

Aseptic Services Review

Supporting the strategic development of aseptic services in England

May 2026

Table of contents

Introduction.....	3
Methodology	6
Findings overview.....	9
Key findings	11
Recommendations	21
Key enablers	26
Next steps	28
Appendices	29

Introduction

Aseptic services provide sterile, injectable medicines prepared in controlled environments to ensure they remain free from contamination and to protect staff from the risks associated with preparing hazardous products. These services support the preparation, manipulation and supply of a wide range of medicines including ready-to-administer products where appropriate. Many essential injectable medicines are not available as licensed ready-to-use products and therefore require aseptic preparation to ensure clinical safety before administration. Aseptic services play a critical role in enabling the safe delivery of high-risk treatments such as chemotherapy, parenteral nutrition (PN), radiopharmaceuticals, and advanced therapies, protecting both patients and staff, and in freeing up nursing time.¹

Injectable medicines account for a significant proportion of NHS expenditure, with more than £7 billion spent annually in England.² Aseptic preparation underpins safe and timely patient care while improving clinical efficiency through reduced ward preparation time and consistent quality assured by regulated processes.³

National reviews have highlighted the strategic importance of these services. Lord Carter's 2020 report, *Transforming NHS Pharmacy Aseptic Services in England*, directly builds on the themes of his 2016 review of unwarranted variation within NHS hospitals. It echoes the need for standardisation, modern infrastructure, improved data, a strengthened workforce, and redesign of service models. The 2020 report highlights that services are highly variable across England, noting many units will be unable to meet future requirements without major modernisation. Services are already facing significant operational and structural pressures including ageing and non-compliant facilities, workforce shortages, and rising clinical demand driven by chemotherapy, biologics, and advanced therapies.⁴ The short shelf life and limited stability of many of these medicines mean they are unsuitable for import, so solutions are required in the UK.

To address these issues, NHS England allocated £75 million between 2022–25 to four 'Pathfinder' aseptic hub sites to test costs, timings, and benefits of hub and spoke models.⁵ However, the wider operating environment has shifted considerably since 2020. Demand has continued to rise with treatments becoming more complex, and more patients being

¹ Specialist Pharmacy Service (2026) *Understanding aseptic services in the NHS*, <https://www.sps.nhs.uk/articles/understanding-aseptic-services-in-the-nhs/>.

² Al-Rawi, S., Greening, M. and Ladds, S. (2023) *Economic evidence for licensed ready-to-administer intravenous products compared with standard vials and ampoules: a systematic review*, <https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/pdf/10.1111/anae.70122>.

³ NHS Business Services Authority (2025) *Prescribing costs in hospitals and the community: England 2024/25*, <https://www.nhsbsa.nhs.uk/statistical-collections/prescribing-costs-hospitals-and-community-england/prescribing-costs-hospitals-and-community-england-202425>.

⁴ Department of Health and Social Care, (2020) *Transforming NHS Pharmacy Aseptic Services in England*, <https://assets.publishing.service.gov.uk/media/5f9afdbdd3bf7f1e405d9a23/aseptic-pharmacy.pdf>.

⁵ Ladds, S. *NHS Infusions and Special Medicines Programme*. Pharmaceutical Aseptic Services Group, https://pasg.nhs.uk/downloads.php?did=675&filename=NHS%20Infusions%20and%20Special%20Medicines%20Programme_Sue%20Ladds.pdf.

diagnosed, while trust finances are under increased scrutiny. In 2024-2025, NHS hospital trusts reported a collective deficit of around £740 million, driven by inflationary pressures, workforce costs, and growing care complexity.⁶ The publication of the *National Cancer Plan for England* in February 2026 adds further demand, committing the NHS to meet cancer waiting time targets and deliver 43.5 million diagnostic tests annually by 2029, a 12.5% increase.⁷

Against this backdrop, the challenge for aseptic services is how to deliver more when resources are constrained. There is an increased need for services to collaborate with each other and use existing resources, either within the NHS or externally, to keep up with the ever-increasing demand for aseptically prepared medicines.

In response to these challenges, NHS England's (NHSE) Infusions and Special Medicines Programme want to develop a 5-year vision that would enable aseptic services nationally to meet future demand, with a particular focus on identifying impactful change which could be delivered within 1-2 years.

The NHS Transformation Unit, an internal NHS consultancy team, have been commissioned to independently conduct interviews with aseptic service leads, hub teams, independent sector providers, outsourced trusts, and system-level leaders from across every region in England. These interviews aim to understand the sector's ability and appetite for increasing capacity for chemotherapy, parenteral nutrition as well as other injectable medicines including Outpatient Parenteral Antimicrobial Therapy (OPAT) antibiotics, complex medicines, and clinical trial preparations.

The interviews have been designed to explore the following statements and identify potential solutions to be developed further in the future vision:

- The NHS needs alternative approaches to meet the future demand for chemotherapy and parenteral nutrition, without solely relying on public capital investment.
- Collaboration (across hub-and-spoke models and public-private partnerships) will be essential.
- The system needs impactful change within the next two years.

This report is structured into the following key sections:

1. **Methodology** – summarises the interview approach and the process used to develop the findings.
2. **Findings overview** – sets out the most significant themes seen across the interviews.
3. **Key findings** – a more detailed insight into the themes seen across the interviews.
4. **Recommendations** – recommends actions based on the interview findings.

⁶ The Independent, *NHS debt funding budget*, <https://www.independent.co.uk/news/health/nhs-debt-funding-budget-b2937119.html>.

⁷ Carnall Farrar, *Inside the NHS's National Cancer Plan for England 2026–2035*, <https://www.carnallfarrar.com/inside-the-nhss-national-cancer-plan-for-england-2026-2035/>.

5. **Key enablers** – sets out the critical factors required to progress these ideas.
6. **Next steps** – suggests practical actions and timeframes, including quick wins and areas requiring long-term investment.

Methodology

The delivery of this report followed four key phases:

1. **Planning and design**
2. **Information gathering**
3. **Qualitative analysis and validation**
4. **Report drafting and finalisation**

1. Planning and design

In this first stage, key stakeholder groups were identified for interview, including NHS aseptic hub sites; NHS trusts which fully outsource; NHS aseptic sites with a partnership model; NHS aseptic sites with no partnership in place; and Independent Aseptic Compounding (IACs).

A semi-structured interview approach was agreed, supported by tailored Key Lines of Enquiry (KLOEs) for each stakeholder group. These KLOEs were reviewed by NHS England during the early interview phase to ensure that the questions remained relevant to the review's purpose, clear, and able to generate responses that could be reliably analysed. They included understanding the stakeholder's current service position, challenges, successes and a focus on what actions should be prioritised in the next 1-2 years to deliver the greatest increase in capacity for the defined areas.

A random sampling approach was used to identify NHS aseptic sites for interview, with the caveat of including at least two sites per region across England. Independent Aseptic Compounding (IACs) were also a core part of the engagement to ensure the challenges were fully understood, and the full scope of potential solutions could be explored. As part of this engagement, we also met with the British Specialist Nutrition Association and facilitated a joint meeting with the Independent Aseptic Compounding on the 23rd February 2026 to capture initial views across the sector, in advance of individual stakeholder interviews.

In total, 41 stakeholders were approached, and 34 interviews took place. 2 further interviews were held exploring regional approaches. A detailed breakdown of participants is provided in Table 1.

