

POCT Middleware in the NHS: Integrating Point-of-Care Testing Data

Point-of-care testing (POCT) middleware refers to software systems that act as a bridge between POCT devices and hospital IT systems. These middleware platforms automatically capture test results from near-patient devices and transmit them to the laboratory information system (LIS) or electronic patient record (EPR), while logging critical details (operator ID, QC status, timestamps, etc.). In essence, they ensure **data integration** across disparate devices, maintain **audit trails** for quality and accreditation, and support compliance with standards like **ISO 15189:2022**. Recent guidance strongly recommends that POCT devices be integrated into LIMS/EPR wherever possible ¹. In fact, the NHS Pathology Review noted that as POCT expands into wards and community settings, **good IT links with the lab are “the only means of maintaining a complete record” of patient results** ². By using middleware to achieve real-time connectivity, POCT teams can eliminate manual transcription errors, accelerate result availability, and meet the stricter governance requirements now embedded in ISO 15189:2022 (which has merged the POCT-specific ISO 22870 into its framework ³).

What POCT Middleware Does: Integration, Audit Trails, and Compliance

A well-implemented POCT middleware performs several vital functions for NHS point-of-care services:

- **Seamless Data Integration:** Middleware automatically transfers bedside test results to central systems (LIS, EPR) in real time. This ensures clinicians see POCT results in the patient's record without delay or manual input. Automated transfer both speeds up turnaround time and prevents transcription mistakes ⁴. (One study found **over 14% of POCT errors were due to manual data entry rather than device faults** ⁵ – a risk connectivity largely mitigates.) Middleware uses standardized communication protocols (e.g. POCT1-A2) to interface with devices, enabling bi-directional exchange of data. The Medicines and Healthcare products Regulatory Agency (MHRA) and other bodies “recommend connectivity and data management systems wherever possible” as the safest, most reliable method for POCT result transfer ⁶.
- **Comprehensive Audit Trails:** Every POCT result is tagged with metadata – *who* performed the test, *which* device and reagent lot were used, *QC status*, any errors or overrides – and middleware records all of this. These audit trails are invaluable for quality assurance and accreditation. ISO 15189:2022 requires labs (and by extension POCT services under their scope) to maintain records that tests were performed by competent staff with proper quality control. Middleware helps fulfill this by enforcing operator login (and lockouts for uncertified users), verifying QC results, and logging all actions. Without a connected system, many devices might not even transmit key data like operator IDs, serial numbers or QC results ⁷, making it difficult to prove tests were done to standard. Middleware centralizes this information, simplifying compliance with **UKAS accreditation** and **ISO 15189:2022** clauses on POCT oversight (the new ISO explicitly brings POCT under the lab's quality management system ⁸ ³).
- **Real-time Alerts and Control:** Most middleware platforms enable remote management of the POCT network. For example, a POCT coordinator can receive an alert if a device goes offline or a

QC fails, and can often **troubleshoot connectivity issues or lock a device remotely**. They can manage operator certifications (e.g. auto-locking users whose training lapsed) and even push updates or configuration changes to devices via the network. These capabilities create an audit trail of all interventions and reduce downtime. They also support patient safety – for instance, by preventing untrained staff from running tests or flagging critical results immediately. This level of control and surveillance is difficult to achieve without a dedicated middleware monitoring all devices on the trust's network.

- **ISO 15189:2022 and Governance:** The latest ISO standard underscores that POCT must be treated with the same rigor as lab tests. **Lab-supported POCT now falls under the lab's accreditation scope** ³, meaning policies for result reporting, quality management, and incident handling must cover POCT devices. Middleware is effectively a **digital governance tool** for this purpose. It enforces standardization across wards (e.g. consistent reference ranges, units, result flags) and provides evidence for compliance during audits (e.g. user login records, QC logs, calibration records all in one system). As one NHS POCT lead put it, features like electronic results transfer, operator lockout, and audit logs have moved from nice-to-have to **“expected as standard” by POCT teams** ⁹ ¹⁰. Middleware is the technology that delivers those features, helping trusts meet governance requirements and ensure no result “falls through the cracks.”

