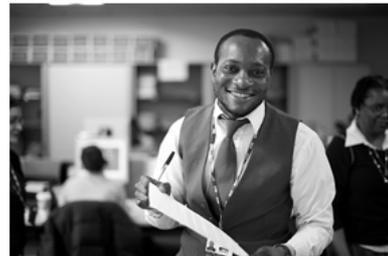


Pharmacy Aseptic Services Review Summary of Key Findings

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

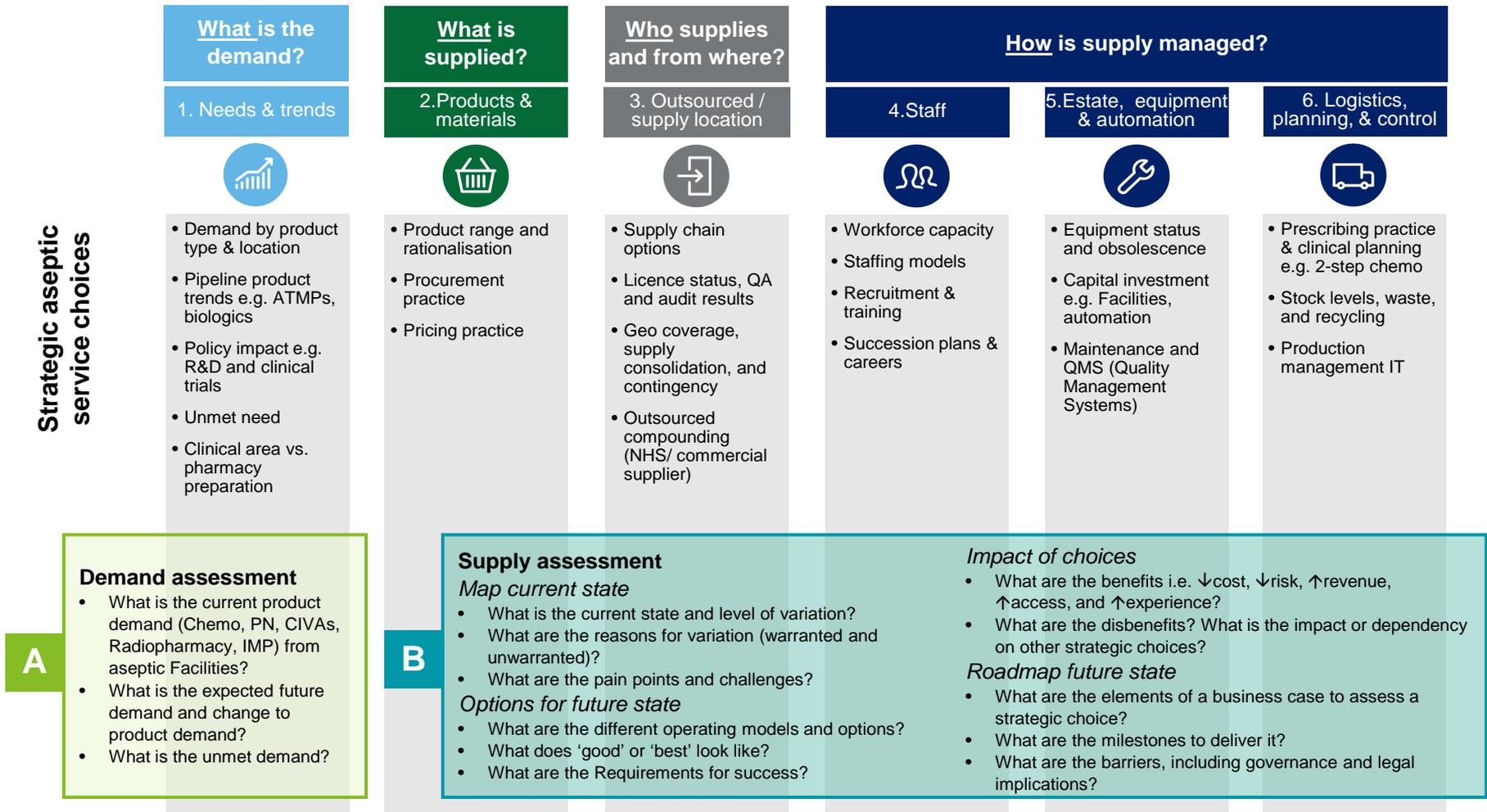
- The aim of the review is to enable NHS Improvement to gain a comprehensive understanding of the **nature and location** of currently available services, which will be used to inform planning for future service provision that promotes **quality and resilience** plus **ensures patient access** to the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

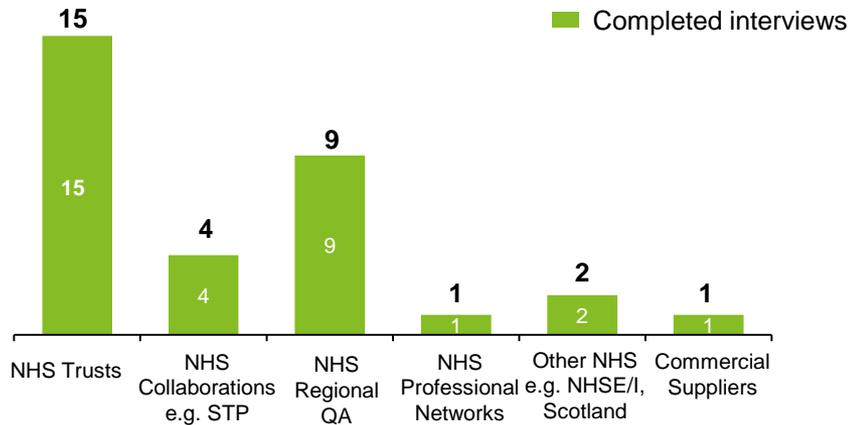


Process for aseptic review

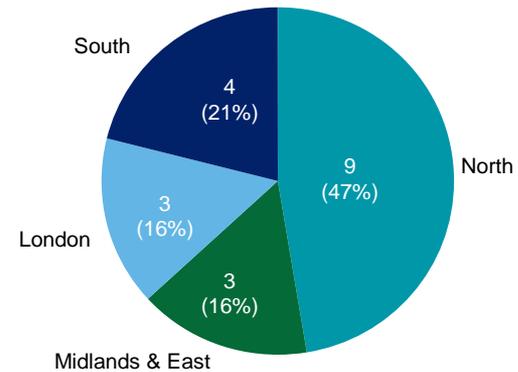
Evidence in this review was collated from engagement with stakeholders and data collection