Table 1 - Interviews by stakeholder group

Category	Target number of interviews	Interviews completed
Hub sites	4	4
Fully outsourced sites	5	3
Partnership sites	3	3
Sites with no hub or partnership	20	16
Independent Aseptic Compounding (IAC)	8	7
NHSE Infusion & Specialist Medicines Programme team	1	1

Category	Target number of interviews	Interviews completed
Additional interviews	0	2
TOTALS:	41	36

2. Information gathering

This stage focused on gathering qualitative data and insights from NHS and IAC stakeholders through semi-structured interviews. This included continued engagement with relevant stakeholders to gain supplementary qualitative evidence on aseptic services to complement the survey responses.

Semi-structured interviews were conducted with the agreed stakeholders, qualitative information was gathered based on the agreed KLOEs.

3. Qualitative analysis and validation

The interview data was then analysed to identify key trends and insights. This analysis has enabled an understanding of how providers are responding to the challenges facing aseptic services including:

- Local ability among NHS aseptic units for growth to meet demand for chemotherapy, parenteral nutrition, OPAT antibiotics, complex medicines / preparations for clinical trials, particularly in the next 1-2 years
- Enablers for successful hub and spoke models
- Understanding barriers to public/private partnership
- Exploring examples of established partnerships between the NHS and industry to understand barriers, critical success factors, speed of implementation, potential for growth
- Engaging IACs to understand strategies for the defined areas, enablers for growth, and views on strategic collaboration with the NHS to address the current challenges.

The approach to data collection and analysis undertaken is in line with the Aqua Book for producing quality analysis for government. A tried and tested process has been used at each stage to ensure quality, this includes:

- Cross-checking our findings as we gather interview data
- Maintaining a detailed audit trail of documentation and coding for thematic analysis
- Checking that no new themes are emerging from final interviews (saturation check)
- Looking for data that contradicts emerging themes to strengthen the analysis
- Providing a detailed context for findings (helps to understand transferability) and the inclusion of quotes, and different perspectives to develop a rich understanding of responses.

4. Report drafting and finalisation

The final stage sees the data analysis drafted into report form, consolidating all inputs into findings and recommendations, before quality assurance checks are undertaken. Once the document has been finalised, a copy of the full report will be shared with all participants involved in the exercise to ensure transparency and collective awareness of the outcomes.

Findings overview

Across the 36 interviews we heard a huge variation in approaches to tackling the challenges facing aseptic services: from units seeking to improve their internal capacity, to those looking to secure a Manufacturer's Specials (MS) licence and innovate to serve a broader population, to those extending a long-term partnership with industry, and some looking to collaborate through a joint venture.

NHS aseptic units are working hard to remain viable, and they do a unique job in providing bespoke, short shelf-life, complex ready-to-administer injectables and clinical trial preparations that cannot easily, nor cost-effectively be provided in another way. There is a significant risk, as NHS financial constraints bite, that trust boards will decide to close units where the aseptic estate is approaching the end of its lifespan. We heard from many interviewees that they were looking for strategic direction given the changed political, financial and operational context in which the NHS is now operating – and the practical challenges they face to remain operational.

The ambition from the 2020 Carter Report to create a transformed aseptic service based around a network of regional hubs across England has not been fully implemented and access to national capital investment is limited. Four Pathfinder aseptic hubs sites are in development, but none are yet operational. We heard from many NHS sites that the ability to free up ward nursing time with ready-to-administer injectables (the original premise of the 2020 strategy) is constrained by trust finances. Collaboration between hub and spoke sites, where this is happening, is reportedly varied and remains localised while hubs are establishing themselves. Those not directly involved with a Pathfinder hub, were keen to understand the status of the Pathfinder programme and whether there was still strategic intent (and the funding) to implement it in full, to create the 'national network of regional hubs' that was envisaged in the 2020 strategy. A comparison of the findings from this review to the 2020 findings can be found in Appendix A3.

We heard from Independent Aseptic Compounders that local relationships are generally stronger with the NHS organisations they work with and supply; but that the strategic relationship between NHS England and Independent Aseptic Compounders (IACs) is under strain. All welcomed the engagement that our interviews brought and highlighted that working together at a strategic level offers an opportunity for joint problem solving that could benefit the NHS.

Findings summary

Overall, across all those we interviewed it was felt strongly that there is not a coherent set of solutions currently that address the challenges faced by NHS aseptic services in 2026. The service 'landscape' was described by those we interviewed as:

“Under strain, fragmented, increasingly fragile, and constrained above all by workforce, estates, and regulatory pressures — with no clear national direction to guide local decision-making.”

Stakeholders overwhelmingly supported the ambition of a modernised, resilient aseptic network; with industry partners aligned in wanting to ensure patients get the treatments they need and provide the best value for taxpayers. However, collectively, they believe the NHS currently lacks the national strategy, clarity, infrastructure and dedicated capital required to deliver this.

In summary, across the whole dataset the most significant themes to emerge were as follows:

1. Workforce is the primary constraint on capacity⁸— universally. If the workforce solution is not right – and recognising that this takes time to build - there will be no additional capacity, regardless of investment.
2. There is no clear national aseptic operating model⁹ that defines the roles of different system partners (including commercial) for the current context; principles for how they work together and how the gap between capacity and demand can be effectively bridged — this is causing confusion, duplication, and stalled investment.
3. Partnership with industry is essential, but relationships at a national level are currently fragile and hindered by existing approaches to engagement and a lack of trust which has developed on both sides.
4. A lack of commercial awareness is preventing the NHS from getting the best value for patients.
5. Ageing estates pose systemic risks, with many Section 10 units approaching end-of-life.
6. The regulatory burden is rising faster than NHS trusts’ ability to respond.
7. Clinical trials capacity is severely constrained across the system.

⁸ In NHS operational terms, ‘capacity’ means the ability of a service to meet demand using its available staff, space, equipment, time and funding. It should be noted that there is a mixed view on the definition of capacity between NHS and industry.

⁹ In the NHS, an operating model describes how structures, workforce, processes, data and governance are aligned across national, system and provider levels to plan capacity, respond to demand and deliver improved patient outcomes efficiently. NHS England (n.d.) *NHS England operating framework*. Available at: <https://www.england.nhs.uk/publication/operating-framework/> (Accessed: 22 April 2026).

Key findings

This section sets out the detailed findings providing a more granular view of the issues, opportunities and implications, highlighting the factors that are most influential in shaping future strategic direction. These findings form the evidence base for the recommendations and enablers presented later in the report.

1. Workforce is the primary constraint on capacity

“We’ve never been able to use the full potential of our unit because we do not have the staff.”

1.1 Difficulty maintaining staffing levels

It was felt throughout our interviews that workforce is the single greatest barrier to service resilience. Nearly all trusts we interviewed described difficulty recruiting and retaining aseptic staff with challenges around:

- Pharmacy technician vacancies and attrition
- Lack of scientific/technical workforce
- Significant QA, QC and Qualified Person workforce shortages
- Lack of a workforce pipeline – the service is not visible as a career option
- Geographical proximity with independent compounders leading to some NHS units losing staff in competition

Many NHS units we spoke to either had the space to expand or the ability to increase output with existing equipment (e.g. by extending operating hours and days) but lacked the trained workforce and the revenue investment needed to deliver this.

1.2 Lengthy training and high attrition rates

The combination of lengthy training requirements and high attrition rates means that staffing rosters often appear full but do not translate into operational capacity. Many staff remain unable to perform their full set of duties for an extended period, which contributes to inefficiencies and reduced output. As an example, training an aseptic operator safely can typically take a minimum of 6–12 months, but retention is low with many trusts reporting high attrition after completion of training. This can impact through staff needing to ‘act down’ when there are vacancies in lower bands. Interviewees also noted that even experienced staff require retraining when moving between Section 10 units because equipment and processes vary widely. This compounds existing shortages and adds further pressure on teams. Staffing levels need to be set with a margin above expected capacity to account for this.