Major POCT Middleware Platforms Used in the UK

Over the past two decades, a variety of middleware solutions have been adopted across NHS trusts to manage POCT device data. Some are **vendor-neutral platforms** that can connect many different manufacturers' devices, while others are **vendor-specific middleware** designed primarily for a single company's devices (sometimes with limited capability to include third-party equipment). Below is an overview of the major POCT middleware systems in use in the UK and their characteristics:

- **Abbott AegisPOC (formerly RALS):** A web-based, open platform from Abbott that evolved from the well-known RALS system. AegisPOC is **vendor-agnostic**, able to connect hundreds of models of glucometers, blood gas analyzers, coagulation devices, etc. regardless of brand ¹¹ ¹². It provides centralized management of operators (with e-learning and certification tracking), remote device configuration, and extensive reporting for compliance ¹³. Many NHS hospitals historically used **RALS Web** to manage bedside glucose meters; AegisPOC is the modern equivalent, consolidating data from all POC devices onto one platform. Its strength is broad device compatibility and scalable architecture for large POCT networks. (Abbott also bundles middleware with some of its devices, e.g. the i-STAT1 handheld can use either AegisPOC or Abbott's older Precision Web system for data transfer.) Because it's vendor-neutral, AegisPOC can replace multiple proprietary software packages – one reason trusts choose it to simplify their POCT IT landscape ¹⁴. A possible downside is cost and reliance on Abbott for support, but competition in this space has been increasing ¹⁵.
- **Siemens Healthineers POCcelerator / UniPOC:** Siemens acquired the company Conworx in 2016 ¹⁶, merging Conworx's popular POCT middleware tools into its portfolio. Conworx had two main products: **POCcelerator** and **UniPOC**. Today, under Siemens, these form an open data management solution often just called **UniPOC**. Like AegisPOC, Siemens UniPOC is **vendor-neutral** and supports connectivity for **170+ device types** across all major POCT brands ¹⁷. It offers robust device management, user administration, and connectivity to hospital ADT systems for patient identification. Many UK trusts (especially those using Siemens analyzers or within pathology networks that Siemens supports) have implemented POCcelerator/UniPOC to link

devices from multiple manufacturers. One benefit is Siemens' library of device drivers and experience from Conworx – if a new POCT device comes out, chances are Siemens can provide an interface for it quickly. The platform is usually self-hosted on hospital servers. Users report that UniPOC provides comprehensive functionality, though as with any enterprise middleware, **reliance on vendor support and licensing fees** are considerations (Siemens offers service contracts for maintenance).

- **Roche cobas IT 1000 / cobas Infinity POC:** Roche Diagnostics, known for devices like Accu-Chek Inform II glucose meters and CoaguChek coagulation meters, has its own middleware solutions. **Cobas IT 1000** was Roche's legacy data manager, and more recently **cobas Infinity POC** is the updated platform. These systems are optimized for Roche's POCT portfolio (glucose, INR, blood gas/electrolyte analyzers, etc.), providing connectivity and management tailored to those devices. For example, a trust using Accu-Chek glucose meters might use cobas IT to manage operator certifications and to upload results automatically to the LIS. Roche's middleware historically was somewhat siloed – it excelled at connecting Roche devices but was limited with third-party devices. This led to **fragmentation in some POCT departments**: one NHS article noted that various companies' middleware "only support their own POCT products," causing an array of separate systems that don't talk to each other ¹⁰. In recent years Roche has made its platform more open (especially after collaborations with Conworx prior to Siemens' acquisition), so cobas Infinity POC can interface with non-Roche devices to an extent. However, **functionality is often best when connecting Roche's own devices** ¹⁸. Hospitals that run mostly Roche POCT kit may find cobas Infinity meets their needs well. Others with a mix of brands often integrate Roche devices via a vendor-neutral solution instead, or even run dual systems (e.g. Radiometer blood gases on one system and Roche glucose on another). This is an area where middleware choice can either **unify or silo** data, depending on the strategy.

