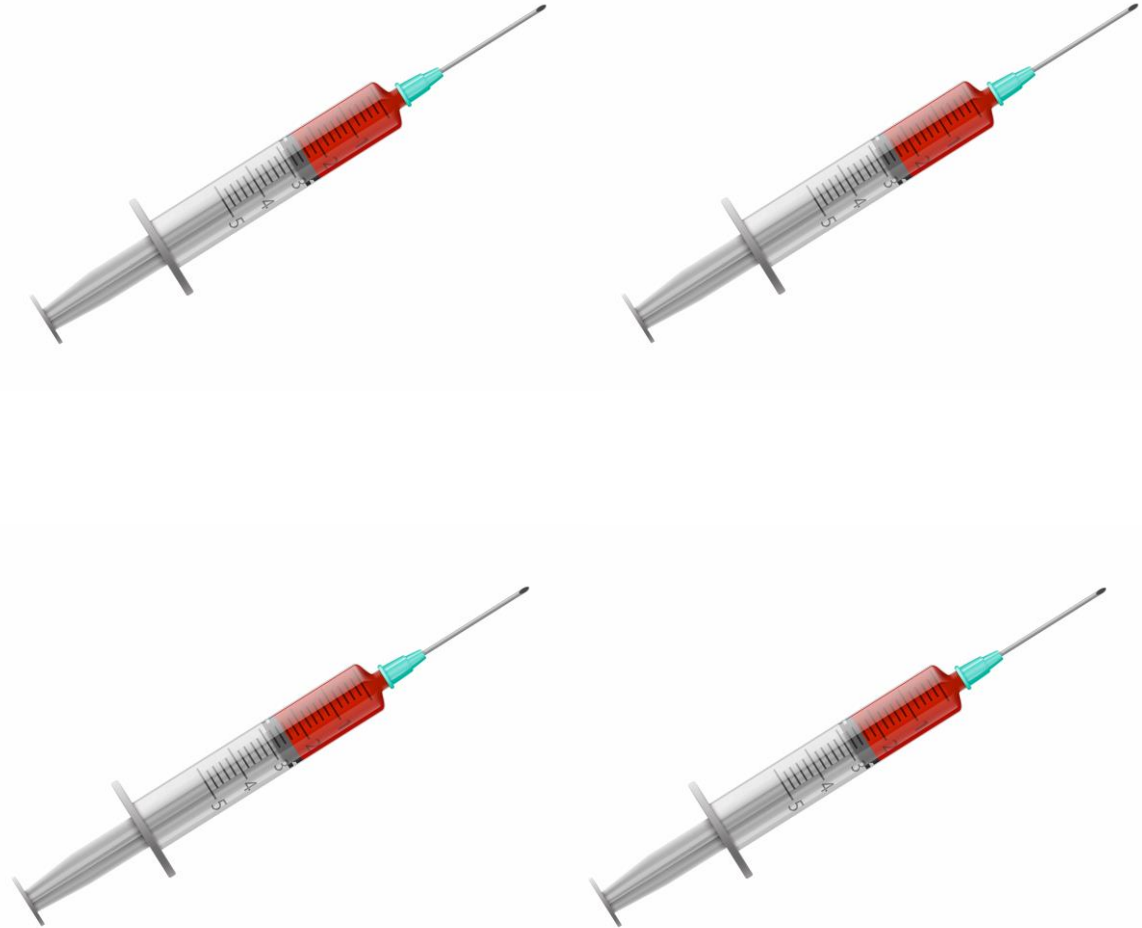
- Local trust units using released capacity to make new and innovative treatments, bespoke medicines, products with limited shelf life (<12 hours) and clinical trials.
- No funding from I&SMP
- Funding through usual trust routes and potentially through spend to save schemes.

## Progress

- £75m of capital for the period 2022-25 allocated to 5 pathfinder hub sites to test the costs, timings and benefits realisation of the proposals. Data captured will support the development of a future business case for 2026-29 to complete the national network of hubs.
- Governance and assurance framework for the capital allocations developed and business cases progressing through – 2 out of 5 approved so far.
- First hubs will start to build this year.
- Phased production plans over 2-3 years.
- Short life working group to be established to look at providing a draft URS for various hub models to guide business cases
- Successful business cases and templates to be shared.