Conducted 32 interviews across 43 stakeholders

Interviews by organisation type

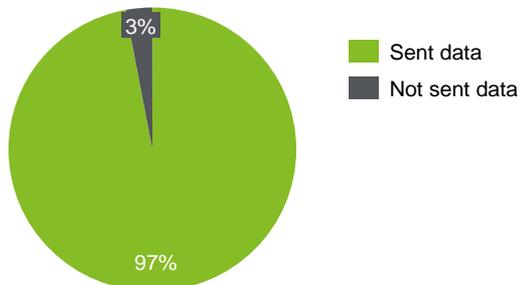


NHS Trust & Collaboration Interviews by region



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

% Facilities that returned data



Secondary research and additional data sources

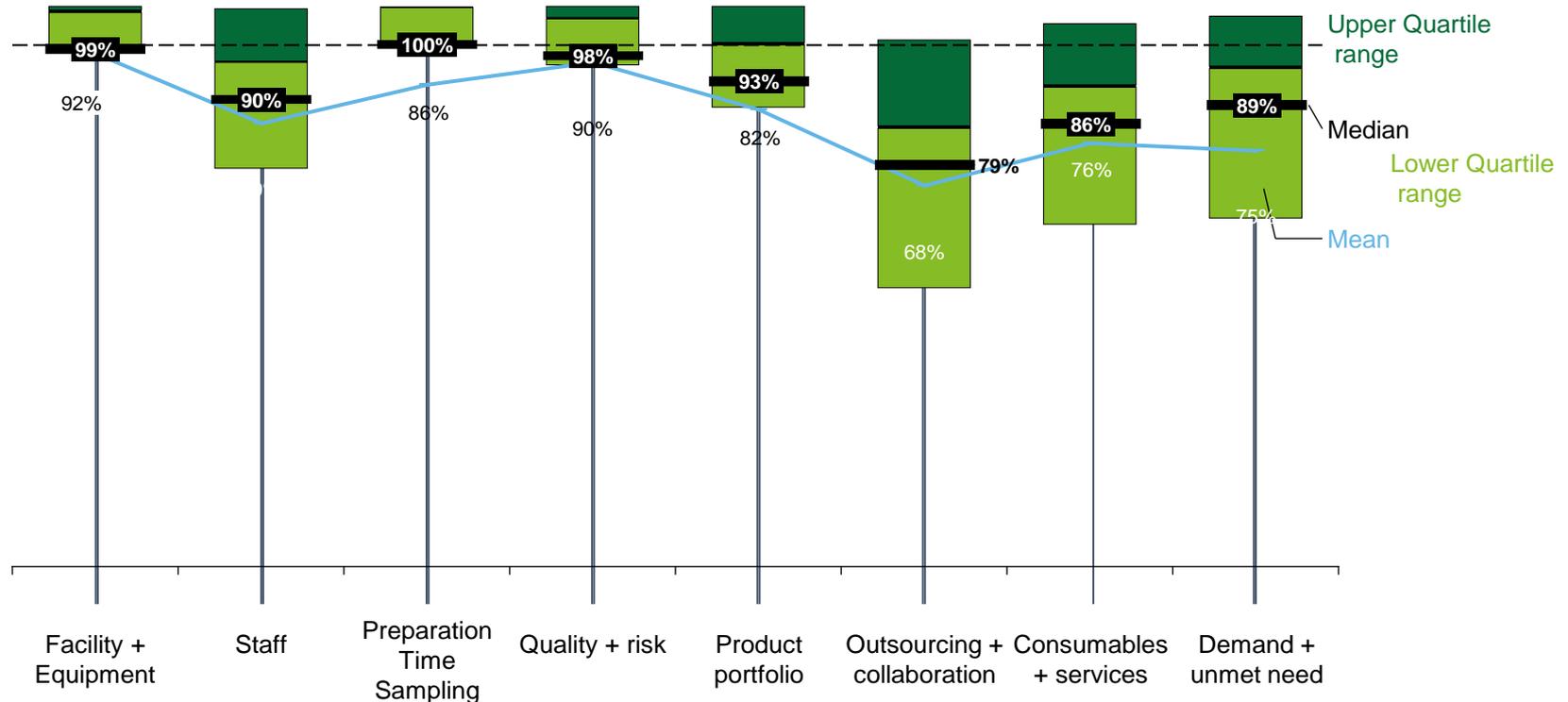
- NHS Benchmarking
- MHRA
- Model Hospital
- NHS Digital
- HSJ Intelligence
- EvaluatePharma
- DataMonitor
- Companies House
- MINT UK