Independent Aseptic Compounders also noted high attrition rates for new hires linked to the demands of working in high specification aseptic facilities.

1.3 No national training structure

Those NHS units who had been most successful had developed their own apprenticeships and career pathways, but were lacking practical support nationally, regionally and locally to really make a difference. With no national training pipeline, and the removal of structures such as training rotations for hospital pharmacists and pharmacy technicians, there is reduced awareness of aseptic services as a potential career option.

1.4 Implications

Workforce is the single most important determinant of capacity across every stakeholder group we interviewed. Without workforce, there is no capacity, regardless of capital investment. Capital investment is at risk if this is not considered a first order priority. Secondly, lengthy training requirements for both NHS and IACs mean lead in times need to be considered when managing capacity to meet demand. A strategic approach is required between NHS and industry to avoid unintended system consequences e.g. the ripple effect caused by NHS shutdowns on overall capacity, and the impact this has on everyone's ability to service routine NHS requests.

2. There is no clear national aseptic operating model

"What exactly should hubs make? And what do spokes keep? Nobody knows."

2.1 Hub and spoke model is undefined

While widely supported in principle by the NHS stakeholders we interviewed, by the very nature of the programme, the four NHS Pathfinders have all developed their own approach to what a 'hub' could be and how they intend to operate. None of the Pathfinders are operational yet – the target date set is 2027. As a result, it is unclear which model should be adopted, under what circumstances, and to what benefit. There is no nationally agreed definition of what a 'hub' is or what a 'spoke' is in practise and how they should operate together. It is also unclear to what extent the hubs can support the broader NHS.¹⁰ Given this, the limited public capital and the forecasted national shortage of chemotherapy capacity to meet demand, action is required to directly address this issue.

2.2 A National Product Portfolio is missing and critically needed

Every region expressed the need for a national list determining what NHS sites should retain; what NHS Hubs should produce; and what Independent Aseptic Compounds should cover. The table below captures what we heard from interviewees:

¹⁰ It should be noted that the evaluation of the Pathfinder programme is planned and not yet taken place.

Table 2 - Summary of interviewee views on a National Product Portfolio

What NHS Spokes should retain	What NHS Hubs should produce	What Independent Aseptic Compounders should cover
• Short-expiry chemotherapy • Bespoke and complex preparations • Clinical trials preparations • Emergency preparations • ATMPs or niche diagnostics	• Batched medium-expiry chemotherapy • Long-expiry CIVAS • Ready-to-administer antibiotics • Standardised PN (if adopted) • Products with established stability profiles	• Large-volume PN • Long-expiry, large-volume, ready-to-administer injectables • High-volume CIVAS

Further work and engagement are required to develop and finalise the National Product Portfolio and understand whether there is sufficient overall system capacity to meet demand. This needs to be a 'live' list that is periodically reviewed to ensure it reflects national priorities as these change.

2.3. Logistics is an underestimated critical dependency.

Several interviewees identified logistics as a critical dependency for the NHS, with a perception that limited thought has been given to how products could be delivered across the country. Integration with clinical scheduling is also essential to ensure timely delivery, minimise waste, and ultimately support patient care pathways. Distributing aseptic ready-to-administer products safely and efficiently requires:

- temperature-controlled logistics
- expiry and shelf-life management
- real-time inventory systems to coordinate distribution.

Some products require a fast turnaround, and some geographies (rural and coastal regions for example) present additional logistical challenges and will require longer expiries on products as a result. The NHS production units (Pathfinder or MHRA licenced) need the right logistical expertise to develop and operate a successful model.

2.4 Implications

Without a clearly defined aseptic operating model with national product definitions, hubs cannot design facilities that will meet the needs of the NHS; spokes will struggle to secure the strategic investment needed to remain operational; and the Independent Sector won't be able to respond to NHS needs. The current situation is causing confusion, duplication, and stalled investment – both within the NHS and in industry. A national blueprint for the

aseptic operating model is urgently required. The Pathfinder Hubs and corresponding delivery models need to be implemented successfully and evaluated before further investment is made.

3. Partnership with industry is essential but relationships are fragile

“We cannot invest millions without knowing what the NHS will buy.”

3.1 NHS reliance on Independent Aseptic Compounders

The NHS is heavily¹¹ reliant on industry manufacturing ready-to-administer aseptic injectables and will continue to be even once NHS Pathfinder Hubs are operational. Independent aseptic compounders are important strategic partners to the NHS, with considerable knowledge, expertise and capacity in manufacturing and distributing aseptic medicines, at scale, efficiently, under strict MRHA regulation. In many trusts we spoke to, parenteral nutrition preparation is 100% outsourced. Independent aseptic compounders are also frequently called on without warning to support (either directly or indirectly) when NHS units shut down, buffering the increased impact of this on overall system (NHS and industry) capacity. However, there has been little strategic recognition of this role by the NHS to date, and the national relationship is currently fragile.

3.2 Loss of trust and fragmented communication between NHS and industry

Alongside the NHS's reliance on independent compounders, several NHS interviewees highlighted concerns about operational reliability, including extended lead times, missed deliveries, significant delivery costs and variable responsiveness during periods of surge demand. In some cases, these experiences have actively driven trusts to retain or re-establish local capacity as a resilience measure, even where this may not represent the most cost-efficient option.

At a local organisational level relationships between the NHS and industry were varied between purely transactional through to genuine strategic partnership where teams operated based on a shared approach, shared vision, shared problem solving – and a meeting of minds on a human level.

The national relationship with independent aseptic compounders, and the UK trade body, the British Specialist Nutrition Association (BSNA) has been strained in recent years, hindered by current approaches to engagement preventing a full and open dialogue, and a lack of trust has developed on both sides. During our interviews, some stakeholders noted that engagement with NHS England had been limited, signalling an opportunity to establish more regular and structured communication. The IACs that we spoke to overwhelmingly wanted more communication, greater engagement, and strategic direction from NHS leaders on how best to engage with the NHS as a partner – and at what level to do this.

Outside NHS England, there is a lack of understanding of the remit of the Infusions and Specialist Medicines Programme versus that of other departments in NHS England. The programme represents a wide range of different NHS units and provides strategic advice and implementation tools after being established to implement the recommendations of Lord Carter (2020). Whilst it guides and collaborates within and outside NHS England, it is not responsible for procurement, contracting nor commissioning for the NHS.

3.3 Lack of demand signalling and data sharing

There is strong commercial appetite from industry to support the NHS and invest in the infrastructure needed to respond to NHS requirements. However, industry partners require some form of shared and consistent demand signalling, together with a shared understanding of risk, to be able to secure the investment needed. This is common practice within health systems in other countries, and other industries. Changes in the system such as the investment in Pathfinders have an impact on strategic commercial relationships (and therefore the ability to invest) that underpin the provision of aseptic injectables to the NHS.

At the same time, NHS England interviewees reported ongoing challenges in securing accurate, complete and timely data from industry, particularly in relation to capacity, utilisation and constraints. This has contributed to a perception of one-way transparency, in which NHS organisations are expected to share detailed intelligence while commercial partners are more reluctant to disclose commercially sensitive information. This asymmetry has reinforced mistrust and constrained meaningful strategic planning.

