Health Innovation Wessex

Managing the risk of innovation adoption:

A case study of a hospital sterile service department

PENTAX Medical Infection Prevention Solutions:
AquaTYPHOON™
PlasmaTYPHOON+
PlasmaBAG ECO

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Part of the Health Innovation Network
Local change, national impact

Executive summary

Health Innovation Wessex (HIW) was commissioned by PENTAX Medical to **explore the adoption of innovation in endoscopic reprocessing** in Croydon Health Services NHS Trust's sterile services department. As experts in innovation adoption, HIW welcomed the opportunity to surface learning about how the Trust managed regulatory ambiguity concerning the use of proven and safe infection prevention solutions to manage risk and drive innovation in these services.

This case study, designed and undertaken by HIW, explores the adoption of PENTAX Medical's AquaTYPHOON™, PlasmaTYPHOON+ and PlasmaBAG ECO. These proven and safe advanced infection prevention solutions designed for endoscope reprocessing currently **fall outside national regulatory guidance** due to the regulations not yet being updated for these new devices[1].

Faced with **regulatory ambiguity**, the service implemented a robust internal framework of governance, evidence-based decision-making and leadership support to **manage risk** and **drive innovation**. By acknowledging joint responsibility, leveraging strategic partnerships, and building a strong business case, the unit demonstrated how **innovation can be responsibly adopted** in a complex regulatory environment.

Diagram of six interconnected themes developed from the case study

The case study highlighted key **behavioural drivers**. These included confidence in internal expertise, trust in manufacturer credibility, and a progressive mindset. These behavioural traits enabled the department to **lead change** and position itself as a regional reference site for innovation in sterile service industry.

To prevent regulatory inertia hindering innovation opportunities[2], health services can responsibly adopt innovation by adjusting their view of risk[3] and adopting a progressive mindset.

[1] Health Innovation Wessex (2024) Independent evaluation of PlasmaTYPHOON+
[2] Life Sciences Sector Plan - GOV.UK
[3] Matching hunger for innovation with appetite for risk

> *Some innovations naturally* ***outpace existing regulatory frameworks****. In such cases it is important to* ***take a pragmatic yet cautious approach*** *by conducting thorough risk assessments, involving clinical governance and ensuring that proper validation, traceability and infection control reviews are in place. These steps give us the* ***confidence to adopt emerging technologies responsibly****.*

Note: Due to the small number of interview participants in this case study and to preserve participant anonymity, interview quotes are not attributed to specific individuals or staff roles

Background

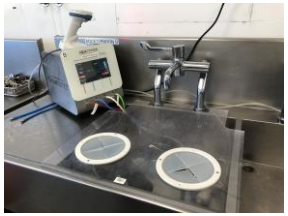
Croydon University Hospital sterile service department operates **six days a week** with a total of 33 staff. The department processes **approximately 1,400 endoscopes per month**. The department currently uses **two AquaTYPHOON™** units and **three PlasmaTYPHOON+** units.

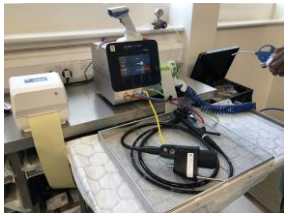
PENTAX Medical's AquaTYPHOON™[1], PlasmaTYPHOON+ and PlasmaBAG ECO[2] are advanced **infection prevention solutions** designed for **endoscope reprocessing**. AquaTYPHOON™ is an automated, **brushless pre-cleaning system** that cleans internal channels within seven minutes, eliminating the need for single-use manual brushes, detergent, and reducing water consumption. PlasmaTYPHOON+ is a **compact drying system** that completely dries internal channels within three minutes. Paired with PlasmaBAG ECO, a single-use **storage bag**, the system maintains the disinfected state for up to 31 days.

All these innovations have demonstrated benefits in speed, efficacy, safety, carbon footprint, cost savings, and ease of use[1,2,4], however, currently **fall outside the regulatory guidance** (HTM 01-06[3]). Technological advancement has **sparked a much-needed debate** amongst the manufacturer, hospital sterile service departments and the regulatory community of Authorised Engineers in Decontamination (AEDs).