- **Radiometer AQUIRE:** Radiometer's blood gas analyzers (like ABL90 series) are widely used in UK critical care units. Radiometer provides **AQUIRE** as a dedicated connectivity and management system for its POCT devices. AQUIRE Enterprise can connect all Radiometer analyzers in a hospital network, enabling features like remote monitoring of analyzer status, centralized control of user access, and automatic transfer of blood gas results to the LIS/HIS. A key strength of AQUIRE is deep integration with Radiometer's device capabilities –for example, it can remotely lock out analyzers that are due for maintenance or pull detailed calibration data for audits. Radiometer has also built POCT1-A2 compliance into AQUIRE, which means it can interface with certain non-Radiometer devices that support the standard ¹⁹ ²⁰. In practice, though, UK POCT teams often use AQUIRE primarily for blood gas and co-oximeter devices, while managing things like glucose meters on a separate system. The **user interface** of AQUIRE is noted to be very operator-centric (reflecting its focus on patient-dedicated devices in ICUs). Radiometer's approach can be considered semi-open: it **allows other devices, but primarily serves Radiometer customers**. It remains a popular choice in NHS trusts for ensuring critical blood gas results are captured reliably. One challenge can be integrating AQUIRE with trust IT – for example, firewall rules or network setups might need adjustment for AQUIRE's communication with analyzers and with the LIS.

- **Nova Biomedical NovaNet / BioConnect:** Nova Biomedical's StatStrip glucose and ketone meters, and Stat Profile blood gas analyzers, are used in some NHS hospitals (notably for ICU glucose monitoring due to their stability in critically ill patients). Nova provides a middleware called **NovaNet™ Device Management Software** to connect these analyzers. NovaNet handles wireless connectivity from Nova's meters (e.g. via docking stations or Wi-Fi) and ensures test results are sent to the LIS ²¹ ²². It also manages operator IDs and can link to hospital ADT feeds for patient demographics ²³. NovaNet's advantage is that it's purpose-built for Nova

devices, ensuring **timely, accurate capture of results “wherever and whenever needed”** ²⁴ ²⁵ . In fact, Nova positions NovaNet as eliminating the need for third-party middleware for their devices ²⁶ . The term **“BioConnect”** is sometimes used in the context of Nova – for instance, a UK distributor noted successful integration of a POCT device with “Bioconnect (Nova)” ²⁰ . This suggests NovaNet/BioConnect refers to the same Nova middleware suite. While NovaNet can forward results to any LIS or EPR (or even feed into a broader middleware like RALS if needed ²⁷ ²⁸), its scope is mostly limited to Nova’s analyzers. Hospitals using Nova for critical care testing often run NovaNet alongside another system for other POCT devices. Nova’s middleware is **POCT1-A2 compliant and LIS-agnostic** ²³ , so integration technically is straightforward. The decision to use NovaNet vs. a universal middleware often comes down to scale: a site with a large Nova install base might leverage NovaNet fully, whereas a site with just a few Nova devices might opt to pipe those into an existing multi-device system.

- **Werfen GEMweb Plus:** Werfen (Instrumentation Laboratory) produces the GEM series blood gas analyzers (GEM 5000, 4000, etc.) common in some hospitals. Their middleware, **GEMweb Plus**, is tailored for connectivity and management of GEM analyzers and associated IQM (Intelligent Quality Management) data. GEMweb allows remote oversight of GEM device status, central configuration of cartridges and lots, and consolidated result viewing. It can send results to the LIS and often is used in critical care settings alongside or integrated with other systems. Like Radiometer’s solution, GEMweb is mostly vendor-specific (Werfen). However, the **POCT1-A2 standard** has made it possible to interface GEM devices with third-party middleware too, and indeed the Sterilab interfacing example lists **“Gemweb (Werfen)”** as well as integration of GEM devices via Siemens or Abbott platforms ²⁰ . For an NHS trust, a decision may be made to either use GEMweb for standalone management of blood gases, or to connect GEM analyzers into a larger vendor-neutral system. GEMweb’s advantage is **full support of GEM-specific QC and alerts**. Its drawback is maintaining yet another separate system if other POCT devices are not on it.
- **EKF Diagnostics – EKF Link:** A more recent entrant, **EKF Link** is a middleware solution launched by EKF Diagnostics (makers of HemoCue-like hemoglobin analyzers, glucose/lactate devices, etc.). EKF Link is promoted as a **lightweight, open connectivity platform** for POCT, not limited to EKF devices ²⁹ ³⁰ . It’s essentially a downloadable software package to connect POC analyzers to hospital IT, featuring secure data transmission and remote access. The selling point for EKF Link is flexibility for smaller scale deployments – for example, a trust or GP network could use it to gather results from a few EKF analyzers in clinics and send them to the main lab system ³¹ . It can run on a local PC or server and supports HL7 result messaging. Because it’s newer, its device driver library may be smaller than the established players, but EKF has emphasized interfacing **“to most vendors’ POC analyzers”** in an open manner ²⁹ . Some NHS POCT teams are trialing such solutions especially for community settings or niche devices. A consideration is the **ongoing support and updates** – being a smaller vendor, EKF’s capacity to rapidly integrate new device drivers or EPR interfaces is something to watch. Still, EKF Link highlights the trend of more middleware options coming to market (helping drive costs down and innovation up) ¹⁵ .
- **CliniSys Integrated POCT Solutions:** Rather than a standalone middleware product, CliniSys (the supplier of many NHS LIMS systems like WinPath and GLIMS) offers integration services to bring POCT devices into the existing lab IT ecosystem. CliniSys has historically partnered with third-party middleware (notably Siemens POCcelerator) for device interfacing ³² . In practice, CliniSys can provide an interface so that POCT results flow directly into the LIMS (and from there to EPR) and can centralize the management to some extent. They describe their solution as forming “that bridge between devices, the LIMS, and CliniSys ICE (order communications)” ³³ . In recent years, as more POCT analyzers come with their own manufacturer data managers,