3.4 Implications

The NHS is heavily reliant on commercial partners to deliver aseptic injectable medicines. Partnership with industry is therefore essential and requires sustained, two-way investment in strategic relationship building by both NHS organisations and industry partners; underpinned by clear expectations, appropriate data sharing and consistent demand signalling.

4. A lack of commercial awareness is preventing the NHS from getting the best value for patients

“The ‘make vs buy’ decision is a problem – the NHS doesn’t know what the true cost is to make it themselves”

Findings in this section relate primarily to decision-making at individual NHS trust level, rather than the role of NHS England. Across interviews, there was wide variation in how aseptic services are understood, prioritised and governed within trusts, particularly at board level. In many cases, aseptic services were described as technically complex, largely invisible to senior leadership when functioning well, and poorly understood in terms of their clinical significance, cost base and impact on wider organisational resilience, research income and patient flow. This variability in understanding shapes how services are valued

and invested in and directly affects the capability of trusts to assess the true cost of in-house production, compare this with commercial alternatives; and make informed strategic decisions about where capacity should be retained, expanded or outsourced. As a result, commercial decision-making in aseptic services is often constrained by limited cost transparency, competing operational pressures and uneven organisational insight, rather than by deliberate resistance to partnership or efficiency.

4.1 NHS true unit cost of production is not understood

While many NHS trusts understand their immediate staffing and consumables costs, few have visibility of the full unit cost of aseptic production, including estates, overheads and depreciation. This reflects structural challenges in how aseptic services are funded and governed within trusts, as well as limited access to commercial and costing expertise. As a result, trusts are often unable to compare in-house production with commercial prices on a like-for-like basis, constraining strategic decision-making and contributing to fragile or sub-optimal capacity choices.

4.2 Limited commercial understanding is reducing the ability to respond effectively to demand

There was evidence of limited commercial awareness within some NHS operational teams, and in certain cases a prevailing public sector mindset that hindered constructive engagement with industry partners. This was reportedly acting as a constraint on the combined capability of NHS and industry manufacturing systems to respond effectively to fluctuations in demand. Industry stakeholders described instances of unrealistic expectations placed on them — such as requests for substantial increases in supply at very short notice — despite both sectors operating under similar constraints.

We also received anecdotal reports of practices that adversely affected system efficiency, including NHS units continuing to manufacture routine standard products in-house, thereby diverting capacity away from specialist and bespoke preparations. Also, failing to provide timely notice of planned shutdowns, resulting in unplanned pressures on industry capacity that reduce the ability to meet routine NHS requirements. Generating higher than anticipated volumes of bespoke or ad hoc orders further contributes to operational unpredictability.

4.3 Procurement arrangements vary across England and favour price over value

From a procurement perspective, we heard that several regions had procurement frameworks in place that were benefiting NHS trusts in those areas needing transactional outsourcing. However, we also heard from independent aseptic compounders that the structure of those framework contracts was a barrier to industry supporting the NHS to secure better strategic value from its contracts - the short-term nature of the agreements, with no commitments to buy for example, was preventing investment in developments such as automation that would increase efficiency, and improve value to the NHS.

Other aspects of the procurement process were felt to be operationally inefficient or limited industry's ability to respond when this was needed e.g.: duplicative submissions to different frameworks; KPIs and contractual commitments varying between frameworks and regions; and the specified product portfolio in some contracts limiting the range of suppliers who could join the framework, in turn limiting the manufacturing capacity accessible to trusts - of strategic importance when there is an unplanned shortfall in NHS capacity. It is worth noting that NHS Pathfinder Hubs, once operational will be subject to the same processes should they wish to supply products to the wider NHS as authorised specials manufacturers.

4.4 Implications

A lack of understanding of true production costs is affecting NHS trusts' ability to understand value for money and therefore make informed strategic decisions on where NHS manufacturing capacity must be maximised, and where industry is better placed to secure the best value for money for patients in the manufacture of aseptic injectables. This is critical in an area of the NHS that is heavily reliant on industry.

A lack of commercial awareness at operational levels within the NHS is unintentionally having a negative effect on the NHS's ability to provide aseptic injectable medicines and cope with fluctuations in demand.

Greater value could be derived by the NHS from its relationship with industry by reevaluating its approach to procurement, strategically and operationally, to recognise what is of value to the NHS in the broadest sense – not just price, and how best to transact this and at what level – national, regional, local.

5. Ageing estates pose systemic risks, with many Section 10 units approaching end-of-life.

"The Trust has no appetite for another aseptic rebuild project."

5.1 Ageing estate poses a strategic risk for Section 10 provision

Across all regions, interviewees reported that a significant proportion of Section 10 units are operating in an ageing estate with facilities that are nearing end-of life and are unable to meet Annex 1 of the EU Good Manufacturing Practice guidance requirements.¹² A large number reported that they were working hard within current financial constraints to make the case for investment with their trust boards but were looking for national and regional strategic direction. In the absence of this some organisations have already made the move to explore other models of delivery, including closing units and outsourcing. This is a situation which will only amplify without action. Despite this, many stakeholders also emphasised the need to retain local Section 10 units to maintain clinical responsiveness

¹² European Commission (2022), *The Rules Governing Medicinal Products in the European Union. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Annex 1: Manufacture of Sterile Medicinal Products.*

and highlighted that outsourcing short-expiry complex preparations is not a resilient long-term solution, given its limited commercial viability, and high cost.

5.2 Investment uncertainty is heightening the risk

Many interviewees commented on uncertainty linked to the development of further phases of NHS Pathfinder Hubs, whether additional investment would be forthcoming; whether existing hubs would be able to supply outside of their immediate geography and what products they would be producing. Those in some regions with a pathfinder site were looking towards the hubs to pick up some of the capacity gap, but without a hub and spoke model, not understanding exactly what and how, and the implications for their unit. There was also a risk highlighted that some trust executives may not yet have full visibility of the complexity of aseptic services which has led to underinvestment in aseptic estates, and may lead to further underinvestment, particularly in the current financial climate.

5.3 Implications

The combination of challenges that both ageing estates and a fragile workforce bring to Section 10 units threaten their long-term sustainability. Ageing facilities are more difficult and costly to maintain, but also less attractive to current and prospective staff, and are more vulnerable to unplanned shutdowns, all of which exacerbate existing workforce shortages and operational inefficiencies.

As estates decline, if trusts do not invest in maintaining high quality Section 10 production capacity, reliance on outsourced provision is likely to grow despite its recognised limitations for short-expiry and complex and bespoke preparations. Trusts are also navigating significant planning uncertainty, making it challenging to decide what to invest in when there is financial pressure to make savings. Collectively, these factors heighten strategic risk and prevent services from remaining resilient and operationally viable at a time when this is most critical.

6. The regulatory burden is rising faster than NHS trusts' ability to respond.

"We need support to get through a licence journey, not just to be told we failed."

MHRA licensing is widely regarded as a complex, resource-intensive process that requires dedicated and highly skilled leadership. Numerous interviewees described an annual growth in regulation requirements and how this can be unattainable without the dedicated expertise. They described MHRA licensing as a laborious and lengthy process where the support they required to succeed was not available to them (either due to capacity or financial restrictions). Consequently, some sites have chosen not to pursue MHRA licensing and instead remain Section 10 units, as the burden of meeting regulatory expectations outweighs their available workforce capacity and expertise.

6.1 Implications

Rising regulatory expectations are constraining the ability of many NHS aseptic units to sustain MHRA-licensed activity. In the absence of sufficient workforce capacity, funding and dedicated leadership, some trusts are choosing to limit scope or remain Section 10 providers as a pragmatic risk-management decision. This is reducing system flexibility, constraining clinical trials capacity, and increasing reliance on external provision for aseptic medicines.

