Pharmacy Aseptic Services Review
Summary of Key Findings

28th March 2018
Introduction
Introduction

Context

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

Each non specialist acute trust in England then produced a Hospital Pharmacy Transformation Plan by April 2017. Many of these contained plans to consolidate aseptic services. At the same time there is growth in the volume of products that need aseptic preparation and there have been significant withdrawals from the market in the commercial sector.

Aim

• The aim of the review is to enable NHS Improvement to gain a comprehensive understanding of the nature and location of currently available services, which will be used to inform planning for future service provision that promotes quality and resilience plus ensures patient access to the medicines provided by these services.

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

Project scope

• Aseptic services by and for acute hospitals in England
• MHRA Licensed and unlicensed (i.e. Section 10) activity
• In-house NHS aseptic services and outsourced sources (both from NHS Providers and non-NHS commercial suppliers)
• Product categories: chemotherapy, parenteral nutrition, clinical trials / investigational medicinal products, and pharmacy-led radiopharmacy (results for this available separately)
**Approach for aseptic review**

We gathered evidence to map the current state and evaluate strategic choices to improve service sustainability, resilience, and future-readiness.

### Strategic aseptic service choices

- **What is the demand?**
  - Demand by product type & location
  - Pipeline product trends e.g. ATMPs, biologics
  - Policy impact e.g. R&D and clinical trials
  - Unmet need
  - Clinical area vs. pharmacy preparation

- **What is supplied?**
  - Product range and rationalisation
  - Procurement practice
  - Pricing practice

- **Who supplies and from where?**
  - Supply chain options
  - Licence status, QA and audit results
  - Geo coverage, supply consolidation, and contingency
  - Outsourced compounding (NHS/ commercial supplier)

- **How is supply managed?**
  - Workforce capacity
  - Staffing models
  - Recruitment & training
  - Succession plans & careers

### Demand assessment

- **Map current state**
  - What is the current product demand (Chemo, PN, CIVAs, Radiopharmacy, IMP) from aseptic Facilities?
  - What is the expected future demand and change to product demand?
  - What is the unmet demand?

### Supply assessment

- **Options for future state**
  - What are the different operating models and options?
  - What does ‘good’ or ‘best’ look like?
  - What are the Requirements for success?

### Impact of choices

- What are the benefits i.e. ↓cost, ↓risk, ↑revenue, ↑access, and ↑experience?
- What are the disbenefits? What is the impact or dependency on other strategic choices?

### Roadmap future state

- What are the elements of a business case to assess a strategic choice?
- What are the milestones to deliver it?
- What are the barriers, including governance and legal implications?
Process for aseptic review

Evidence in this review was collated from engagement with stakeholders and data collection.

Conducted 32 interviews across 43 stakeholders

Interviews by organisation type

- NHS Trusts: 15
- NHS Collaborations e.g. STP: 4
- NHS Regional QA: 9
- NHS Professional Networks: 1
- Other NHS e.g. NHSE/I, Scotland: 2
- Commercial Suppliers: 1

% Facilities that returned data

- 97% Facilities that returned data
- 3% Facilities that did not return data

Data template returned by 195 Aseptic Service Facilities and Radiopharmacy facilities in 142 Trusts

NHS Trust & Collaboration Interviews by region

- South: 9 (47%)
- North: 4 (21%)
- Midlands & East: 3 (16%)
- London: 3 (16%)

Secondary research and additional data sources

- NHS Benchmarking
- MHRA
- Model Hospital
- NHS Digital
- HSJ Intelligence
- EvaluatePharma
- DataMonitor
- Companies House
- MINT UK
Sample for data collection

No data received within the deadline

1. Ashford And St Peter's Hospitals NHS Foundation Trust
2. Medway NHS Foundation Trust
3. Mid Cheshire Hospitals NHS Foundation Trust
4. Moorfields Eye Hospital NHS Foundation Trust
5. The Robert Jones And Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
6. The Walton Centre NHS Foundation Trust
7. United Lincolnshire Hospitals NHS Trust
8. Warrington And Halton Hospitals NHS Foundation Trust

Distribution of completion rates per worksheet (excluding non-responders)
Evidence confidence

1. Needs & trends
   - Demand + unmet need
     - Volume prescribed over time

2. Products & materials
   - Product portfolio
     - Volume made in-house under licence or S10
     - Chemo standardisation
     - PN standardisation
     - Charging practices
   - Drug level sampling
     - Shelf-life variation
     - Facility + equipment
       - Staff
       - Outsourcing + collaboration
         - Product portfolio
         - Consumables + services
     - Cost per item