CliniSys leverages those when possible and uses their middleware layer when a direct device driver is needed ³². Essentially, if a trust is using a CliniSys LIMS, they may choose to integrate POCT via CliniSys's modules to avoid a separate middleware UI. However, many still use a dedicated system in conjunction (since full remote device management may not be as mature in the LIMS-driven approach). CliniSys did highlight that their POCT management solution can save a POCT team a lot of legwork (literally – one manager joked it “saved a fortune on new shoes” by enabling remote oversight rather than trekking to each ward ³⁴). CliniSys's strategy underlines that ultimately **POCT middleware is part of the wider digital pathology infrastructure** – the goal is a seamless flow from bedside test to lab record to EPR with minimal separate systems.

Other middleware names that may be encountered in UK contexts include **UniPOC** (the Siemens/Conworx solution, as discussed), **POCcelerator** (legacy name, now essentially part of UniPOC), and older systems like **Telcor QML** (more common in North America) or **Epocal's EDIS** for the epoc BG devices (Siemens epoc now uses UniPOC or RapidComm). It's worth noting that **no single middleware does everything**. Each has strengths and limitations, and a large healthcare network might even use multiple in tandem. A national-scale project in Wales found that “*there is no POCT middleware available that will do everything we needed*” – achieving country-wide connectivity required compromise and multiple solutions working together ³⁵. The trend, however, is toward consolidation: vendor-neutral platforms and interoperability standards are gradually reducing the need for device-specific silos ¹⁰. As more middleware options appear, cost barriers are also slowly coming down, making connectivity more affordable for NHS organizations of all sizes ¹⁵.

Common Issues and Challenges in Practice

When running a POCT middleware across a busy hospital or network, certain **recurring issues** have been observed. NHS POCT teams often share these pain points through Datix incident reports, audit findings, and user feedback. Understanding these challenges can help in mitigating them:

- **Patient/User Identification Errors:** A frequent issue is mismatch of patient or operator IDs between the device, middleware, and hospital systems. If a user enters an incorrect patient ID on the device (or selects the wrong patient from a worklist), the result may attach to the wrong record or be rejected by the LIS. Such “**wrong patient**” errors are serious – e.g. a glucose result filed in another patient's notes can lead to inappropriate insulin administration. Even when using barcodes, errors occur (e.g. scanning a tube barcode instead of patient ID, or a patient with multiple identifiers). Many trusts have raised Datix incidents for results assigned to wrong patients due to ID entry mistakes. Middleware can only do so much – it can validate formats and enforce scanning, but the risk isn't zero. Similarly, **operator mismatches** happen when a POCT device is used by someone without a valid login or with someone else's ID. Middleware might then hold the result as “orphan” or not transmit it. This delays the result appearing in the EPR until sorted out. Regular synchronization of operator IDs with the hospital directory is required to avoid these gaps. A UK study on glucose POCT errors noted that data entry mistakes can prevent results from reaching the chart or send them to the wrong chart ³⁶. Connectivity should eliminate manual transcription of results – but if the identifying data is wrong at entry, the electronic system will propagate that error quickly.
- **Connectivity Failures & Downtime:** Like any networked system, middleware can suffer connectivity outages. These may be due to IT issues (server downtime, network failure, firewall changes) or device-side problems (Wi-Fi drops, broken docking stations). When connectivity is interrupted, **results may not transmit in real time**. Most POCT devices have internal memory to store results and will upload when connection restores, but if the outage is prolonged or