7. Clinical trials capacity is severely constrained across the system.

There is considerable variability in the scale of clinical trials medicines preparation in NHS aseptic units. Often, sites are unable to support clinical trials or are constrained in the number of preparations they can provide, although there is a strong and consistent desire to do more if capacity allowed. There was also variation in how clinical trial income generation was recognised and whether it was attributed back to aseptic budgets to support ongoing development of services.

Across the units, there is a shared recognition of the value that clinical trials bring, both for patients and for the organisation. Interviewees expressed genuine enthusiasm for trial involvement but identified several barriers. A recurring challenge is the lack of an in-house Qualified Person to support clinical trials beyond reconstitution of existing Investigational Medicinal Products, whilst others noted that staff have a limited understanding of the specific quality requirements associated with clinical trials, which creates uncertainty and can hinder a unit's ability to support clinical trial work.

Many units highlighted that outsourcing long expiry ready-to-administer injectables would free up internal capacity, enabling greater focus on clinical trials. Isolator access is another limiting factor, as isolators are commonly prioritised for chemotherapy, leaving insufficient capacity for the more complex and time-consuming clinical trial preparations. Several sites suggested if they were only responsible for short expiry chemotherapy and clinical trials, they would be better positioned to support trial activity.

7.1 Implications

Aseptic units within NHS trust sites are well-placed to support clinical trials, as their proximity to clinical teams enables rapid preparation and timely supply of medicines directly to patients, reducing delays that can affect trial timelines and patient outcomes. This is especially important for products with short shelf lives or stability constraints, where timely administration is critical.

In contrast, when units do not provide clinical trial services, patients may be required to travel further or wait longer for personalised treatments. This can restrict access to innovative therapies, limit recruitment into research studies, and reduce the ability to deliver

care close to home. A lack of local provision can therefore not only disadvantage patients but also reduce the organisation's ability to participate in or attract clinical research.

For a hospital trust, delivering clinical trials offers significant benefits such as increasing their eligibility for research funding and commercial trial income, which can be reinvested into facilities, workforce development and service improvement. A strong research profile can make a trust more attractive for partnerships with regional aseptic hubs and commercial organisations, as well as for attracting and retaining clinical specialists who wish to pursue research. Overall, offering aseptic clinical trial services supports both improved patient care and long-term organisational sustainability.

Recommendations

The recommendations outlined in this section draw on insights gathered through recent stakeholder engagement and build on the findings of previous reports. Following the implementation of much of the 2020 Carter Review, this engagement has been instrumental in generating the intelligence needed to inform and shape future strategic direction. The following proposals are designed to provide clear evidence-based options that reflect stakeholder priorities; address identified gaps and could create a strong foundation for the development of a coherent and sustainable delivery plan.

All recommendations should be developed and implemented via engagement with those currently delivering aseptic services with senior leadership and decision-making backing.

R1: Create a national aseptic workforce plan that defines practical, time-bound actions.

Timeframe to create: Immediate (0-1 years)

Timeframe to implement: Medium term (1-3 years)

Create a National Aseptic Workforce Plan to address urgent and emerging challenges in training, recruitment, and retention across NHS aseptic services. The plan should define practical, timebound actions that enable services to operate safely, sustainably, and at the capacity required to meet clinical demand—rather than setting out high level ambitions without implementation detail.

A central component of the plan would be the development of nationally standardised core competencies and a ‘training passport’ that reduces training time, removes duplication, supports staff mobility across organisations (acknowledging this is already happening), and supports the development of clear, attractive technical and scientific career pathways.

Recognising that further engagement is needed to develop the workforce plan, a suggested list of inclusions gathered from our engagement is included below:

- Introduce standardised national core competencies across all clinical aseptic roles (technical, scientific, pharmacy and QA/QC).
- Establish a national training passport to make competencies transferable between organisations and reduce repeated training.¹³
- Shorten training time by focusing on underpinning knowledge and theory, core-standardised methods, consistent training materials and reduced local duplication.
- Strengthen science and technical career pathways, improving recognition, visibility, structured development and national coordination of placements.

¹³ Subsequent to the stakeholder interviews commencing, the ISMP workforce workstream shared a competency spreadsheet for QA/WC roles which is currently being improved to be more digital and user friendly.

- Develop a template risk assessment for allowing experienced staff to operate prior to local training depending on evidence from previous role(s)
- Address the finite availability of QA and QC resources by enabling shared capabilities, coordinated competencies and reduced duplication of QA/QC assessment.
- Improve recruitment pipelines through coordinated work with Higher Education Institutions (HEIs), apprenticeship providers and workforce planning teams.
- Create clear, supported progression routes¹⁴ to improve retention.
- Align workforce growth with projected future aseptic service demand, including resilience and training expectations.

R2: Develop a national blueprint for the aseptic operating model in England.

Develop a national blueprint for the aseptic operating model in England that sets out a clear minimum NHS model, a nationally agreed product portfolio, reflecting live priorities, and a structured approach to what should be delivered once nationally, what should be coordinated regionally, and what should remain local.

Establishing a single, coherent national model would reduce unwarranted variation, strengthen capacity planning, support local decision making (including investment) and ensure a consistent, sustainable approach to meeting current and future aseptic demand across the country.

The Pathfinder Hubs and corresponding delivery models need to be implemented successfully, become fully operational and the merits be evaluated. This recommendation builds specifically on the recommendations from the Carter Report (2020) and on learning from Pathfinder sites.

R2.1 Minimum NHS model

Timeframe: Immediate (0-1 years)

The national blueprint should describe a minimum NHS model which sets out the essential components that every Trust in England must have in place for hospitals to provide a high quality and equitable service for patients. It defines the core standards, product scope and principles for governance arrangements that all services must meet, while allowing flexibility for local organisations to build above this baseline.

The ability for an NHS Trust to make on site short expiry, high cost, “fragile” medicines was repeatedly highlighted throughout the engagement as critical to continue to serve the more complex and bespoke medical needs of a local population including equitable delivery of clinical trials. It is recommended that work is undertaken to define the NHS minimum model to support the required investment to sustain this minimum model.

¹⁴ Subsequent to the stakeholder interviews commencing, the ISMP workforce workstream has shared nationally career pathways as well as an EDT gap analysis and EDT catalogue.

R2.2 Product portfolio

Timeframe: Immediate (0-1 years)

A national product portfolio reflecting live priorities should describe the types of products the different organisation types within the NHS aseptic model focus on – spokes, hubs and industry. Organisations may choose to deliver outside of this but having a shared view of what is generally produced and where will facilitate better strategic decision making at regional, system and local levels.

R2.3 Optimise the investment made in the Pathfinder sites by exploring what can be “done once”

Timeframe: Immediate (0-1 years)

Work should be undertaken in areas that could be “done once” across the NHS, and also with industry. This includes:

- Developing procurement and commercial documentation to support hub and spoke contracting e.g. frameworks or Service Level Agreements
- Developing Quality Assurance and Quality Control documentation appropriate for sharing
- Exploring a shared QMS system across NHS hubs
- Exploring ability to share stability data.

R2.4 What should be done at both a national and regional level

Timeframe: Medium term (1-3 years)

Regional understanding of local challenges will be fundamental to the successful implementation of any plan. National involvement should focus on describing the “what”, leaving regions to agree “the how”. The key enabler E1 covers the regional work in more detail and includes making better use of existing infrastructure e.g. Chief Pharmacist and specialist networks already in existence.

