pharmacy

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How to Engage Trust Boards with Aseptic Services

From Regulatory Compliance to Patient Safety, Organisational Resilience & Strategic Investment

WUTH case study | October 2026

Dr Chris Green-Director of Pharmacy
Helen Clark-Aseptic Services Manager
Wirral University Teaching Hospital NHS FT

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But first….five fascinating (or not) facts about the Wirral……











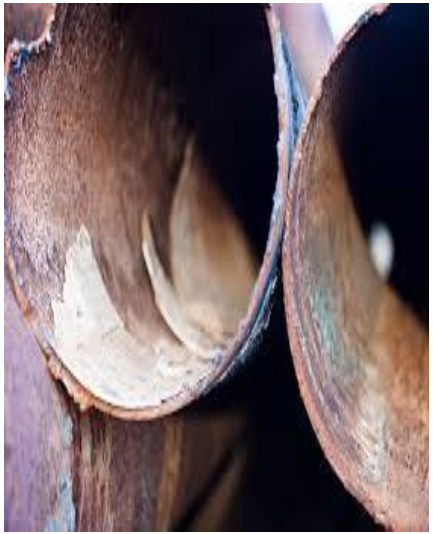
Problem 1-The Unit

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Air handling unit



Ducting



Vinyl / metalwork





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Problem 2- Traditional Escalation Can Fail

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01 INVISIBLE SERVICE

Aseptics sits behind clinical pathways: patients see treatment, not the specialist manufacturing infrastructure that enables it.

02 TECHNICAL RISK IS LOST

GMP, contamination control and licence obligations are complex. Risk messages can be softened or delayed through successive management tiers.

03 ACCOUNTABILITY ≠ AUTHORITY

In industry, senior quality leaders have strong executive access. In the NHS, those accountable for sterile manufacture may lack direct Board access or control of capital.

04 COMPETING PRIORITIES

Estates, equipment replacement and specialist quality staffing compete with more visible operational pressures; costs of failure sit across several budgets.

THE RESULT | Risks reach the Board as a funding problem—or a crisis—rather than an early patient-safety decision.

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A Different Approach



- Aseptic services are a critical clinical infrastructure service—not simply a pharmacy production function
- Board decisions determine whether risks are managed proactively or in crisis.
- Engagement must translate GMP and facilities concerns into patient, financial and operational consequences.

Show the Problem, not just Audit Score

Show the problem, not just the audit score

- WUTH's ageing facility experienced deteriorating flooring and fabric, AHU limitations and condensation-related environmental concerns.
- July 2024 Section 10 audit raised major concerns; October 2024 mock MHRA inspection identified GMP non-compliance.
- Translate each deficiency into a credible failure mode, patient consequence and mitigation limit.

Start With What the Board Cares About. Patient safety & Regulatory Assurance

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FDA U.S. FOOD & DRUG ADMINISTRATION

- In 2012, 753 patients in 20 states were diagnosed with a fungal infection after receiving injections of preservative-free methylprednisolone acetate (MPA) manufactured by NECC. Of those 753 patients, the U.S. Centers for Disease Control and Prevention (CDC) reported that 64 patients in nine states died. The government has since identified a total of 793 patients throughout the country harmed by NECC's contaminated MPA. More than 100 patients have now died.

INDEPENDENT

Third child dies from drip-feed infection

Liz Hunt • Monday 09 May 1994 23:02 BST • Comments

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A THIRD child has died after contracting a blood infection from an intravenous feed at a Manchester hospital while undergoing treatment for cancer, writes Liz Hunt.

Jennifer Raw, 12, of Bryn, Greater Manchester, who died on Saturday, had been in intensive care at the Royal Manchester Children's Hospital since developing the same infection which killed Belinda Coffey, five, and Timothy Davies, nine, last month. Another toddler, Raymond Gahagan, the first to become infected, is now recovering.

All four patients had cancer and were undergoing treatment which suppressed their immune systems and made them vulnerable to infection.