3. Outsourced / supply location
   - Outsourcing + collaboration
     - Product portfolio
     - Supply models
     - Level of outsourcing
     - Current supply networks
     - Intro + tracker
       - Future licence plans

4. Staff
   - Staff
     - Tenure of leaders
     - # QPs and QPs in training
     - Vacancies
     - Turnover
     - Staffing models
     - Task allocation variation
     - Staff capacity
     - Overtime
     - Capacity calculation variation
     - Hours of training
     - Opening hours variation

5. Estate, equipment & automation
   - Facility + equipment
     - Age of Facility and condition
     - Age of isolators/cabinets and condition
     - Age of AHUs and condition
     - Under-utilised equipment
     - Use of automated filling

6. Logistics & ordering
   - Facilities + equipment
     - IT systems to manage production and ordering
     - Transportation ownership

Key:

- High confidence
- Medium confidence
- Indicative
- Not possible due to poor quality / incomplete data
Current state

Radiopharmacy data not included, although findings are highlighted where relevant
Summary of key learnings about current state

NHS Aseptic Facilities in England need to transform to deliver a future-ready, resilient, high quality, safe, and efficient service

Demand for aseptically prepared products is increasing at c.5% per annum. Alongside meeting the growth of core chemotherapy and parenteral nutrition (PN), there is need to anticipate future demand for advanced therapy medicinal products (ATMPs, such as gene therapy), growth in clinical trials, and potential to address the sizeable unmet need for central intravenous additives (CIVAs) and monoclonal antibodies (MAbs).

Many Aseptic Services have successfully adopted dose-banded chemotherapy and enabled efficient high volume production. In contrast, PN is mostly made under Section 10* to the specific requirements of individual prescriptions and there is less awareness of the potential to standardise.

The NHS relies upon commercial suppliers for at least a third of aseptic compounding and the commercial supplier market is concentrated and highly competitive with low single digit operating margin (c.5%). Many Licensed NHS Facilities reported that they already supply customers**. There remains an opportunity to optimise geographical coverage and maximise efficient batch production to achieve better return on investment.

Aseptic preparation is a labour intensive process and many Aseptic Facilities face significant problems with workforce recruitment, training, and retention. Lack of staff capacity is preventing c.60% Aseptic Facilities from offering desired services and a standard method to calculate capacity is needed to plan for national and local workforce requirements.

An in-house NHS Aseptic Service is asset intensive: estate and equipment needs ongoing maintenance and periodic renewal, so high utilisation is preferable to maximise return on investment.

Digital systems and collaboration with clinicians are critical to reduce waste, to control and share stock, and to optimise the timely flow of products, information, and prescriptions.

Notes: *Section 10 of the Medicines Act enables a Pharmacist to supervise preparation of products against a prescription without needing a Specials Licence from the MHRA;
** external to their organisation, other NHS Trusts, as well as providers in other UK home countries and commercial suppliers
Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018; Companies House; MINT UK
What is the demand?

1. Needs and trends
Summary of demand needs and trends

Demand for aseptically prepared products is increasing at c.5% per annum. Alongside meeting growth of core chemotherapy and PN there is need to anticipate future demand for ATMPs, growth in clinical trials, and potential to address the sizeable unmet need for CIVAs and MAbs.

1. Needs & trends

- The demand for aseptic medicines is increasing in all product categories: electronic prescribing of chemotherapy is growing at a constant 4.8% CAGR* and PN prescribing appears to have accelerated in the last year (from 4.7% to 8.0% growth per annum).
- Over time, products have also increased in complexity and require more time and skill to manipulate. Consequently NHS Aseptic Service workload is increasing at a faster rate.
- Electronic prescribing records show that demand for Clinical trial products and antibiotics is also growing, but not as fast (c.1% CAGR).
- It is unknown what proportion of demand is appropriate (i.e. based on real clinical need).

Pipeline product trends e.g. ATMPs, biologics

- Aseptic medicines are predicted to continue to increase as a proportion of global drug spend and injectable medicine sales are growing at 7.3% CAGR.
- Oncology drugs are an increasing proportion of the global research & development pipeline.
- Whilst few Trusts are currently involved in clinical trials of ATMPs, following national tendering for 7 genomics sites, the demand for preparation of ATMPs may increase.