R3: Invest in the relationship between NHS and industry to yield greater benefits.

Timeframe: Immediate (0-1 years)

Investing in developing a genuine partnership approach at a strategic level with industry for the benefit of patients and taxpayers should include:

- Exploration of how communication can be improved between NHS and IACs at a national and regional level, recognising both the important role of the British Specialist Nutrition Association and the additional challenge brought by competition legislation when discussions are in a group forum.
- Create a two-way feedback loop between NHS and industry to develop a trusted relationship.

- Develop shared demand signalling between NHS and industry that is focused on both parties sharing just enough data to support better commercial conversations, rather than all data.

R4: Focus on “what could make a difference tomorrow”.

R4.1 Standardisation

Timeframe: Immediate (0-1 years)

National support is needed to understand and appropriately challenge the drivers for bespoke products. Standardisation would support increased capacity and can shortcut local negotiations on what is needed. A national view on standardisation and clinical appropriateness is essential.

R4.2 Improving productivity

Timeframe: Immediate (0-1 years)

There are pockets of great examples of productivity improvements that result in greater capacity across the country but no mechanism to spread and scale these currently. Examples include understanding and reducing waste and improving upstream ordering processes to support better management of workflow within a unit.

Developing and promoting a way to share productivity improvement ideas would allow capacity gains to be made at a local level.

R4.3 Commercial agility

Timeframe: Medium term (1-3 years)

Development of the NHS' commercial agility falls into four recommended areas of focus:

- Work should be undertaken to understand the true NHS unit production cost to support informed investment decisions. Guidance on what needs to be considered (e.g. overheads, pay costs, raw ingredients, consumables etc) and a centrally developed tool to do these calculations will support a consistent assessment of value for money for patients.
- Establish a Chief Pharmacist learning and support initiative, co-designed with industry, to strengthen approaches to commercial strategic partnerships, collaborative working, how the NHS can be a better customer and suppliers can be a better partner.
- Reevaluate aseptic procurement strategically and operationally with a drive to deliver value in its broadest sense, not just price. This should also include a review of contracting mechanisms to remove duplication and streamline routes for the NHS to secure aseptic products.
- Strengthen trust board understanding of aseptic services by improving visibility of their clinical criticality, cost drivers, income stream potential from clinical trials,

regulatory complexity and impact on organisational resilience, patient safety and research income, to support more informed strategic investment and “make versus buy” decisions.

Key enablers

The successful development of a future vision would depend on several key enablers to support the delivery of the recommendations outlined in this report. These enablers reflect insights gathered and highlight the foundational conditions needed to translate identified priorities into sustainable change. Together, they provide the organisational, operational, and cultural support required to ensure the vision can be realised effectively and with lasting impact.

E1. Regional intelligence groups

Timeframe: Immediate (0-1 years)

Regional intelligence groups should be responsible for the application of the national aseptic blueprint. Our engagement highlighted the variation in challenges between regions and having a “one-size-fits-all” approach will not respond to these, e.g. a region with a dense population and multiple aseptic sites vs a rural, sparse population with fewer aseptic sites. The regional intelligence groups should:

- Have standardised governance and two-way feedback loops with a national team. The team will be dependent on the ask – e.g. Infusions and Specialist Medicines Programme for advice, Commercial for procurement etc.
- Consider what is needed for their region based on population, geographical coverage, age of estates.
- Have an overview of the aseptic estate across the region (including local risks) and collate and share meaningful data to support demand signalling both to neighbouring units and industry.
- Facilitate mutual aid/contingency agreements (taking into account legal restrictions), focusing on the population as a whole rather than sovereign providers.

E2. Implementation supported by governance that allows the voices of key stakeholders to be heard

Timeframe: Immediate (0-1 years)

Stakeholders described a disconnect between current national programme activities and regional and local activities. Groups have been established outside of the NHS England governance to try to respond to this perceived disconnect and it is recommended that the implementation plan considers how these groups do, or do not, play a role in implementation. This is furthered by an inconsistent awareness of the engagement activities and national outputs of the Infusions and Specialist Medicines Programme, and their specific remit versus that of other parts of NHS England.

Once agreed, the future vision for the service must be supported by a robust implementation plan that is supported by a cross-section of staff working in the aseptic system currently, as well as senior leaders and decision makers. All stakeholders share the same goal of

ensuring safe, timely and effective delivery of aseptic services and should work together to deliver this.

MHRA is a critical stakeholder in securing the future of NHS aseptic services and must also be a part of the implementation.

E3. Modernise regulatory requirements

Timeframe: Long term (3-10 years)

A programme of support is needed to help units applying for a MHRA licence for both their application and development of units. This expert pool of resource should be available to regions, so they respond to their local challenges. It is in the NHS interest that units are successful in achieving MS licence status.

It is also recommended that consideration is given to legislation change that supports provision of mutual aid and resilience within a given geographical area and responds to delivery of aseptic services in modern NHS organisational forms e.g. NHS Groups and ICBs.

E4. Logistics considerations

Timeframe: Immediate (0-1 years)

Wider understanding of available logistical expertise is needed to develop and operate a successful model to support distribution of products produced by the NHS. An example given through the interviews was to support MHRA approval of using central distribution centres as an accepted NHS mechanism.

Next steps

This report will be shared with all participants of the interview process.

NHS England will review the recommendations and enablers and build appropriate strategic responses that reflect the ongoing changes across NHS central, regional and ICB structures and functions.

Appendices

A1 Key lines of enquiry

Table 3 details the KLOEs used across interviews, there were four variations designed for different stakeholder groups.

Table 3 - Key Lines of Enquiry (KLOEs)

For aseptic hub sites, and fully outsourced sites	For sites with partnerships in place
- Do you have future plans to further evolve the provision? - Specifically is there any potential growth within Chemotherapy, Parenteral Nutrition, OPAT antibiotics, complex medicines or preparations for clinical trials? - Have you/are you planning to access research funding to support this work? - What do you think are the barriers to pursuing a public-private partnership? - Do you have any identified spoke sites and how is this relationship working so far? - What do you think would be beneficial to have in place to result in a successful hub and spoke model? - What would need to be true for you to provide beyond your hub/spoke network? - What actions should be prioritised to deliver the greatest increase in capacity in the next 1-2 years for the defined areas?	- What made you put this arrangement into action? - What do you believe are the critical success factors? - How easy/difficult was it to establish (barriers)? - What was the time frame from idea inception to day 1 operational? - How is it working (benefits/limitations)? - Do you have future plans to further evolve the provision? - Specifically is there any potential growth within Chemotherapy, Parenteral Nutrition, OPAT antibiotics, complex medicines or preparations for clinical trials? - Did you have to go through a business case process to get the site set up and if so please could you share details of what this looked like? - If you didn't have this arrangement in place already, would you go back and put it in place again? - What actions should be prioritised to deliver the greatest increase in capacity in the next 1-2 years for the defined areas?
For aseptic sites (who are not a hub or do not have a partnership in place)	For IACs
- Does the overview document provided resonate with your service and if so what, if anything, are you currently doing to respond to this? (see A2) - What local solutions are being considered? - Have you/are you planning to access research funding to support this work? - What do you think are the barriers to pursuing a public-private partnership? - Do you have a local hub site and if so, have you had any conversations about providing services to your site? - What do you think the future of your aseptic service is?	- Are the below areas of interest to you beyond initial plans for capacity: - Chemotherapy - Parenteral Nutrition - OPAT antibiotics - Complex medicines, preparations for clinical trials? - Other aseptic injectable medicine? - If yes – is this nationwide or regional? [exploring any negative responses] Please can you advise what the blockers are and what would need to be true to overcome them (being as specific as possible)? [exploring any positive responses] What could the full system (aseptic hubs through

What actions should be prioritised to deliver the greatest increase in capacity in the next 1-2 years for the defined areas?	to full system) be doing to facilitate greater capacity? - In order to successfully create a strategic collaboration, what building blocks need to be in place to move forward? - What actions should be prioritised to deliver the greatest increase in capacity in the next 1-2 years for the defined areas?
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A2 Securing the Future of Injectable Medicines in the NHS

Securing the Future of Injectable Medicines in the NHS

A £7 Billion Lifeline

The NHS in England spends over £7 billion each year on injectable medicines — treatments patients depend on at the point of care, including chemotherapy, clinical trial drugs, and intravenous nutrition. But the current capacity is not keeping up with demand.