Police investigate hospital deaths of three babies given contaminated feed

Inquiries launched in London and Cambridge after more than 20 premature babies were given ITH Pharma product

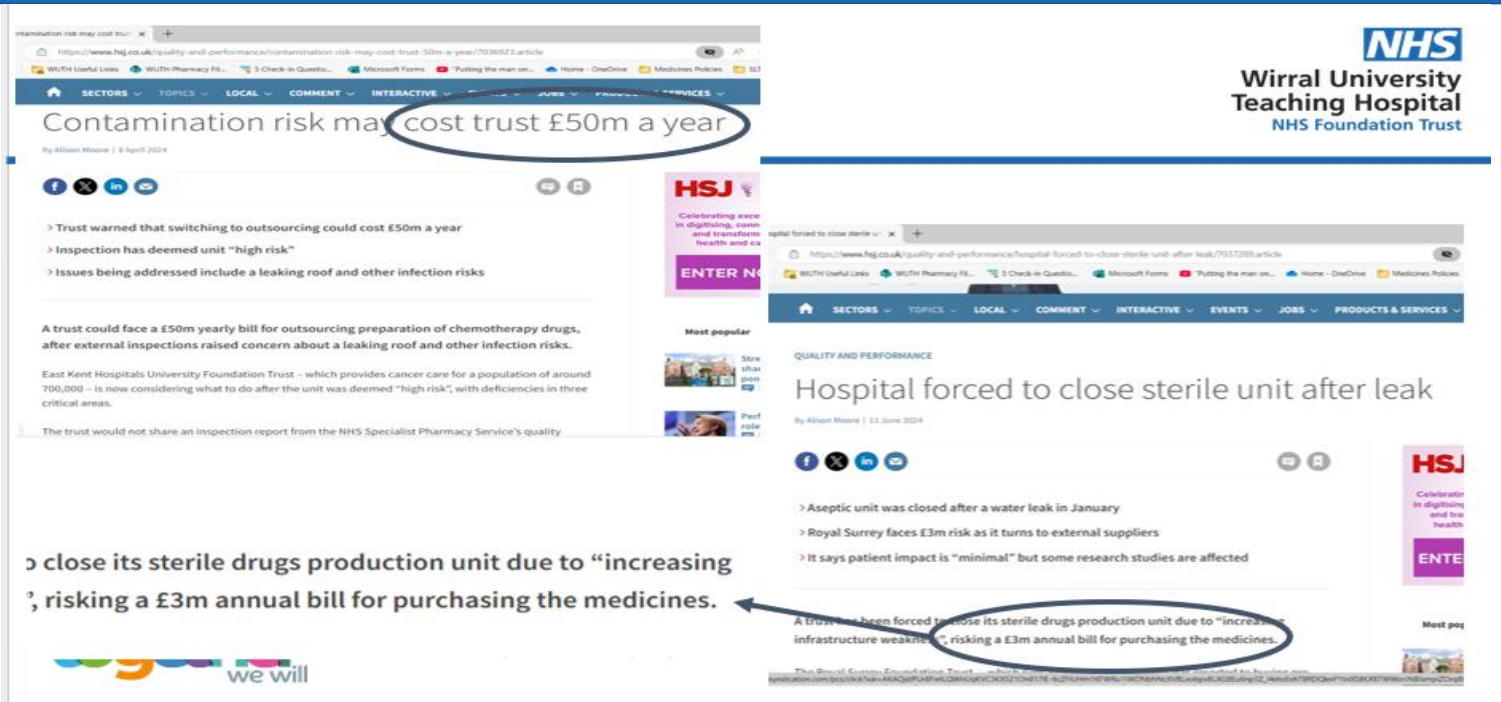


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Financial Stewardship: Total System Cost, Waste, Outsourcing and Disruption