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

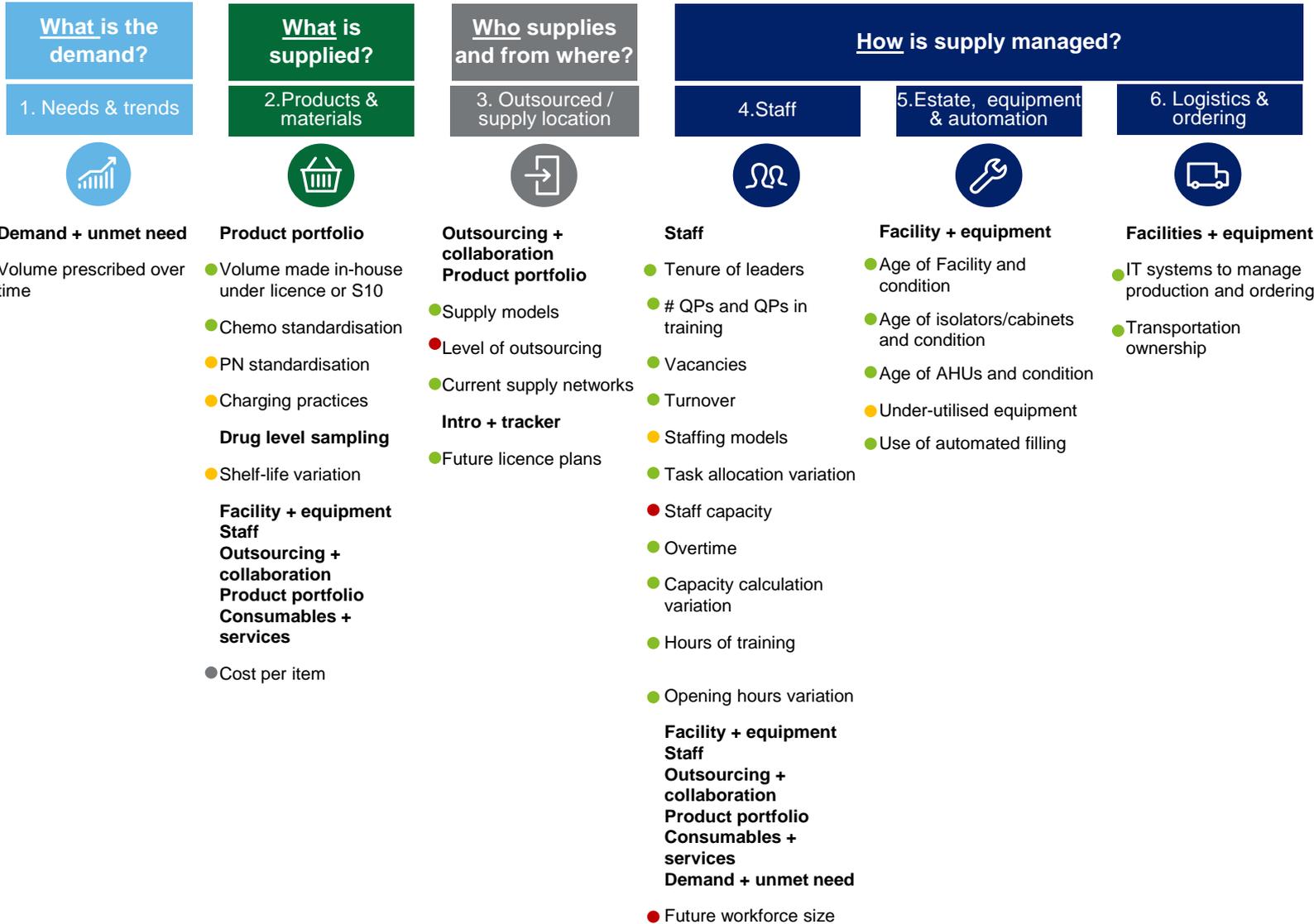
Distribution of completion rates per worksheet (excluding non-responders)





Evidence confidence

Data template worksheet name & data analyses





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

What is the demand?



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)

What is supplied?



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

Who supplies and from where?



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

How is supply managed?



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

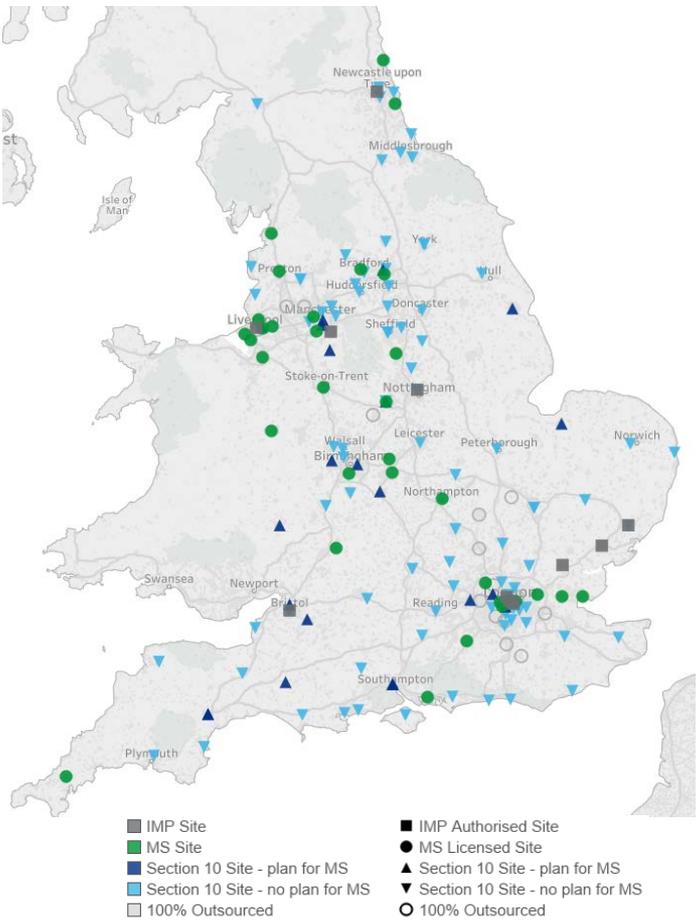


An in-house NHS Aseptic Service is asset intensive: estate and equipment needs ongoing maintenance and periodic renewal, so high utilisation is preferable to maximise return on investment



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

Location and type of Aseptic Facilities



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?