Over 4 million doses, over 100,000 patients, of cancer treatment are prepared annually, yet demand is increasing by 5% each year.



Patients are already experiencing weeks-long delays in hospital beds waiting for home intravenous nutrition.



By 2030, an estimated 1 in 10 patients needing injectable chemotherapy every year may face delays with life-saving chemotherapy due to lack of capacity.

The Fix: The Infusions & Special Medicines Programme

This is the biggest national programme focused on ensuring safe, ready-to-administer injectable treatments are available whenever and wherever needed.



£240 million in capital funding will fund future infrastructure developments.



Without investment, ageing infrastructure and workforce shortages put **patients and staff at risk**.

What's at stake



87% of NHS medicine production units have critical regulatory compliance issues.



One in ten intravenous administrations result in medication errors.



Overstretched nurses are being pushed to prepare complex infusions on the wards, increasing risks.

We cannot import our way out of this challenge. The solution is onshore, bold, and ready to administer.

The Opportunity

✓ £475 million in annual productivity gains.

✓ One million hospital bed days released each year.

✓ Expanded support for clinical trials and advanced therapies.

✓ Greater equity in access to innovative treatments.

✓ Reinforced NHS leadership in global healthcare innovation.

✓ Over 2000 jobs generated in STEM and apprenticeship roles.

Protect patients. Enable innovation. Future-proof the NHS.

A3 2020 Carter Report findings compared to the findings of this report's stakeholder engagement

The following is a comparison of our key findings with the recommendations from the 2020 Carter Report.

1. Workforce constraints

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
Workforce is the primary constraint on capacity	Support and transform the aseptic workforce (p30)	Strong alignment	The Carter Report clearly identifies workforce as an enabler to delivering the Hub and Spoke Target Operating Model. Our findings confirm this unequivocally; but also make the distinction that workforce is <i>the</i> hard constraint preventing the capacity growth needed to meet future Chemotherapy and PN demand across the whole system.
Long training times, high attrition, lack of pipeline	Develop new roles, skills mix and workforce models (pp 30-34)	Partial alignment / New	The Carter Report recommendation remains valid but needs adjusting to reflect the criticality of the aseptic workforce as a capacity constraint. Our findings suggest nationalised training pipelines, and formal career pathways rather than incremental local solutions.
QA/QC workforce shortage	Regulation and safety are core themes in the Carter Report but QA/QC scarcity is not highlighted.	New	Our findings suggest that QA/QC roles need to be explicitly prioritised as capacity-defining roles.

Summary: Our findings are in alignment with the Carter Report recommendations, but our recommendations propose a strengthening and a re-frame to **recognise the aseptic workforce as a first-order national system priority**.

2. National operating model (hub and spoke)

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
No clear national aseptic operating model	Implement a national hub-and-spoke Target Operating Model (pp26-30)	Partially aligned in intent, not in delivery	The vision in the Carter Report is clear (centralised high-volume production; local bespoke and clinical trials work). However, the operating model has not been sufficiently defined or implemented, so is amplifying uncertainty at a time when solutions are required to address a new set of challenges: i.e. the provision of chemotherapy and PN. The role of the independent sector in this system is also not factored.
Undefined hub vs spoke roles	Implement a national hub-and-spoke Target Operating Model (pp26-30) specifically: "These hubs should support spoke facilities across England and ensure safe, high quality and resilient supplies by 2026/27" (p30)	Aligned in intent, not in delivery	As above, the vision is aligned, but the hub and spoke model has not been implemented and without explicit definitions, the model cannot be optimised to address current challenges within aseptic services (i.e. spoke facilities); and trusts are unable to make realistic strategic planning assumptions.
Missing National Product Portfolio	Expand use of standardised, Ready-to-Administer (RtA) products	New	The Carter Report emphasis is on the production of large scale standardised RtA products to 'release nursing time to care' but does not suggest a product portfolio. Our findings suggest this is needed to respond optimally to forecast capacity shortages in chemotherapy. Anecdotally, demand for RtA products to release nursing time is low, because of the additional cost of these products to trusts at a time of financial constraint.
Logistics underestimated	Develop relationships with potential logistics partners (p51)		The Carter Report references logistics and recognises the requirement for implementation. Our findings suggest that logistics (temperature control, shelf-life, geography) needs to be considered as a first order design priority for NHS capacity to be optimised beyond immediate localities.

Summary: Our findings are in alignment with the Carter Report's outline Target Operating Model, but we suggest that the latter requires **much greater national specification and enabling infrastructure** to respond effectively to the current operational and financial context.

3. Role of industry and partnerships

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
NHS dependence on Independent Aseptic Compounders has increased	The Carter Report suggests in several places that the NHS should work with commercial compounders, where appropriate (pp 6, 11, 13, 14)	Not aligned	While the Carter Report includes industry in supporting the NHS to build a system with resilience and capacity (p6); it also states that the commercial sector 'lacks the capacity to meet increased demand (...) and unmet need in the NHS'. The 2020 strategy actively sought to increase NHS resilience and reduce dependence on independent aseptic compounding. Our findings suggest that: 1. In the last 5 years dependence on IACs has in fact deepened. Contrary to the Carter Report assessment, latest analysis from NHSE suggests that as much as 60% of aseptic product use in the NHS could be being produced by IACs. 2. IACs have fed back that they could expand capacity with the right conditions to secure investment. 3. There is an opportunity for strategic collaboration to optimise overall system capacity to meet demand and get better value for the NHS.
Fragile national relationships; lack of trust	Not applicable	New	This was not considered in the Carter Report. Our findings suggest that delivery mechanisms (engagement, governance, communication) have been insufficient given the strategic importance of industry to the NHS in the delivery of aseptic

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
			medicines. Coupled with the NHS's strategic intent to enter mass manufacturing directly in competition with IACs, this has sent a strong adverse message.
Lack of demand signalling and data sharing	Not applicable	New	The Carter Report does not address demand signalling or long-term investment signals to industry. This is a gap for a service that is heavily reliant on industry manufacturing capacity and is forecasting a shortfall*.

*NHS England forecast a shortage in manufacturing capacity to meet chemotherapy demand by 2030.

Summary: Our findings suggest that **more mature commercial behaviours and structures** are needed to address the current set of challenges and to maximise the potential of existing relationships with industry, recognising them as a genuine partner to delivery, and building back trust.