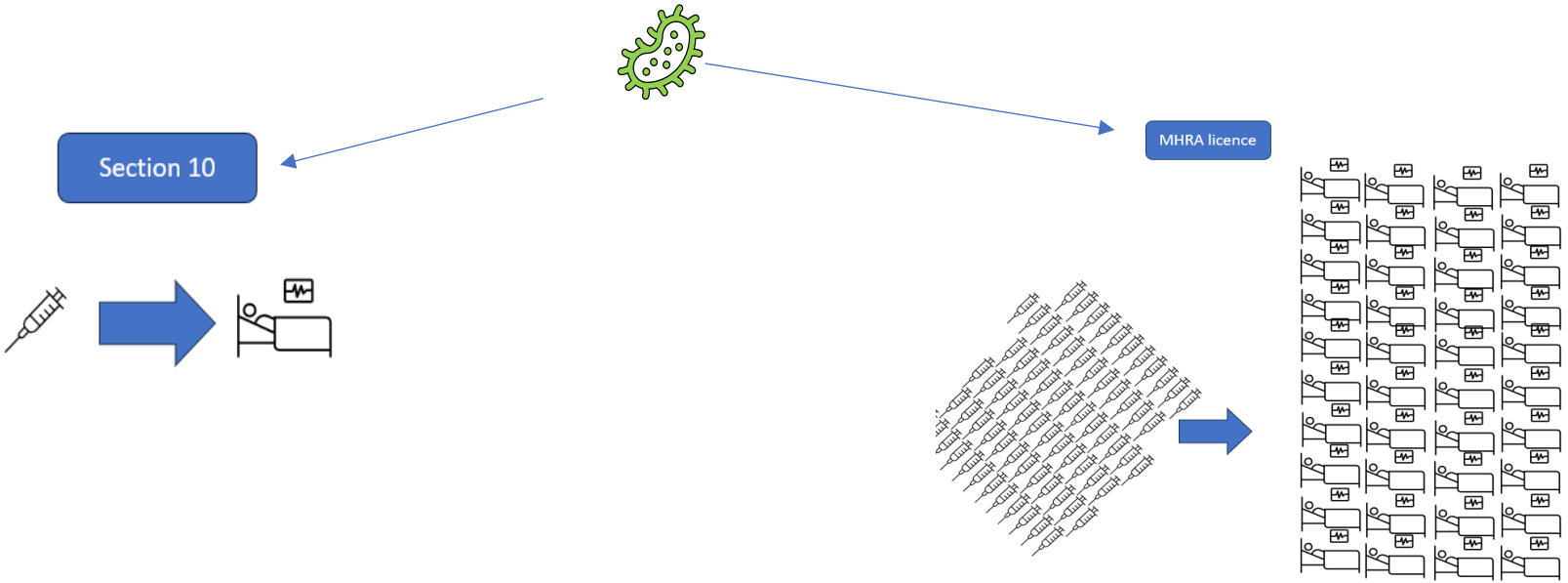
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Explain the Regulatory Distinction



State the Options Clearly & Link to Risk.

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- Do nothing?
  - Closure inevitable (voluntary or otherwise)
- Brand new facility?
- Upgrade?
- Upgrade & Expansion?
- Brand new facility for locality/region/ICB?

State the Risks…..and Evidence Them!

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Patient Risk	Contamination Risk	Financial risk
20	10/15	25 → 15

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Be Bold, Clear & Consistent

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Triggers for closing down the unit