This independently developed case study was **commissioned by PENTAX Medical** to explore how Croydon University Hospital's sterile service department **managed the risk** and navigated the adoption of innovative technologies that fall outside of the current regulatory environment.

Building on **previous evaluation work** by **Health Innovation Wessex** on PlasmaTYPHOON+[4], this case study presents **real world insight** into how a hospital has conducted its risk management to inform local decision-making to adopt these innovations.





Images of AquaTYPHOON™ (left) in the pre-cleaning area and PlasmaTYPHOON+ (right) in clean area of the endoscopy decontamination unit

[1] PENTAX Medical: AquaTYPHOON™ endoscope channels pre-cleaner
[2] PENTAX Medical: PlasmaTYPHOON+ & PlasmaBAG ECO endoscope drying and storage solution
[3] Health Technical Memorandum HTM01-06: Decontamination of flexible endoscopes
[4] Health Innovation Wessex (2024) Independent evaluation of PlasmaTYPHOON+

Case study design

The case study sought to capture the experience of staff in adopting these innovations within their department. The design involved a **highly focused exploration** of staff experience of setting up, the decision-making processes, adapting activities, and challenges in using the adopted innovations.

Data collection for the case study involved:

- Half-day **site visit** including the observation of endoscopy decontamination unit within the sterile service department
- Five in-person, semi-structured **staff interviews**
- One additional staff **response by email** to the interview questions
- Brief review of **non-confidential documents** (e.g. validation results and traceability record).

Interviews were audio recorded and auto-transcribed using Microsoft Word transcription function. The transcription was reviewed by the evaluation team for accuracy and any personally identifiable information was redacted before data analysis began. Due to the small number of interview participants and to preserve participant anonymity, **interview quotes included in the case study are not attributed to specific individuals or staff roles**.

Data from the observation, interviews and non-confidential documents were **processed and triangulated** using the six-phase reflexive thematic analysis process[5]. Theme development involved **discovering patterns or recurrences of similar points** within data that contributed to **staff decision-making and behaviours** around managing risks in adopting innovation.

Six interconnected, discursive themes were developed. The following slide (**slide 6**) shows **the overview of themes**, followed by the **narrative description of the themes** in **slides 7 - 8**.

[5] Braun, V., & Clarke, V. (2021). A worked example of Braun and Clarke's approach to reflexive thematic analysis. *Quality & Quantity*, 56, 1391–1412. https://doi.org/10.1007/s11135-021-01182-y

Overview of themes

Forward thinking leadership

The hospital is a reference site for PENTAX Medical to showcase and to lead innovation in the sterile service industry

Recognition by the NHS Trust of the joint risk of innovation adoption

The NHS Trust acknowledged that manufacturers hold some of the risk to patient safety and that manufacturers' claims can be challenged legally in the case of patient harm. Instructions for use (IFU) were the mechanism generating and managing the risk

Evidence-based risk mitigation

A business case for adopting the innovation was underpinned by robust internal validation and auditing processes

Strategic partnership with the manufacturer

Agreeing a sustainable contract with the manufacturer allowed the hospital to significantly reduce capital outlays and ongoing costs

Internal governance support

The senior leadership demonstrated strong support for the department's effort to drive and adopt innovation

Navigating regulatory gaps

The hospital recognises that innovations can sometimes outpace regulatory guidance and risks need to be mitigated to move forward

Managing risks: Joint risk and management of complexity

The adoption of AquaTYPHOON™, PlasmaTYPHOON and PlasmaBAG ECO infection prevention solutions at the hospital's sterile service department reflects a carefully thought-out strategic approach to **managing innovation risks amid regulatory ambiguity**. Instead of waiting for an AED to update the regulations and evolve with the proven innovations, the department constructed **a robust internal framework** of governance, senior support, evidence-based decisions, and leadership in operational pragmatism to manage the perceived risks of **implementing technologies that fall outside of current regulation**.