memory fills, data can be lost. For example, a blood gas analyzer in ICU might queue results if the interface server is down; staff might be unaware and assume results went through. This can lead to dangerous delays. NHS incident logs include cases where results were significantly delayed due to interface failures – e.g. a critical troponin result only appearing an hour later, prompting a retrospective Datix. Downtime procedures are therefore essential: staff need to know if the middleware or LIS is down, they must revert to printing results or phoning them to the clinical team, and then manually document them. An audit in one hospital showed that even short LIS connectivity outages caused confusion and repeat testing. Investing in robust IT infrastructure (redundant network paths, backup servers) and working with the IT department to plan for downtimes is key. The **physical hospital environment** can also pose challenges to connectivity (thick walls causing poor Wi-Fi in some wards, etc.); a recent NHS trial noted that metal structures and old building designs can hinder POCT device wireless connections ³⁷. Mitigations include site surveys for signal strength and options like offline data caching or alternate upload methods (e.g. USB export in a pinch).

- **Integration Failures & Data Gaps:** Sometimes a result travels from device to middleware, but fails to post to the LIS/EPR. These integration failures can stem from interface engine rules, HL7 message format issues, or simply an unmapped test code. For instance, if a new POCT cartridge type is introduced (with new analytes) but the LIS expects different coding, those results may be rejected. A known issue is **duplicate patient entries** – if the patient identifier from POCT doesn't exactly match one in the LIS (e.g. missing leading zeros or NHS number vs local ID mismatch), the system might create a new record or hold the result in an "unmatched" queue. POCT teams often have to manually reconcile such cases. In some Datix reports, **results were "lost" in the interface** – in reality held in middleware awaiting correction, but effectively not charted in time. Regular interface maintenance is needed: mapping tables should be updated for new tests, and middleware logs monitored for any unacknowledged messages. Another integration challenge is when POCT devices require additional data that isn't being provided; for example, an older device might not transmit QC status or operator ID along with results ⁷, leading to incomplete records on the LIS. Ensuring all "pertinent data" (operator, device ID, lot number) is transmitted and stored is part of integration testing. When such data isn't integrated, audits become harder – one hospital's audit found that half of manually entered HbA1c results lacked the proper comment that it was a POCT result with operator initials ³⁸. In short, a successful middleware integration is not a one-time set-and-forget; it needs ongoing quality checks.

- **User Management and Training Issues:** Middleware will only be as good as the data it receives – and that depends on end-users (often nurses or clinicians) properly operating the devices. A recurring challenge is **expired operator certifications**. If a nurse's annual POCT competency lapses, middleware is supposed to lock them out (to meet training policy). But in practice, this can lead to frustration on a ward if a staff member urgently needs to do a test and finds themselves locked out. There have been incidents where, under pressure, users find workarounds – e.g. using another nurse's login or a generic account, which then breaks the audit trail. Such workarounds might show up in audit as the same operator ID doing an impossible number of tests in multiple locations. It's a governance challenge to balance strict lockouts with service needs; many POCT teams mitigate this by providing ample training sessions and sending expiry reminders (often via the middleware's email alerts). Another common issue is **mismatches in user lists** – for example, if a nurse marries and their surname changes, the LIS login might differ from the POCT login until updated, causing confusion. Keeping the operator database synchronized with HR records is an administrative burden, but necessary. Middleware can assist by interfacing with hospital Active Directory or e-learning systems in some cases ³⁹. Finally, not all users find the middleware interface intuitive – a busy ward sister might not regularly log into the middleware portal, so may miss error flags or pending quality issues. It's

important that POCT teams provide user-friendly dashboards or periodic reports (e.g. notifying a ward of any tests that failed to transmit or any QC non-conformances).