# Standard products Vision

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



# Infusions and Special Medicines – Standardisation

## Background/Achievements

- [Standardisation - Core messages](#)
- Specifications for initial standardised products being developed

## 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

## Progress

- Expert panel working group established to provide consensus on product specifications and to support stability work
- Supporting commercial compounders to alleviate lead times. Moving to certain standardised products has demonstrated a positive impact
- Stability assessments being carried out by expert assessors and studies will be commissioned to fill the gaps.
- Modernisation of Pro-File catalogue of NHS manufactured medicines – specification developed for supplier discussions
- Modernisation of Medusa IV Guide by Imperial College Healthcare NHS Trust



# 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.



# Infusions and Special Medicines – Workforce

## Background/Achievements

- [Northern Pharmacy Technical Services Workforce Project Report – SPS - Specialist Pharmacy Service – The first step for professional medicines advice](#)
- Priorities and action plans identified : [ISM Workforce Working Group priorities](#)
- Six task and finish groups established:
  - Using workforce data to understand current status and model changing demand
  - Defining tasks and competencies
  - Standardising roles and job descriptions
  - Gap analysis and standardisation of education and training
  - Understanding factors affecting career choices
  - Defining career pathways for all staff groups

## Progress

- Focus on creating the pipeline for a new and sustainable workforce
- Working group developed actions and taking them forward.
- Scope is technical workforce only; not clinical
- High level project plans: [ISM Workforce Working Group Project Plans](#)
- Call for evidence open: <https://forms.office.com/e/vLGj9M56JY>

# 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





# Infusions and Special Medicines – Digital and Innovation

## Background/Achievements

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

## Progress

- Short life working group formed to produce semi-automation/automation guidance. First meeting to be arranged in October
- Opening of discussions with MHRA to streamline the introduction of robotics to authorised aseptic facilities
- Seeking to engage with chemotherapy prescribing system suppliers about potential national level solutions for drug set up and revision

# 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

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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](#)

# Infusions and Special Medicines – Quality Assurance

## Aims

- Replace the 1997 NHS Executive Letter EL(97)52 with new guidance
- Define the roles and responsibilities for:
  - NHS trusts providing aseptic services
  - NHS Specialist Pharmacy Service Quality Assurance (SPS QA) in auditing services against quality standards.
  - NHS England
- Describe the inter-relationships with regulatory bodies - MHRA, CQC and GPhC

## Scope

- Applies to aseptic reconstitution of any medicinal products, IMPs and ATMPs, where this is performed in an NHS aseptic facility under pharmacy management or oversight
- Does not apply to:
  - Reconstitution of medicinal products in a clinical area
  - Products manufactured under an MHRA authorisation
  - Radiopharmacies (pending outcome of separate national review)