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Internal risk assessment



Regulatory enforcement

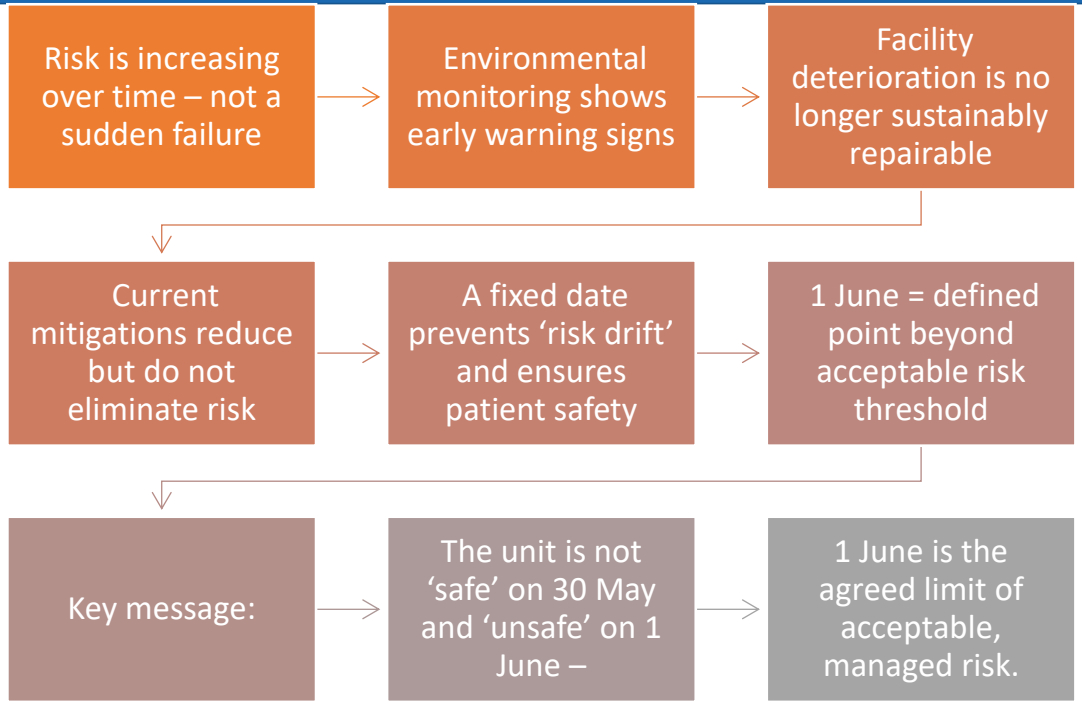


Patient safety incident.



Explain Increasing Risk

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Suspension of manufacturing

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- **Why did we recommend ceasing manufacturing?**



- Facility deterioration poses unacceptable contamination and quality risks.



- Section 10 audit: “rising contamination risk and outdated clean room does not meet standards.”

MHRA

- Mock MHRA inspection: “facility non-compliant with GMP and UK legislation.”

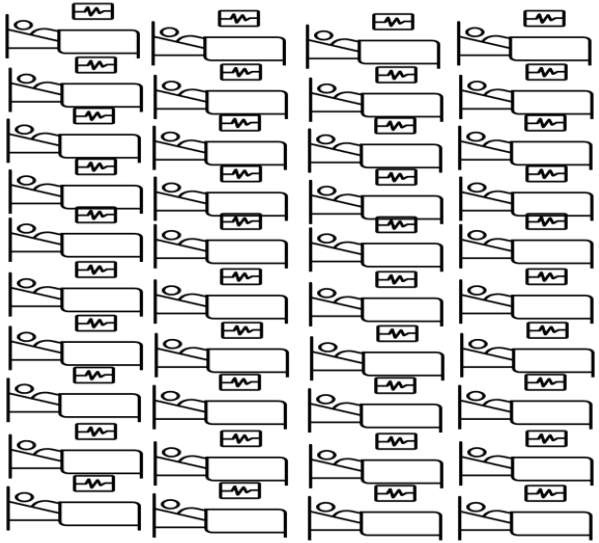


- No agreed plan for compliance with legal requirements. Funding unlikely to be achievable.

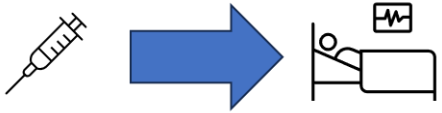
Shutdown phases.

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Manufacturing



Section 10



Shut down



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Questions Every Board Should Ask

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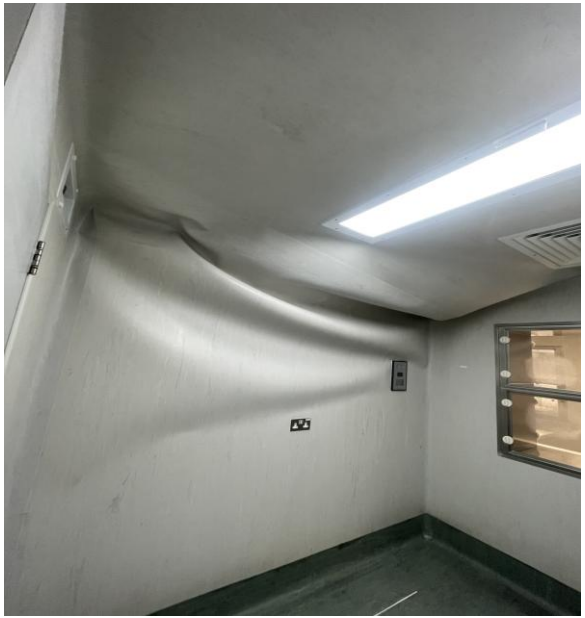
- Could we demonstrate a defensible state of control to an inspector today?
- What would happen to patients if the unit stopped tomorrow?
- Who owns quality, facilities and workforce risks—and who can stop production?
- What is our five-year & beyond asset replacement and workforce plan?
- Are we measuring outsourced expenditure and avoidable waste across the system?