Unmet need and clinical area vs. pharmacy preparation

- There are 2 strategies to address “unmet need”. Whilst most NHS stakeholders continue to follow an NPSA risk-based approach, a minority of Facilities have developed an efficiency aspect to their product portfolio assessment strategy.
  - NPSA risk-based strategies focus on the small volume of “red” CIVAs and MAbs (if any) and do not consider the workload impact on senior nurses of preparing many simple manipulations before drug rounds.
  - Volume-based and efficiency strategies aim to use stocked pre-fills (either outsourced or made in-house) to save nurses time.

Policy impact e.g. R&D and clinical trials

- Government R&D policy is likely to continue to increase clinical trials and demand for IMPs**
- NIHR funding has increased in every region on average 8% per annum, but the scale and growth in funding varies per region.

Notes: *Compound annual growth rate, ** Investigational medicinal products include drugs and placebos being tested or used as a reference in a clinical trial
Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018; Companies House; MINT UK
What is supplied?

2. Products and materials
Summary of current state products & materials

Many Aseptic Services have successfully adopted dose-banded chemotherapy and enabled efficient high volume production. In contrast, PN is mostly made under Section 10* to the requirements of individual prescriptions and there is less awareness of the potential to standardise.

- **Excluding CIVAs**, 80% of the units made in-house by the NHS are chemotherapy, 15% are PN, and 5% are Clinical Trial doses
  - Irrespective of Facility licence status, 76% of chemotherapy, PN, and clinical trial units are prepared under Section 10*
- **Including CIVAs**, 45% of the units made in-house by the NHS are CIVAs, 44% are chemotherapy, 8% are PN, and 3% are Clinical Trials
  - Irrespective of Facility licence status, 51% of these products are prepared under Section 10
- c.90% of chemo volume is dose-banded and 68% Facilities believe further standardisation is possible
  - Dose-banding has been approved at Trust-level for 95% of Facilities and 90% have implemented the dose-banding CQUIN to incentivise uptake by clinicians
- On average, c.24% of the PN portfolio is scratch bags made in-house and c.41% are complete unlicensed regimens outsourced to commercial or NHS suppliers; therefore there is significant opportunity to standardise PN
  - According to good practice, it may be possible to reduce the number of formulations and develop a standard list of licensed base bags for most adult patients
  - Some Trusts have also developed base bags with standard additions for neonatal PN (see page 142)
  - Fewer Facilities believe there is opportunity to standardise (i.e. increase the use of licensed base bags): 49% for adult PN and 36% for neonatal PN
- Shelf-life at named drug level varies significantly across Facilities
  - The differences may be explained by: inherent differences in drug presentation, differences in operating procedure or licence status, or extended shelf-life gained from a stability study
- 90% of Aseptic Services recover costs fully or partly through budgets agreed with their Trust; however, 22% report that their budgets are in deficit

Notes: *Section 10 of the Medicines Act enables a Pharmacist to supervise preparation of products against a prescription without needing a Specials Licence from the MHRA
Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018; Companies House; MINT UK
Who supplies and from where?
3. Outsourced / supply location
Summary of current state outsourced / supply location

The NHS relies upon commercial suppliers for at least a third of aseptic compounding and the commercial supplier market is concentrated and highly competitive with low single digit operating margin (c.5%)

- There are 180 known NHS Aseptic Facilities in England (excluding Radiopharmacies) and 17 sites that 100% outsource
- Aseptic Facilities have many different supply models; they vary by licensing, the extent to which the Trust outsources or supplies others, and whether the outsource suppliers are NHS or commercial non-NHS companies
  - A third of Facilities are managing both significant in-house NHS preparation and purchasing outsourced commercial supply; most Facilities prepare under Section 10 since only 24% Facilities have an MHRA Specials Licence
- Trusts who have chosen to outsource did so for cost efficiency, investment, or capacity reasons. Recipient Trusts are more often choosing non-NHS Commercial suppliers for outsourced products, in lieu of other NHS Trusts
  - Commercial suppliers currently tend to outperform licensed NHS suppliers in flexibility, responsive customer service, and economies of scale
- Excluding CIVAs, overall at least 36% of aseptic compounding volume is outsourced to either NHS or non-NHS commercial suppliers: the rate of outsourcing appears to be higher for PN (49%) than chemotherapy (35%)
  - This is likely to be an under-estimate of the level of outsourcing since some stakeholders have been unable to submit volume figures for outsourced supply
- Baxter, Qualasept Pharmaxo, and ITH Pharma are significant commercial suppliers to the NHS
  - On average, the commercial supplier market has low, single digit operating margin (5.1%) and EBITDA** (6.5%) which restricts their ability to fund future capital investment and prompts suppliers to divest unprofitable product lines

Notes: ** Earnings before Interest, Tax, Depreciation, and Amortization; Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018; Companies House; MINT UK
Summary of current state outsourced / supply location

Many MHRA Specials Licensed NHS Facilities reported that they already supply customers**. There remains opportunity to optimise geographical coverage and maximise efficient batch production to achieve better return on investment.