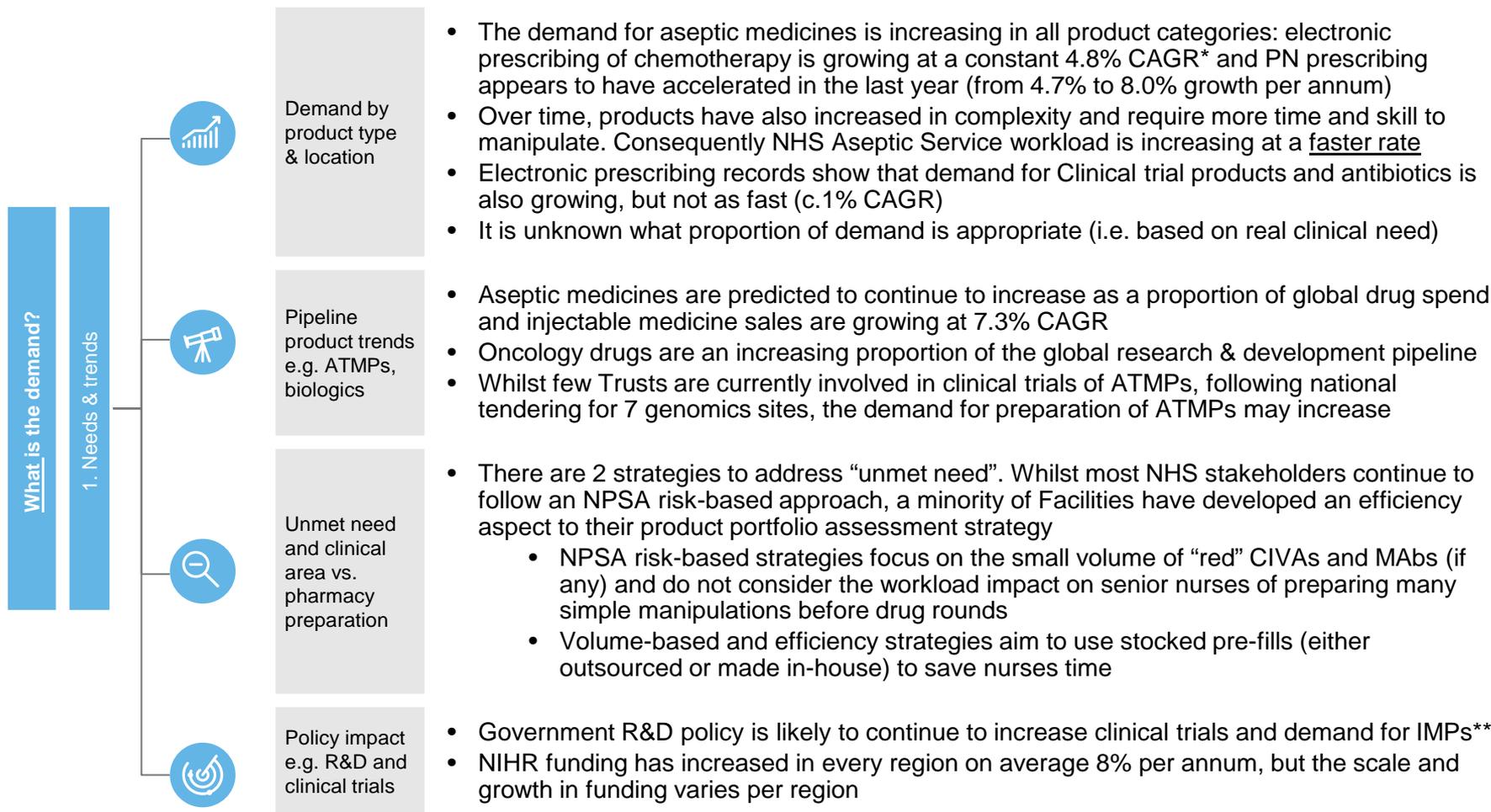
1. Needs and trends



Summary of demand needs and trends

Improvement

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



What is supplied?