The central strategy and enabler of adoption was service managers' **acknowledgement of joint risk and responsibility, between the NHS Trust and the manufacturer, for patient safety**. As registered medical devices, these innovations are evidenced and have robust guidance for use from PENTAX Medical. With the assumption the Trust follow the guidance, in the event patient safety issues arise service managers can be certain they would not be solely responsible. This attitudinal position is reinforced by **trust in PENTAX Medical's reputation** and the **unit manager's long-standing expertise.** This outlook enabled the adoption of the innovations and **outweighed the formal regulatory opinion** by the local AED.

"I find the Pentax guide to be clear and comprehensive, and I acknowledge that strict adherence to its recommendations is essential. I also understand that, when following the validated decontamination method, Pentax assumes responsibility for any adverse outcomes."

A strategic partnership with the manufacturer also played a critical role. Through a tailored product lease scheme, the unit managed to **reduced large capital outlays** and **transferred maintenance and performance risk to the manufacturer**. This flexible, service-based model **enabled future-proofing** and provided the opportunity for the unit to become a reference site. The preference for a **single-supplier ecosystem** (a contractual agreement with the manufacturer to supply all flexible endoscopes and its infection prevention solutions) further reduced operational complexity. It was acknowledged that fully de-implementing drying cabinets reduced the unnecessary costs of running the old and the new at the same time.

Managing risks: Organisational enablers

Internal governance and leadership support further empowered the unit. The manager had **autonomy to make decisions** on equipment, staffing and processes, creating psychological safety for staff to innovate. Decisions to de-implement the previous manual cleaning [brushing] method and use of large drying cabinets were not only based on patient safety and cost-effectiveness but also **supported by an organisational culture of innovation**.

"We saw [AquaTYPHOON, PlasmaTYPHOON+ and PlasmaBAG ECO] as quality-driven innovation aligned with our operational needs and patient care standards."

To justify the adoption, the unit developed a detailed business case **grounded in rational cost-benefit thinking**. Projected savings, impact on staff wellbeing, reduction in waste and enhanced traceability for patient safety were key metrics that persuaded senior managers how the risks of adopting the innovation were mitigated.

Staff expressed **frustration with the confinement of outdated standards** (particularly HTM 01-06) which had not kept pace with the technological advancement in recent years. Rather than accepting this as a barrier, the **forward-thinking leadership** acknowledged joint responsibility for patient safety with the manufacturer, conducted internal validations, maintained traceability logs, and actively engaged with their AED, even when disagreements arose.

"…With AEDs, they always have this extended risk approach… Therefore, we need to do our own validation… It gives us that assurance that the end product is safe for patients."

The department's approach reflected a **nuanced understanding of regulatory gaps**, not as threats to innovation, but as an **opportunity where local expertise could step in**. The progressive mindset to prioritise innovation, safety and efficiency over regulatory compliance was a key behavioural driver behind the unit's independent action to adopt the innovation.

Case study summary

This case study demonstrates that innovation outside regulatory frameworks can be **responsibly adopted** when supported by **a robust internal ecosystem of governance, evidence and leadership**. It shows how behavioural drivers, such as acknowledging joint responsibility and risk for patient safety, confidence in internal expertise, trust in manufacturer credibility, evidenced-based decision-making, and organisational backing for innovation, enabled this sterile service department to **manage potential risks** of adoption.

Calls to action

Sterile service staff and managers: The case study shows how it is possible for a sterile service department to adopt proven innovation even with the existence of regulatory ambiguity. Technical staff should continue to raise work-related challenges to ensure innovations are considered for safety and effectiveness.

Service organisations: Senior managers play a pivotal role in driving the adoption of innovation in their organisation. This case study has shown that senior support empowers service / unit managers to build an evidence-based robust business case for innovations that could benefit patients, staff and organisations.

AED community: Feedback from the manufacturer and sterile service departments can inform and encourage the AED community to review and update relevant regulation and collectively respond to industry-led innovations in sterile services. Due to the pace of technological advancements in this field, continuing to engage with the AED community will help build the evidence base and inform changes to regulations - and prevent the regulation becoming a systemic obstruction.

Innovators: Manufacturers must ensure product credibility, by producing evidence to satisfy adopting units, and accept they have a key responsibility to provide evidence-informed guidance for device use. This case study has highlighted how the acknowledgement of joint responsibility is important for service managers in decontamination units to make the decision to adopt.

The evaluation team

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