- 82% of small to medium acute and DGH* aseptic Facilities are unlicensed by the MHRA and only 10% plan to get a MHRA Specials Licence. There is a trend of increasing product rationalisation and outsourcing.
- 32% of large acute, teaching, and specialist hospital aseptic Facilities have a MHRA Specials Licence and an additional 13% are pursuing a licence so they can supply other Trusts.
- On average licensed Facilities prepare c.51% of units under Section 10 and this is higher in licensed DGH Facilities (72%).
  - There are different competencies required to manage a high volume, lean supply chain to produce batches of stock products under licence. In contrast, Section 10 products require more responsive, agile supply chains to rapidly meet bespoke demand. It may be more efficient and provide greater return on investment for Facilities to develop specialisation in either agile Section 10 preparation or lean Licensed production. Please see pages 30 to 33 for further details.
- There is a significant flow of products between sites in and around the major metropolitan cities and 28 NHS Trusts supply other Trusts.
  - Trusts in London and the North have more customers over a greater geography; logistics may be suboptimal due to overlapping delivery areas.
  - Parts of the South, Midlands and East regions do not have any supply relationships between NHS Trusts because there is a lack of licensed Facilities in these geographical areas. However, several Facilities do have plans to apply for a Specials Licence.

Notes:  * district general hospital; ** Earnings before Interest, Tax, Depreciation, and Amortization; *** external to their organisation, other NHS Trusts, as well as providers in other UK home countries and commercial suppliers

Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018; Companies House; MINT UK
How is supply managed?

4. Staff
Summary of current state staff (1 of 2)

Aseptic preparation is a labour intensive process and many Aseptic Facilities face significant problems with workforce recruitment, training, and retention. 103 out of 180 Aseptic Facilities have at least one vacancy.

How is supply managed?

1. Staff

- Staffing models
  - MHRA SpecialsLicensed Facilities have a greater proportion of band 2 to 4 staff and a lower average labour cost; S10 Facilities use more time from Technicians and band 7 to 8 Pharmacists
  - The proportion of staff per band also varies per region: the North uses the highest proportion of bands 2 to 4; London has the highest average labour cost due to the High Cost Area pay supplement
  - Task allocation per staff band varies considerably, the most variable tasks are: aseptic service verification, first check, and in procedure checks
  - It is likely that some of the variation across Trusts is unwarranted and productivity could be increased by increasing economies of scale in (existing and newly) licensed Facilities and identifying good practices from high quality low cost services

- Recruitment & training
  - Staff turnover is high (15-20%), particularly for operator roles in the Midlands and South, and turnover is costly due to the significant time and expense to recruit and fully train new staff
    - The time to train new Assistants and Technicians varies from <2 weeks in large London Facilities to 5 to 7 weeks elsewhere. Further analysis is needed to evaluate the quality of training and whether there is opportunity to spread adoption of training materials
  - There are vacancies at all junior bands, and band 7 has the highest vacancy rate (c.14%). Although this is in line with the overall NHS vacancy rate, it is higher than the rate for Pharmacy as a whole (c.8%), which may indicate a poorer perception of Technical Services
    - Anecdotally the Carter Report has further increased the attractiveness of Clinical Pharmacy as a career choice for Pharmacists, to the detriment of Technical Services
  - Band 4 and 6 staff are sometimes rotational roles, but the majority of staff do not rotate
    - Pharmacist rotations can help expose more staff to Aseptic Services as a future career specialisation, but this must be balanced against the additional time to train rotating staff

Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018
Summary of current state staff (2 of 2)

Lack of staff capacity is preventing c.60% Aseptic Facilities from offering desired services and a standard method to calculate capacity is needed to plan for national and local workforce requirements

How is supply managed?

Lack of staff capacity is preventing c.60% Aseptic Facilities from offering desired services and a standard method to calculate capacity is needed to plan for national and local workforce requirements.