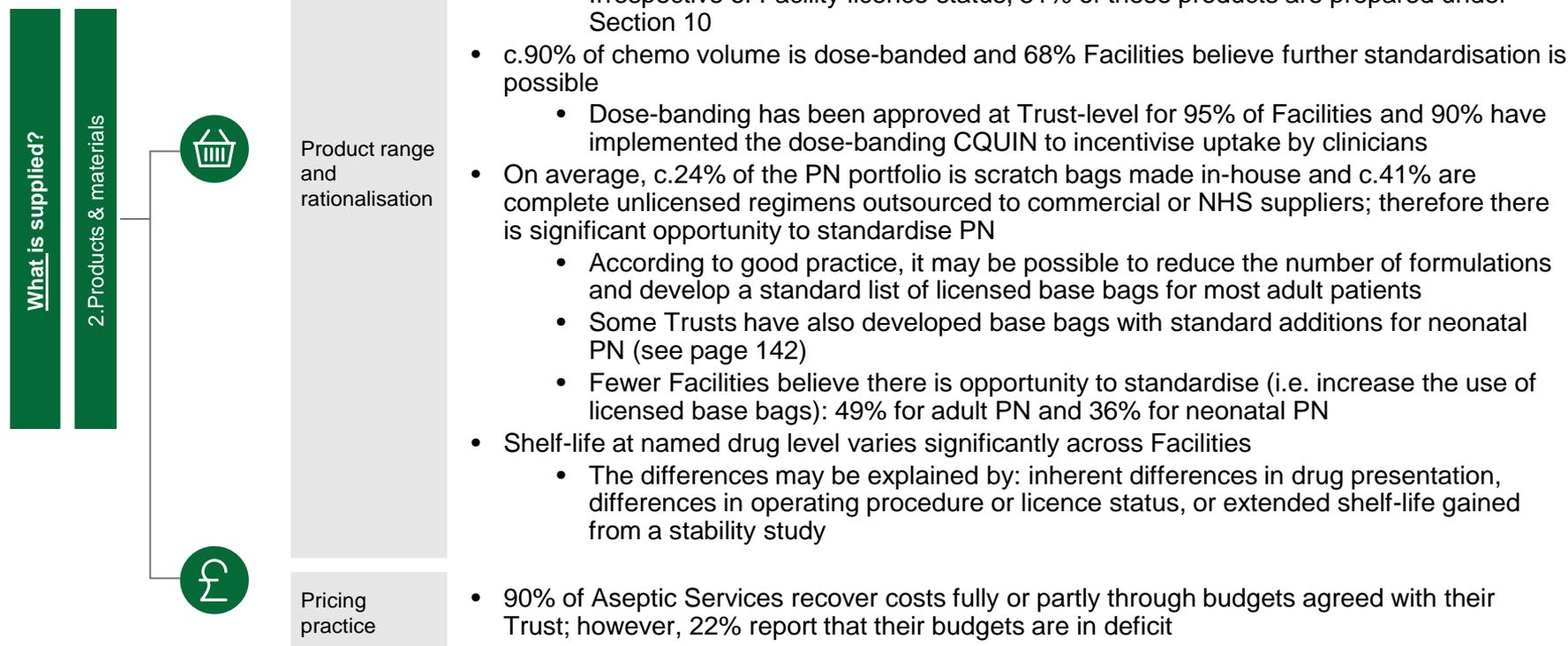
2. Products and materials



Summary of current state products & materials

Improvement

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

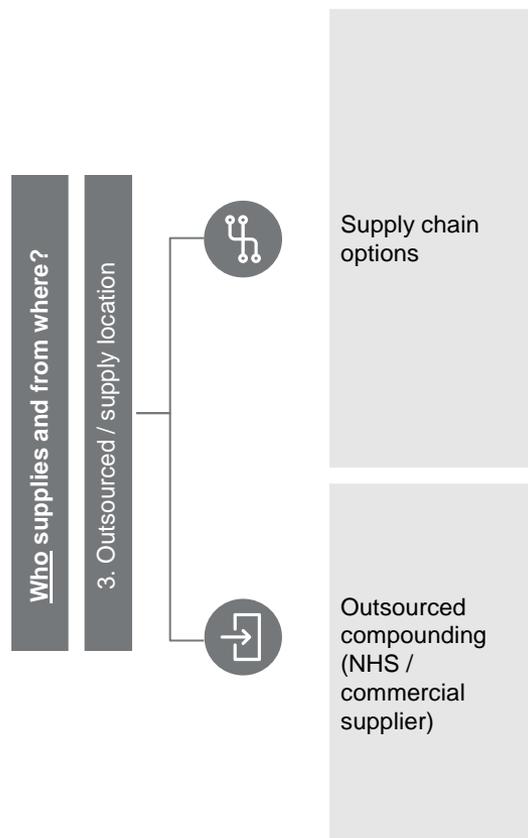


Who supplies and from where?

3. Outsourced / supply location

Summary of current state outsourced / supply location *Improvement*

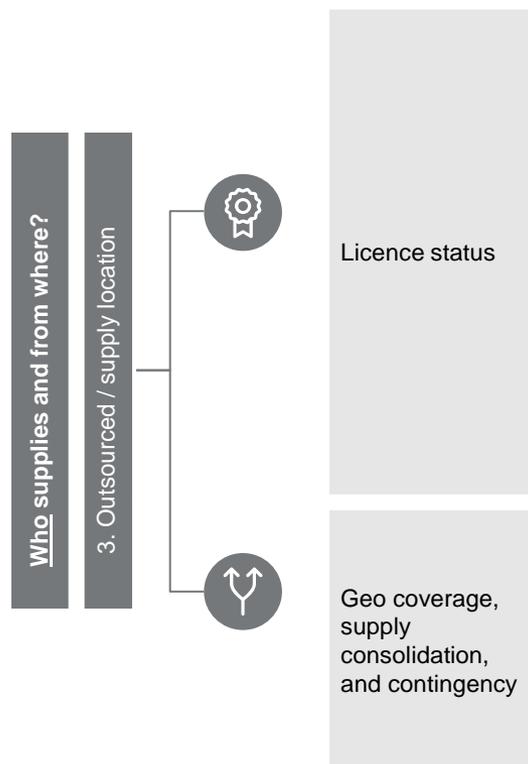
The NHS relies upon commercial suppliers for at least a third of aseptic compounding and the commercial supplier market is concentrated and highly competitive with low single digit operating margin (c.5%)



- 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

Summary of current state outsourced / supply location *Improvement*

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

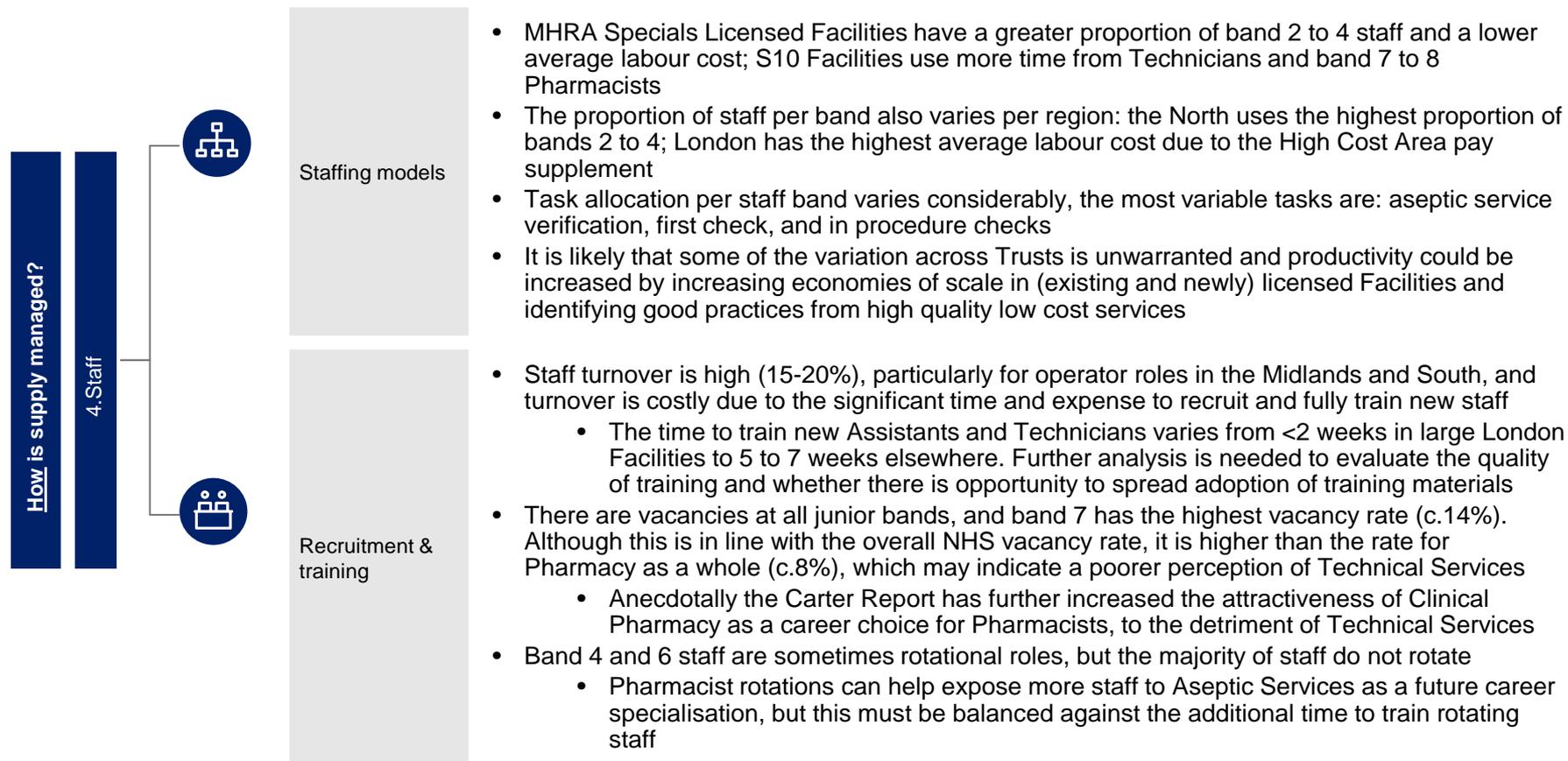
How is supply managed?