Closing message

- Aseptic services are too important to be noticed only when they fail.
- Board engagement succeeds when technical risk becomes a clear choice about patient safety, continuity and investment.
- The objective is sustained assurance—not a one-off business case.

Not Quite Finished.

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Proactive management of facility Shutdown….

Helen Clark-Aseptic Services Manager
Wirral University Teaching Hospital NHS FT

Jackie Wilkinson-Associate Director of Pharmacy - Infusions and Special Medicines
Countess of Chester Hospital NHS FT

Mitigation strategy & risks: Outsource

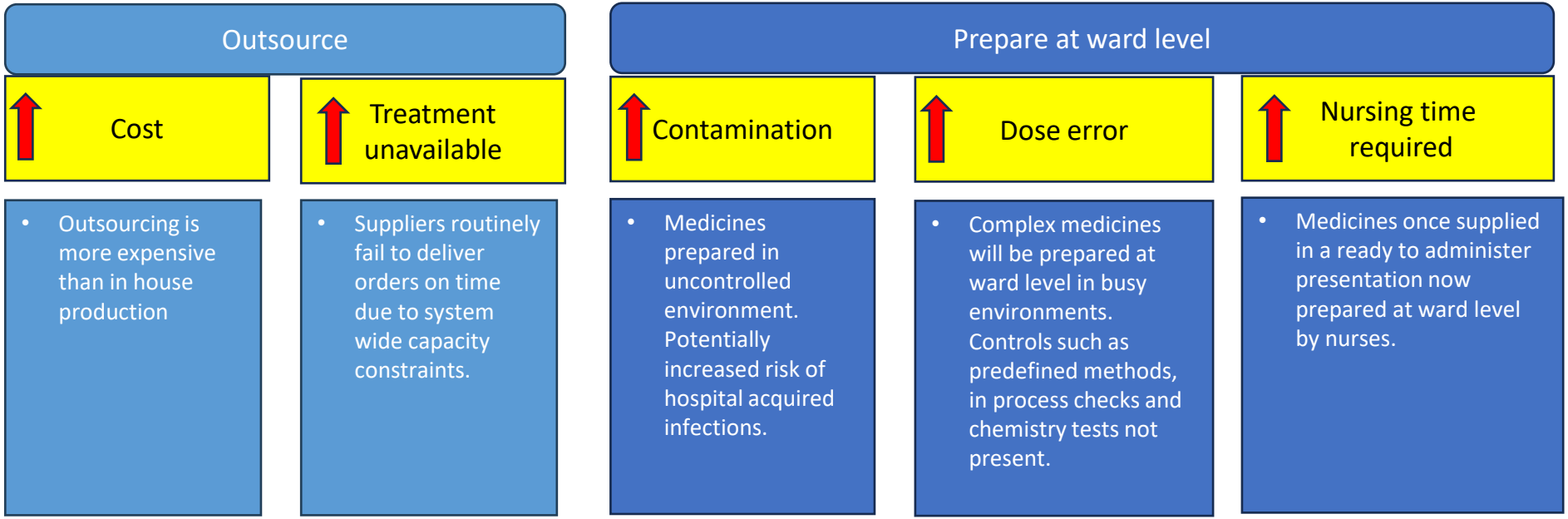
- Compounding market has limited capacity / resilience - supply failures are highly likely:
  - Nurses will be required to make complex high-risk medicines in clinical areas
  - Treatments will be unavailable / delayed
- Not all products are available, we are currently a sole national supplier for several product lines

	All manufactured products used at WUTH.	Only what can't be prepared at ward level
Cost per annum	**£1,134,181**	**£596,806**
Note: 99% of batch manufactured products are in tariff.		

Mitigation strategy & risks: Nurse preparation in clinical areas.

- Places a significant burden on nursing staff.
- Est. 30,000 items a year.
- Increases risk of error and contamination by preparing medicines outside of the controlled environment of an aseptic unit.
- Savings achieved by vial sharing will be lost as the practice is not allowed outside the aseptic unit.