- **Result Delays and Duplicate Testing:** When any of the above issues occur, the end result is often a delay. If an A&E clinician doesn't see a POCT result in the EPR, they might assume the test wasn't done and repeat it, or wait on a lab test instead – defeating the purpose of POCT. There have been real cases of *“POCT result not found – repeat ordered”* which can both inconvenience patients and incur extra cost. In one documented scenario, a virtual ward service noted that manual workflows (without connectivity) were causing **result availability delays that affected downstream care**, due to forms being incomplete and lab staff having to intervene ⁴⁰. Delays can also compromise patient care: consider a septic patient where a lactate result is critical – if the blood gas analyzer's connection was down and nobody noticed the result didn't transmit, treatment could be improperly delayed. Many POCT middleware systems now have **alerting mechanisms** (like middleware UI turns red, or emails POCT staff) if a result hasn't gone through after X minutes. But someone has to be monitoring those. A best practice is to have A&E or ICU staff aware of backup viewing methods – e.g. knowing they can check the device screen printout or the middleware web portal if the result isn't in EPR. Another contributor to delay is results held for review: some setups intentionally hold certain critical results for lab approval (e.g. a positive troponin from a clinic glucometer might need lab validation). This is a governance decision but can cause confusion if not clearly communicated to clinical teams.

In summary, **middleware greatly reduces errors and delays overall**, but it introduces its own management challenges. Many of these revolve around integration and human factors. The good news is that connectivity issues are usually visible and fixable – as one publication put it, connectivity **“permits audits to ensure quality assurance procedures are followed...and ensures timely error prevention”**, whereas manual processes hide these issues ⁴. When incidents do occur, they should be seen as learning opportunities to improve the system setup and user training. A strong partnership with IT is vital here (few POCT teams can resolve HL7 interface errors or network dropouts alone – that's where your IT integration specialists earn their keep).

Hidden Downsides: Costs, Lock-In, and Resource Burden

While the benefits of POCT middleware are clear, there are some lesser-discussed downsides and practical considerations that NHS laboratories and POCT coordinators should keep in mind:

- **Licensing Costs and Budget Impact:** Middleware systems are not cheap. They typically involve upfront license fees, annual maintenance contracts, and sometimes cost “per device connection” or per test volume. For example, adding a new fleet of glucose meters might require purchasing additional device licenses for the middleware. Historically, this has been a barrier – smaller hospitals found the cost hard to justify for only a few devices. As one POCT lead noted, the **cost of achieving connectivity had been a challenge**, though it is *“slowly becoming more affordable”* as more solutions enter the market ⁴¹. Still, hidden costs can include the need for dedicated servers or virtual machines, database licenses (if using an Oracle/SQL backend), and costs to interface with the LIS/EPR (some EPR vendors charge for each new device data feed). Budget planning should account for ongoing costs: software updates, hardware replacements, and **scaling as the POCT service grows**. If connectivity isn't budgeted from the start of a POCT deployment, trying to retrofit it later can be tricky. NHS procurement frameworks now often bundle middleware when tendering for devices – this can secure better pricing, but it also sometimes locks you into one vendor (e.g. a “free” middleware may only work with that company's analyzers). Overall, POCT managers should build a business case highlighting the

efficiency and safety gains to justify the expense. And remember to include training and support costs, not just the software – a well-resourced middleware is only as good as the people maintaining it.

- **Vendor Lock-In and Fragmentation:** As touched on earlier, one major risk is being locked into a particular vendor's ecosystem. If you adopt a manufacturer's proprietary middleware, you might find it **doesn't play nicely with others**. This can lead to a fragmented setup – multiple middleware systems running in parallel for different devices, which is inefficient. Although many companies advertise “open” connectivity, the reality is often that third-party device support is limited or less feature-rich ¹⁰. For example, you might connect a non-ABC brand device to ABC's middleware and find that you can't get remote control functions or certain data fields from it, because the interface is generic. Some trusts have mitigated lock-in by choosing completely independent middleware (like AegisPOC or UniPOC) that have no allegiance to any device vendor ⁴². These vendor-neutral systems avoid being tied to one manufacturer, theoretically giving you flexibility to choose the best device for each niche. However, even with those, you are then **locked into that middleware vendor** – switching to a different middleware later could be a massive task (requiring re-validating every interface, retraining staff, migrating data). It's important to go in with eyes open: **there is no perfect one-size-fits-all yet** ³⁵, so decide which lock-in you can live with. Some labs choose a dual approach: use device-specific middleware where it offers clear advantages (e.g. Radiometer AQUIRE for tight blood gas control) but also maintain a central hub to which all results ultimately flow for patient record integration. The key is to avoid data silos and ensure everything still reaches the LIS/EPR and your quality reports. One practical tip is to **push vendors on interoperability during procurement** – ask if their middleware can export data to external databases or if it supports open standards. The more they support that, the less of a dead-end it becomes.