4. Staff



Summary of current state staff (1 of 2)

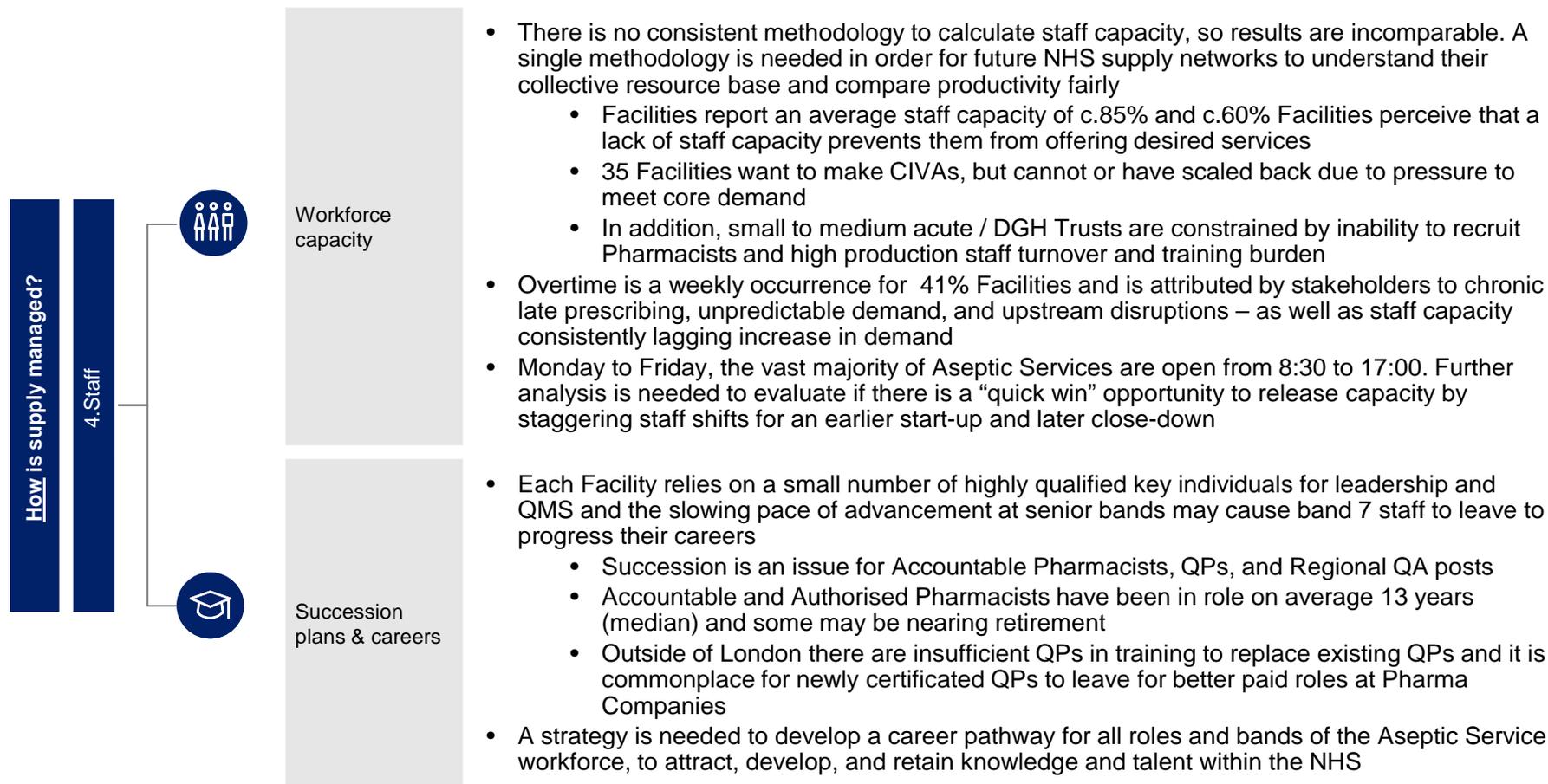
Aseptic preparation is a labour intensive process and many Aseptic Facilities face significant problems with workforce recruitment, training, and retention. 103 out of 180 Aseptic Facilities have at least one vacancy