Outsourcing and ward level production



Collaboration Between Trusts

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From Idea to Reality

- Agree with the idea in principle
- Governance arrangements & legal mechanism
- Staff Consultation
- SLA
- Integrating the teams

From infrastructure risk to system collaboration

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The challenge

Arrowe Park's ageing facility required a full production shutdown.

Commercial outsourcing alone could not reliably cover all patient-specific needs.

The opportunity

Use existing NHS aseptic capacity at Countess of Chester's Martindale House.

Retain specialist staff, expertise and clinical oversight.

The outcome sought

Continuity of access to critical injectables during refurbishment.

A governed cross-Trust model rather than a purely transactional supply arrangement.

Collaboration Built around Patient Pathway

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WUTH: clinical ownership

Prescribe and clinically check medicines.

Securely send authorised prescriptions.

Collect products and reconcile against original prescription.

COCH: aseptic delivery

Martindale House prepares, assembles, finally checks and releases.

COCH quality system governs all on-site activity.

COCH pharmacist undertakes aseptic verification.

Shared: reliable handover

Senior WUTH aseptic leader on site.

Clear escalation and responsibilities.

Transport and handover managed by WUTH.

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Making cross-Trust supply legally and professionally robust

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Regulatory route

Martindale House obtained GPhC registration.

Distinct from an MHRA manufacturing licence.

Supports supply of patient-specific medicines between legal entities.

Accountability

Jackie Wilkinson accountable for aseptic activity at COCH.

One COCH Aseptic Quality System: training, validation, monitoring, deviations and release.

Formal assurance

Service Level Agreement defines responsibilities, costs, quality and escalation.

DPIA addresses secure transfer, access and retention of patient information.

People were central to the mitigation

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Employment & supervision

WUTH staff remain substantive WUTH employees.

Honorary COCH contracts enable temporary work at Martindale House.

COCH supervision applies on site.

Competence & continuity

Experienced staff trained and assessed against COCH local procedures.

Senior WUTH leadership presence maintains continuity and operational oversight.

Staff engagement

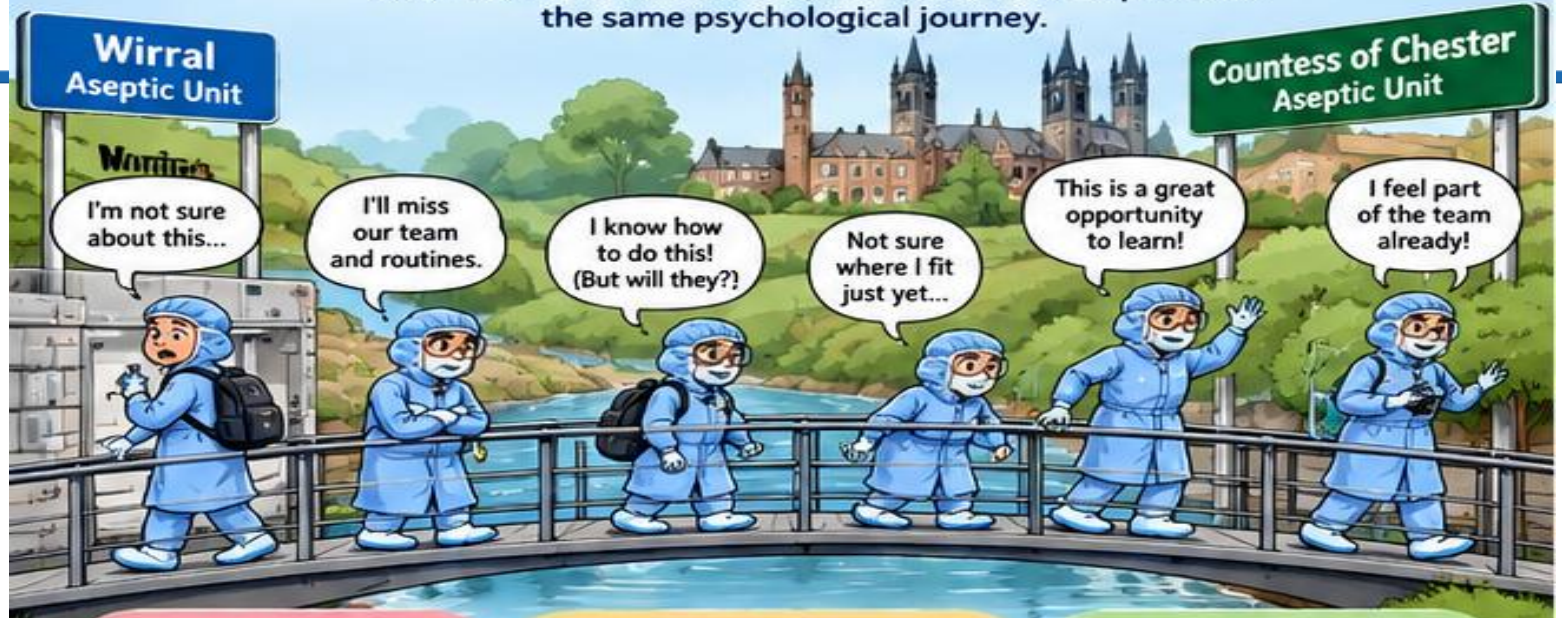
Formal 2025 consultation addressed location, travel, hours and wellbeing.