**Workforce capacity**
- There is no consistent methodology to calculate staff capacity, so results are incomparable. A single methodology is needed in order for future NHS supply networks to understand their collective resource base and compare productivity fairly.
  - Facilities report an average staff capacity of c.85% and c.60% Facilities perceive that a lack of staff capacity prevents them from offering desired services.
  - 35 Facilities want to make CIVAs, but cannot or have scaled back due to pressure to meet core demand.
  - In addition, small to medium acute / DGH Trusts are constrained by inability to recruit Pharmacists and high production staff turnover and training burden.
- Overtime is a weekly occurrence for 41% Facilities and is attributed by stakeholders to chronic late prescribing, unpredictable demand, and upstream disruptions – as well as staff capacity consistently lagging increase in demand.
- Monday to Friday, the vast majority of Aseptic Services are open from 8:30 to 17:00. Further analysis is needed to evaluate if there is a “quick win” opportunity to release capacity by staggering staff shifts for an earlier start-up and later close-down.

**Succession plans & careers**
- Each Facility relies on a small number of highly qualified key individuals for leadership and QMS and the slowing pace of advancement at senior bands may cause band 7 staff to leave to progress their careers.
  - Succession is an issue for Accountable Pharmacists, QPs, and Regional QA posts.
  - Accountable and Authorised Pharmacists have been in role on average 13 years (median) and some may be nearing retirement.
  - Outside of London there are insufficient QPs in training to replace existing QPs and it is commonplace for newly certificated QPs to leave for better paid roles at Pharma Companies.
- A strategy is needed to develop a career pathway for all roles and bands of the Aseptic Service workforce, to attract, develop, and retain knowledge and talent within the NHS.

Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018
How is supply managed?

5. Estate, equipment, and automation
Summary of current state estate, equipment, automation

An in-house NHS Aseptic Service is asset intensive: estate and equipment needs ongoing maintenance and periodic renewal, so high utilisation is preferable to maximise return on investment

- Aseptic Facilities tend to be owned by the Trust (75%) and are more than halfway through the design life but despite their age, most stakeholders report that walls and benches of Facilities are in good condition
  - There is correlation between advancing age and deteriorating condition of estate
- There is an installed base of 403 workstations* and equipment is typically near the end of its design life and needs replacement or renewal
  - Laminar flow cabinets tend to be older and in poorer condition than isolators /AHUs
  - Layout & spatial proportions of estate and poor reliability of equipment have prevented 37 Facilities from offering desired services
- There are workstations that are significantly under-utilised during current opening hours
  - Whilst equipment in Licensed Facilities has slightly higher utilisation, this could increase further to maximise efficient batch production
- There are 219 pieces of equipment not in use, of which 167 are in working condition and are awaiting validation, being retained as a contingency, or used to train new staff

- New Facilities can be delayed or low quality when built by contractors that lack clean room experience and in-house Estate teams may lack resources and guidance
- Since new Facilities and equipment are installed very infrequently, there is insufficient local experience to plan, manage, and trouble-shoot projects. There is opportunity to centralise expertise and knowledge
- 12 NHS Aseptic Facilities (10%) have deployed 28 basic volumetric filling pump automation solutions for PN and CIVAs preparation. Currently there are no instances in England of high volume efficient batch production of aseptic medicines with robots

- The majority of Facilities were unable to provide for this review either maintenance or servicing costs, which is symptomatic of a generally poor understanding of the cost to provide in-house Aseptic Services
- Quality Management Systems (QMS) are sometimes deprioritised by senior leaders due to the pressure to prepare products to meet demand and patient needs

Notes: *workstations are the equipment where aseptic manipulations take place and includes isolators and laminar flow cabinets
Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018
How is supply managed?
6. Logistics, planning, and control
How is supply managed?

Summary of current state logistics, planning, control

Digital systems and collaboration with clinicians are critical to reduce waste, to control and share stock, and to optimise the timely flow of products, information, and prescriptions.

**6. Logistics, planning, & control**

- **Stock levels, waste, and recycling**
  - There are many points in the supply chain for waste to occur and it is inconsistently and poorly tracked. Wasted stock is not routinely reimbursed so many Trusts are potentially losing money.
  - Possible solutions include improvements to: ordering visibility, demand volatility, stock management, risk assessment, risk reduction, and contingency arrangements.

- **Prescribing practice & clinical planning e.g. 2-step chemo**
  - Disorganised clinical practices are a key driver of waste, aseptic service inefficiency, and unwarranted variation. Late prescribing, unpredictable demand for PN, and upstream disruptions to booking and scheduling have a knock-on impact on aseptic preparation.
  - Successful waste reduction initiatives have been driven by collaboration between aseptic service managers and clinical leadership.
  - Small hospitals have disproportionately higher waste due to lower and more variable demand.