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



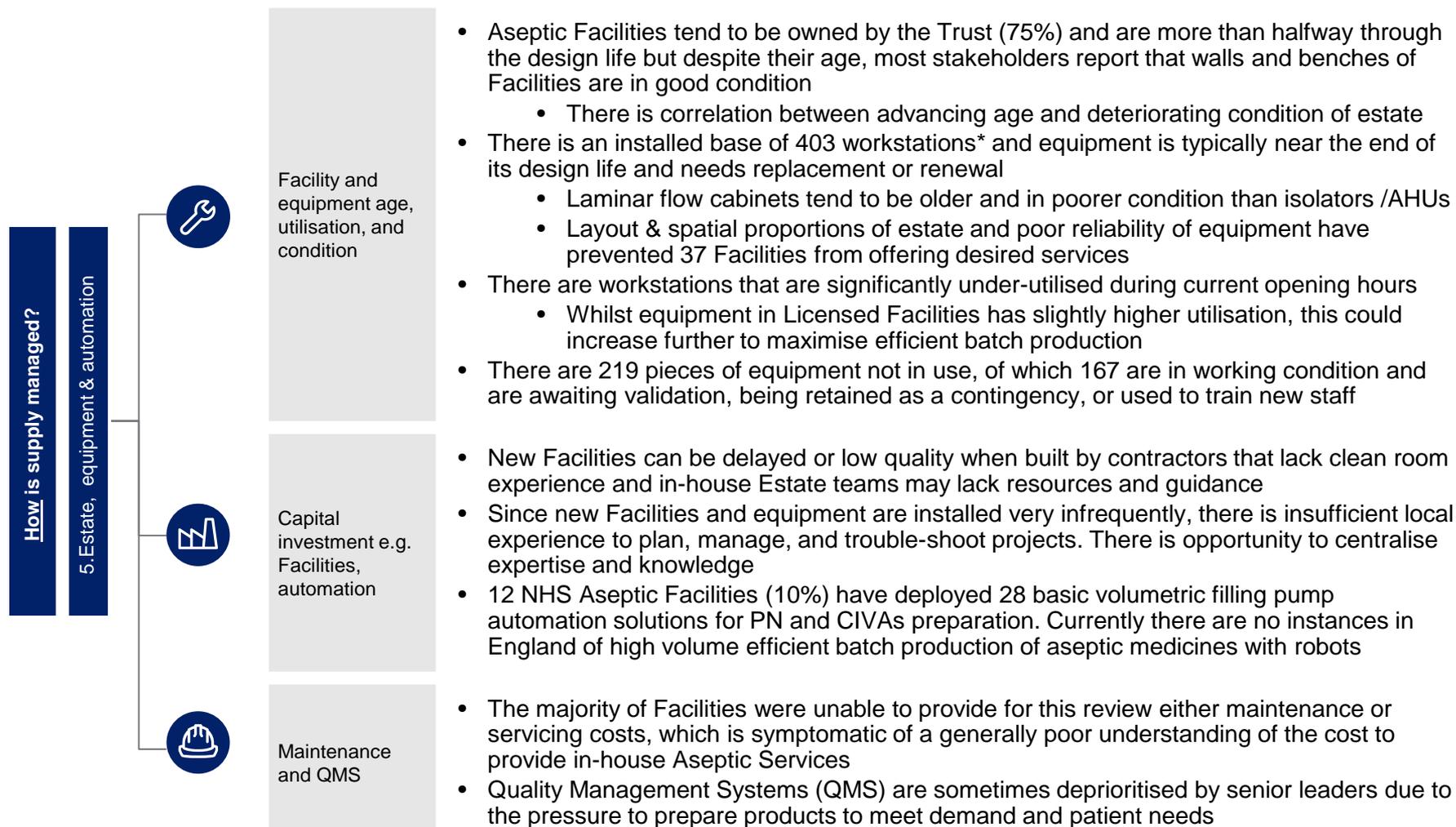
How is supply managed?

5. Estate, equipment, and automation



Summary of current state estate, equipment, automation *Improvement*

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



Notes: *workstations are the equipment where aseptic manipulations takes place and includes isolators and laminar flow cabinets

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

How is supply managed?