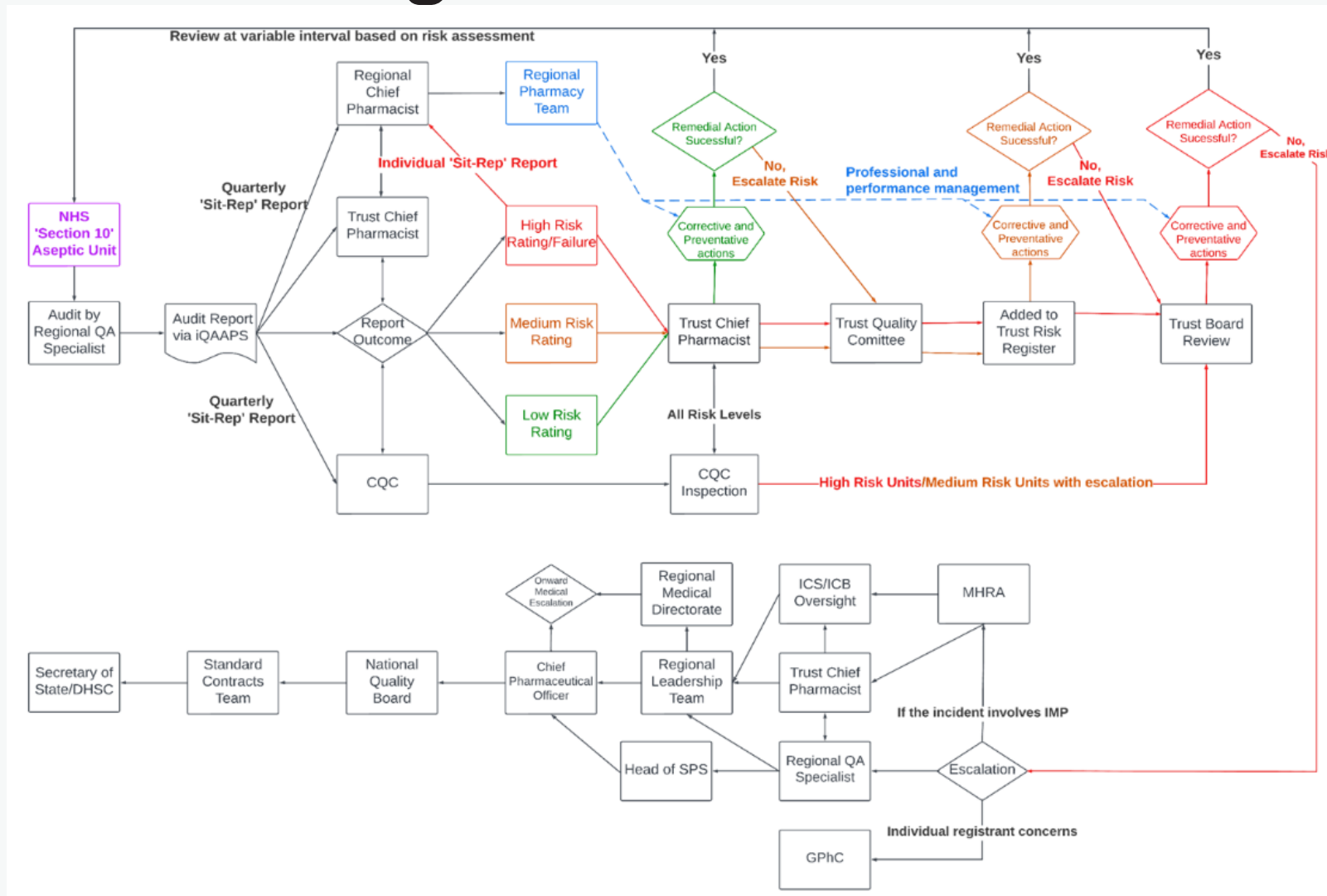


# The guidance

- Takes account of changes in professional training and aseptic practice
- Defines quality standards and restrictions
- Describes the updated audit process
- Introduces the digital quality management tool – iQAAPS
- Outlines reporting, compliance management and escalation routes
- Describes responsibilities of NHS bodies and the role of regulators



# Compliance management





# Responsibilities

## Trusts

- Meet quality standards in provision of services
- Monthly submission of quality indicators through iQAAPS
- Facilitate and respond to audits
- Implement improvement action plans

## SPS QA

- Audit NHS Section 10 aseptic units
- Monitor quality indicators and progress with audit action plans
- Support enhanced compliance management for higher risk units
- Escalate concerns to NHSE Regions

## ICBs

- Oversee and support the governance process within their system
- Ensure trusts complete audit action plans
- Follow up escalated concerns
- In agreement with NHSE Region, impose service restrictions if required to ensure safety

## NHSE Regions

- Receive and review iQAAPS reports
- Support trusts with corrective and preventative actions
- Oversee and implement compliance management processes
- In agreement with ICBs, impose service restrictions if required to ensure safety
- Escalate concerns to national teams

## NHSE National

- Commission, oversee and support the governance and assurance process
- Ensure relevant NHS bodies follow up concerns
- Ensure enforcement is applied where necessary
- Receive and act on escalations from regional teams

# Risk categories

Risk rating	Audit interval	Trust action	Regional reporting	Compliance management
<b>Low risk</b>	Audit interval maximum 2 years	Audit report sent to trust chief pharmacist for implementation of improvement actions	Regional chief pharmacist receives outcome in quarterly sitrep report	N/A
<b>Medium risk</b>	Increase in audit frequency	Audit report sent to trust chief pharmacist for implementation of improvement actions and internal reporting and escalation	Regional chief pharmacist receives outcome in quarterly sitrep report	Compliance management initiated if improvement actions not completed. Service restrictions applied if needed
<b>High risk</b>	Audit review within one month	Audit report sent to trust chief pharmacist for implementation of improvement actions and internal reporting and escalation.	Audit report sent to regional chief pharmacist for performance oversight and support	Compliance management initiated. Service restrictions applied if needed (may include unit closure) Escalation to national teams if required through CPhO and Head of SPS

# Role of regulatory bodies

## CQC

To seek assurance that the governance and assurance arrangements for aseptic services are in place.

Can request site-specific iQAAPS audit reports.

CQC regulate the safe and effective use of medicines in clinical areas.

## GPhC

Regulate registered pharmacy professionals and premises.

Inspection of section 10 aseptic units where they are part of a registered pharmacy footprint - will use site-specific iQAAPS reports.

Respond to concerns about an individual pharmacy professional's practice

## MHRA

Regulate and inspect aseptic units and pharmacy production units that hold an MHRA manufacturing authorisation.

Exceptionally will investigate a serious incident from an NHS aseptic unit, e.g. relating to IMP

# Contracting vision

Longer-term contracts, monitored through key performance indicators, with NHS and commercial compounding services.

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



# 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.
- Standardising NHS framework terms and conditions.
- Workshops with commercial suppliers in 2023 ongoing and output being reviewed.
- Planned review of aseptic on-cost reimbursement to trusts by Specialised Commissioning



England

**Enjoy the  
Symposium!**



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## Thank You



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