- **IT systems**
  - 33% Facilities have electronic prescribing systems (EPMA) in key clinical areas, and this rises to 85% for cancer care.
  - For all product categories, production management and quality management is largely manual. A small number of Facilities have developed their own in-house solutions for label generation, quality management, and production management.
    - Information flow is critical to ensure timely demand visibility for agile Section 10 preparation. There may be good practice in-house or open source IT systems that could be scaled up.

- **Logistics**
  - Most Facilities transport aseptic products to other sites using the Trust’s fleet of vehicles but 45% of Facilities only use aseptic products on the same site where they are made.
  - Best practice cold chain logistics can reduce waste by enabling unused stock products made under licence to be returned (see page 150 for a case study).

Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018
Next Steps

Radiopharmacy data not included, although findings are highlighted where relevant
Next Steps

1. Review of the detailed dataset by the Chief Pharmaceutical Officer and commissioning of a Strategic planning group to develop and implement recommendations

2. Development of metrics for regular data collection

**Draft metrics for discussion**
Selected metrics are feasible (low burden and technically possible) and collected with high coverage and good quality

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**What is the demand?**
1. Needs & trends

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**What is supplied?**
2. Products & materials

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**Who supplies and from where?**
3. Outsourced / supply location

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**How is supply managed?**
4. Staff
5. Estate, equipment & automation
6. Logistics & ordering

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**Product portfolio**
- Volume made in-house under licence or S10
- Chemo standardisation
- PN standardisation

**Outsourcing + collaboration**
- Product portfolio
- Number and names of customers and suppliers
- Level of outsourcing

**Staff**
- Number of QPs and QPs in training
- Vacancies per band and role
- Turnover

**Facility + equipment**
- Age of isolators/cabinets and condition
- Utilisation of equipment
- Use of high volume batch automation

**Facilities + equipment**
- IT systems to manage workload planning and ordering

**Data template worksheet & analyses**

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**Would require alignment on a single methodology to calculate capacity**
## Next Steps

3. Several key questions require further information gathering at a local level

<table>
<thead>
<tr>
<th>Question</th>
<th>Gaps in knowledge</th>
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<tbody>
<tr>
<td><strong>Comparison of cost per unit for in-house manufacture and identification of high quality low cost providers</strong></td>
<td>• Full cost of in-house preparation / production attributable to product category (key costs such as maintenance, servicing, utilities, and depreciation are unknown)</td>
</tr>
<tr>
<td><strong>Financial savings from robotic automation</strong></td>
<td>• Incremental efficiency gained from automation is unknown (accurate studies have not been undertaken) and return on investment needs further evaluation</td>
</tr>
<tr>
<td><strong>Career development and training options for workforce</strong></td>
<td>• Methods to engage and develop workforce need further exploration with Health Education England, Deans, Technical Specialist Education and Training group, and stakeholders</td>
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</table>
| **Identification of number and location of future regional supply hubs and evaluation of ability to meet standards for audit, QA, and licensing** | • Although we have identified supplier recipient relationships, a significant number of these did not provide volume information – therefore we could not determine the location of current major supply hubs  
• The majority of Trusts do not have EPMA and were unable to articulate the level of local demand for aseptic products, future work could link demand to types of patient and service  
• Future hub locations should take into account the sites that win the national procurement for genomic laboratories |
| **Quantifying savings opportunities for outsourcing** | • High quality time and motion studies are not consistently available for a) efficient in-house production per product category, and b) well-managed outsourced supply management  
• Full cost of in-house preparation/production attributable to product category (key costs such as maintenance, servicing, utilities, and depreciation are unknown) |
| **Quantifying savings opportunities for waste reduction or a planned equipment replacement programme** | • In interviews and data collection responses, stakeholders were unable to provide quantitative results from waste reduction initiatives |
| **Quantifying number of workstations needed given optimal utilisation, quality, safety, and transfer of equipment between Trusts** | • Local and regional evaluation of workstation utilisation is needed to analyse how to maximise the use of assets whilst maintaining appropriate segregation between product categories, optimising product flow, and protecting sufficient time for QMS  
• Trusts don’t have a standardised methodology for calculating workstation utilisation |
| **Future workforce numbers** | • There are many uncertainties affecting staffing numbers which need further analysis: future ATMP models, approach to outsourcing and supply networks, approach to unmet need, uptake of innovative staffing models, and uptake of automation |

Source: NHS stakeholder interviews; Aseptic Facility data collection JAN 2018; Deloitte analysis