Rotations across mitigation workstreams protect skills and resilience.

1 Same Change, Different Reactions

Bridges' Transition Model

We all made the same move, but we didn't all experience the same psychological journey.



ENDINGS
Loss, anxiety, resistance
"I miss our unit and the way we worked."

NEUTRAL ZONE
Uncertainty, adjustment, experimentation
"I'm not quite sure where I fit in."

NEW BEGINNINGS
Acceptance, confidence, engagement
"I'm enjoying learning different approaches."

BRIDGES' TRANSITION MODEL

Change is the event. Transition is the internal psychological process.
Staff move through these stages at different speeds – and sometimes go backwards.

2 Whose Territory Is It Anyway?

Organisational Territoriality

Two highly skilled teams. Two established ways of working. One shared workspace.



Territorial behaviour is a natural human response to perceived threats to: identity, autonomy, control, expertise and established ways of working.
It often reflects uncertainty rather than an unwillingness to collaborate.

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3 The Invisible Emotional Baggage

The SCARF Model

Staff brought more than their technical skills – they brought expectations, professional identities and emotional needs.



SCARF MODEL

Status	Certainty	Autonomy	Relatedness	Fairness
Our sense of importance and respect	Our need for predictability	Our sense of control	Our need to belong	Our need for perceived equity

When these needs feel threatened, it can trigger stress, resistance or withdrawal – even when the change is logical and necessary.

4 From Us and Them to We

Social Identity Theory

Successful collaboration doesn't require people to abandon their original identity. It requires them to develop a shared identity.

1. TWO TEAMS

Distinct identities



- Our expertise
- Our routines
- Our team
- Our identity

- Our experience
- Our established ways.
- Our team
- Our unit

2. SHARED SPACE

Negotiation and adjustment



- New relationships
- Different ways of working
- Sharing knowledge
- Building trust

3. ONE TEAM

Shared purpose



- Retain our unique strengths
- Combine our expertise
- A stronger, more resilient service
- Better outcomes for our patients

We may have started as two teams, but through collaboration, shared respect and a common purpose, we became one stronger team.

Why this model gives Boards assurance

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Patient safety

Maintains access to chemotherapy, monoclonal antibodies, PN and clinical trial medicines.

Reduces dependence on fragile external supply.

Quality & accountability

Defined accountable pharmacist and quality system.

Documented clinical checks, verification, release and reconciliation.

Organisational resilience

Preserves a specialist NHS workforce.

Formal governance and ongoing risk review throughout the shutdown.

Costs recovered through agreed arrangements.

The wider lesson: collaboration needs Board sponsorship

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Recognise aseptics as critical infrastructure

Risk is not confined to a pharmacy department: it affects treatment pathways and organisational delivery.

Enable cross-boundary solutions

Legal, workforce, information and quality governance can be designed to support practical NHS collaboration.

Invest before failure

The Chester model mitigates a shutdown; it does not remove the need for planned estate renewal, capacity and sustainable regional provision.

Questions / Discussion



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Specialist Pharmacy Service