4. Commercial awareness and procurement

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
NHS does not understand the true unit cost to produce aseptically prepared medicines	Creating a sustainable and resilient system (p40-41)	Aligned	This is unchanged since the Carter Report which found the same thing (p17) Full cost transparency is critical to commercial capability within the NHS and is required to underpin good decision making about the most efficient and cost-effective production routes.
Limited commercial understanding is reducing ability to respond to demand	Not applicable	New	This wasn't covered by the Carter Report – our findings suggest that limited commercial understanding at operational levels, means that the impact of operational behaviours on capacity is not being factored into decision-making or service design.

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
Procurement favours price over value	Develop and implement new longer-term contracts (10 years plus) (...) with NHS and commercial compounding services. Where appropriate approaches including Open Book Contract Management (OBCM) should be further developed (pp 44 & 50)	Partial alignment	However, our findings also suggest that procurement design is undermining resilience, investment and surge capacity—an issue not touched on in the Carter Report.

Summary: there is some alignment between the findings in the Carter Report. Our findings suggest that **NHS commercial capability must be explicitly strengthened** to realise both value for money and maximise operational capacity.

5. Estates and infrastructure

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
Ageing Section 10 estates pose systemic risk	Continued expertise and facilities in spoke organisations are highlighted by the Carter Report for individual patient needs to be met, and for clinical trials (p26). Hub and spoke model will require strategic decisions by localities on investment in existing aseptic units (p39) There is the need for significant strategic investment (...) to	Aligned	The Carter Report identifies the same risk – however our findings suggest this has now been pulled into sharp focus by the NHS financial position. The investment in Pathfinder Hubs does not mitigate this specific issue. Anecdotally regional network collaboration is only happening in some areas – and in some cases this is leading to disinvestment decisions.

	maintain 'fit for purpose' NHS aseptic dispensing capabilities. (p40)		
Investment uncertainty linked to Pathfinder Programme	The intention behind the creation of NHS manufacturing Hubs was to 'build a system which is resilient and has capacity' (p6) – they were positioned as exemplars. The potential negative effects on system-wide investment was not considered.	New	Our findings highlight the consequences of implementation that weren't foreseen in 2020.

Summary: The Carter Report highlights similar risks. Our finding show that the recommendations have not been fully implemented and that **the ageing estate risk of NHS aseptic sites has potentially increased.**

6. Regulation, QC and MHRA licensing

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
Rising regulatory burden is outpacing NHS capacity	Carter Report references the need for quality assurance as part of a resilient workforce and highlights a shortage of Qualified Person resource (p31). Regulatory growth is not mentioned.	Partly aligned	GMP Annex 1 changes in 2022 have changed the operating environment while workforce shortages in this area continue.
Units choosing not to pursue MHRA licensing	Mandatory licencing in hub sites and increasing licencing in spoke sites was a key theme highlighted in the call for evidence in the Carter Report (p26) as was reference to 'downgrading' (p36)	Partial	The Carter strategy was based on a full implementation of the Hub and Spoke Model in every region – this has not been the case. Our findings suggest that the significant work and investment involved in achieving an MHRA MS licence is

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
			detering trusts when this may be of strategic importance to support collaboration and mutual aid.

Summary: The Carter Report highlights similar issues, but since publication the regulatory environment has changed, and our findings suggest that **these issues are constraining the NHS's ability to maximise its effective production capacity.**

7. Clinical trials capacity

2026 Aseptic Review Finding	Relevant Carter recommendation(s)	Alignment	Comparison
Clinical trials capacity is severely constrained	The Carter Report highlights the strategic importance of local aseptic services continuing to support clinical trials but also concedes that the standard care clinical treatment of patients will always be prioritised (pp 11-12), Aseptic service provision must be included in future planning of clinical trials (p14)	Aligned	Carter explicitly identified clinical trials as a core retained aseptic (spoke) unit function. Our findings indicate that clinical trials capacity is still severely constrained. Commissioned chemotherapy treatments have increased – taking up isolator time. Some units are missing the specialist expertise required to support this work.
Need to outsource long-expiry products to free capacity for clinical trials.	Focus local units on bespoke, complex and trials work (p11).	Aligned	Our findings support this conclusion but recognise that implementation progress is slow and units have had to prioritise routinely commissioned chemotherapy over clinical trials.

Summary: Our findings show that **clinical trials capacity is still an issue**, and that **spare capacity has been diverted to prioritise standard care commissioned chemotherapy treatment.**

A4 Specific preparations

A3.1 Chemotherapy

Interviews with the NHS units showed widespread agreement that chemotherapy is the primary product they manufacture in-house. Stakeholders consistently emphasised that short-expiry, patient-specific chemotherapy should remain onsite, as neither hub sites nor industry providers can reliably meet the required rapid turnaround times.

To release local capacity, sites expressed support for outsourcing longer-expiry, routine chemotherapy. The off the shelf model can maximise the amount sites buy in, make it more feasible for medium expiry items to be bought in and create a significant switch from patient specific products to batch. Decisions on whether this should be supplied by a hub site or an industry provider would remain at the discretion of each individual site.

A3.2 Parenteral nutrition (PN)

PN discussions focused on requirements within hospitals. Most interviewees have fully outsourced PN production and are satisfied this is the right decision. There is the expectation that some hubs may supply standardised PN in the future. From an industry perspective, it is logical for IACs and larger hub sites to produce high-volume PN, as this aligns well with their operating models.

However, a small number of trusts have retained manufacturing capability to meet specialist requirements to supply PN to other organisations.

A3.3 Outpatient Parenteral Antimicrobial Therapy (OPAT)

There is a recognition that OPAT will support the shift of care into community settings, an ambition that has been set out in recent NHS strategic reports such as the Carter review, *Transforming NHS Pharmacy Aseptic Services in England* (2020)¹⁵, and the *NHS 10 Year Health Plan* (2025)¹⁶, to reduce hospital stays and improve NHS productivity. Although there is not a large demand for OPAT currently, because of national direction, there is the expectation that the demand for OPAT will increase.

There is currently no coherent, system-wide view on how homecare OPAT and supply should be delivered. Interviews revealed a contrasting perspective with some units believing that responsibility should sit with hubs or IACs, and others concerned that commercial providers cannot supply OPAT products rapidly enough to meet clinical need, leading them to argue they need to maintain their own local capability.

¹⁵ Department of Health and Social Care (2020), *Transforming NHS Pharmacy Aseptic Services in England*, <https://assets.publishing.service.gov.uk/media/5f9afdbdd3bf7f1e405d9a23/aseptic-pharmacy.pdf>.

¹⁶ Department of Health and Social Care (2025), *10 Year Health Plan for England: fit for the future*, <https://www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future>.

A3.4 Centralised Intravenous Additive Services (CIVAS)

The 2020 Carter review proposed establishing hub-and-spoke aseptic services to centralise the production of ready-to-administer injectables, including CIVAS, with the aim of removing the burden of dose preparation from nursing staff, highlighting significant productivity opportunities this would provide. However, insights from our interviews suggest that this solution addresses a problem that sits outside of aseptic services, and in the current financial climate many trusts are choosing not to invest in the required infrastructure.

Providing CIVAS onsite involves substantial overheads and associated costs, leading most units to express a preference for outsourcing CIVAS, allowing them to prioritise the manufacture of short-expiry products. It is noted that high risk, short life, low use CIVAS products could be produced in local units, but it is not routinely deemed a high enough priority within the limited available capacity. Licenced products, available to purchase in ready-to-administer form without the need for aseptic preparation prior to administration, reduce the burden on aseptic capacity.

Therefore, it is anticipated that regional hubs and IACs may take some of the CIVAS demand. Both are well positioned to deliver CIVAS at scale and achieve cost efficiencies.