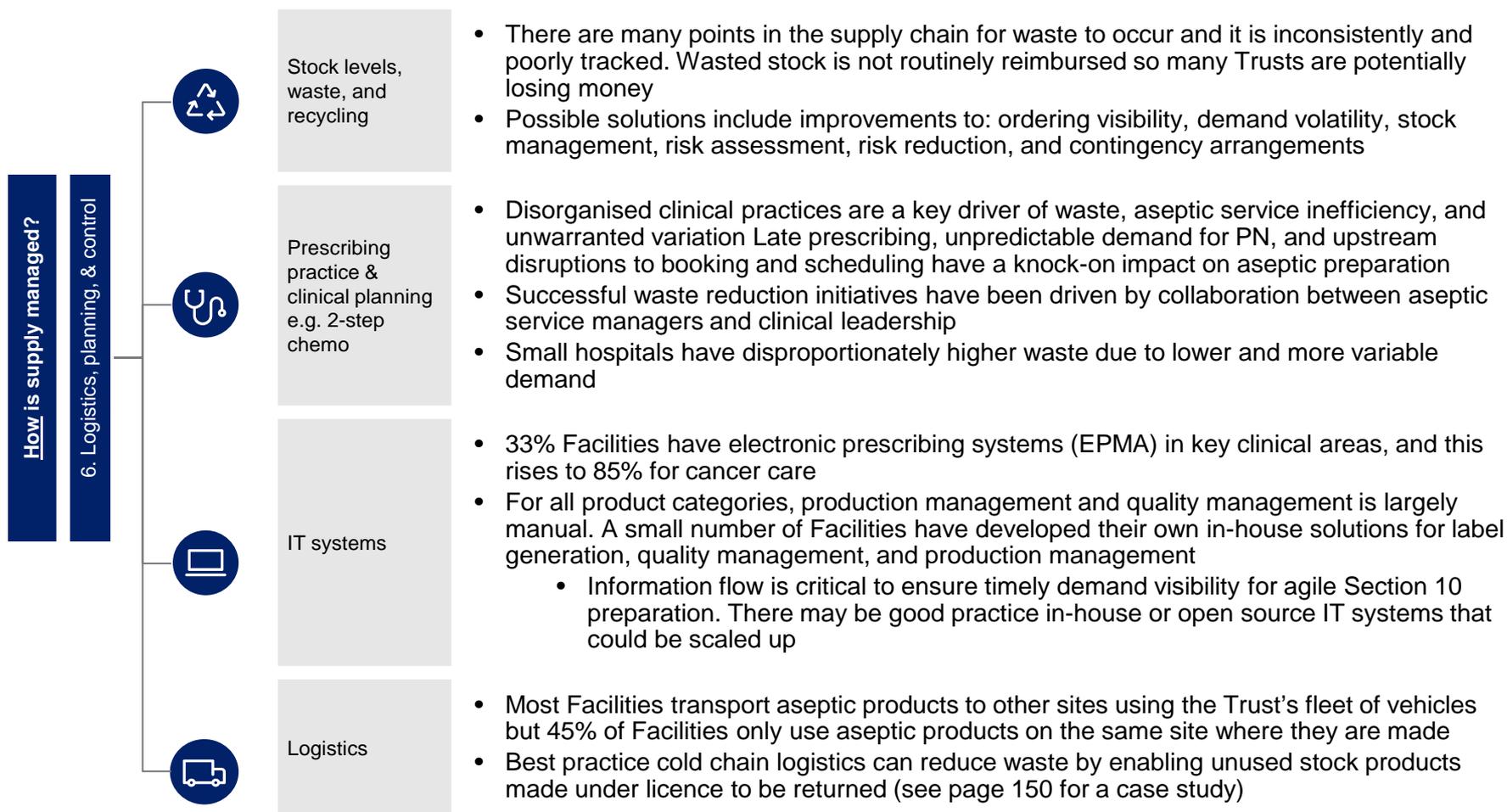
6. Logistics, planning, and control



Summary of current state logistics, planning, control

Improvement

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



Next Steps

Radiopharmacy data not included, although findings are highlighted where relevant

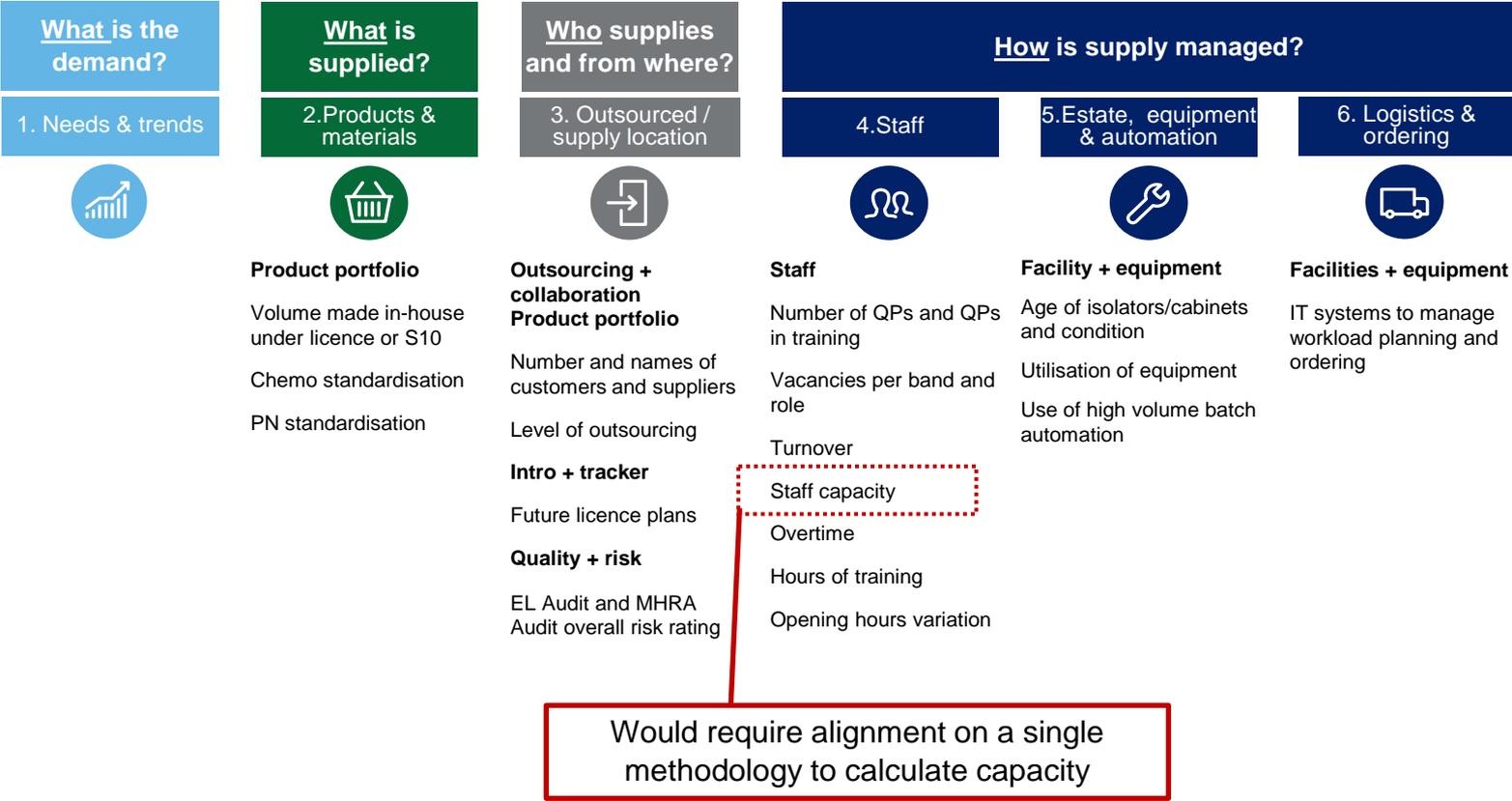
Next Steps

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

Data template worksheet & analyses





Next Steps

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

Question	Gaps in knowledge
Comparison of cost per unit for in-house manufacture and identification of high quality low cost providers	<ul style="list-style-type: none"> • Full cost of in-house preparation / production attributable to product category (key costs such as maintenance, servicing, utilities, and depreciation are unknown)
Financial savings from robotic automation	<ul style="list-style-type: none"> • Incremental efficiency gained from automation is unknown (accurate studies have not been undertaken) and return on investment needs further evaluation
Career development and training options for workforce	<ul style="list-style-type: none"> • Methods to engage and develop workforce need further exploration with Health Education England, Deans, Technical Specialist Education and Training group, and stakeholders
Identification of number and location of future regional supply hubs and evaluation of ability to meet standards for audit, QA, and licensing	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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