- **Reliance on IT Support:** Implementing POCT middleware is not a “plug and play” endeavor. It heavily relies on hospital IT infrastructure and expertise. POCT teams often depend on IT colleagues to set up server environments, maintain network connectivity (VLANs, Wi-Fi for devices, firewall openings for ports/protocols), and troubleshoot interface engines. A middleware outage might require database know-how or application server restarts – things a typical biomedical scientist isn't trained in. Therefore, strong collaboration with IT is essential. However, IT departments are stretched thin in many trusts, and POCT may not be their top priority. Middleware projects have been delayed because firewall rules blocked device communications or antivirus software on a hospital PC kept quarantining the interface application. One LinkedIn commentary noted **firewall and security settings as a common challenge** when connecting POCT devices in hospital networks (especially if devices communicate from community locations over VPN). There's also the matter of software updates: applying patches or version upgrades to the middleware often requires IT involvement and careful scheduling to avoid downtime. NHS Digital initiatives are emphasizing better integration, but on the ground, a POCT coordinator might have to log multiple help tickets to get their ports opened and drivers installed. Moreover, middleware often has to integrate with enterprise systems like Active Directory (for user single sign-on) or send data to data warehouses – tasks squarely in IT's domain. As Fung et al. observe, *ongoing technical support from IT and funding for maintenance and upgrades* should be planned for, as part of the POCT program ³⁹. To manage this, some trusts have created dedicated roles (e.g. a POCT IT specialist or a lab IT liaison) who bridges the gap between pathology and IT. If that isn't possible, building good relationships with the IT service desk and network teams is the next best thing. On a related note, **cybersecurity** is a growing consideration – POCT middleware holds patient data, so IT must ensure it meets NHS security standards (secured ports, encryption, user access controls). Sometimes, security policies can impede convenience (for

example, blocking external remote access to the middleware for vendor support). POCT teams should be prepared to justify and work through these issues with governance committees.

- **Complexity and Training Load:** Introducing a middleware adds an entire software layer that staff need to learn. The POCT team has to be trained in the administration of the system – which can be quite complex, involving configuration of device communication settings, user privileges, result rules, etc. There is a learning curve to fully utilizing the middleware's features. For instance, middleware can produce dozens of reports, but staff need to know how to customize and interpret them. Similarly, when something goes wrong, the team should know how to retrieve error logs or use the middleware's diagnostic tools. This often requires vendor training sessions. There's also an element of **dependency on the vendor** for support: if something breaks that the local team cannot fix, you may need to call the vendor's helpline and possibly wait for a remote session or site visit. If the issue happens off-hours, that's problematic unless you have in-house expertise. Additionally, end-users (e.g. nurses) might need some training on any changes the middleware brings – for example, if a new middleware introduces an **operator ID login step on devices**, nurses must be educated to always log in (otherwise their results won't transmit). Or if the middleware provides a new web portal for ward managers to review their POCT compliance, those managers need to learn how to use it. All this training and change management can be a "hidden" cost in time and effort. Some users might resist or find the system cumbersome initially. Careful implementation planning and showcasing the benefits (like *"you no longer need to manually record results in the folder, it's all automatic now"*) can help get buy-in. Over time, as people see fewer errors and faster results, they usually come around, but that transition period can be bumpy.

Despite these downsides, it's clear that the **pros of POCT middleware outweigh the cons** in a modern NHS setting – provided that these challenges are acknowledged and managed. The days of running a sizable POCT service on paper logs or sneaker-net USB drives are gone. The administrative burden and patient risk from not having connectivity would be far greater ("a tidal wave of admin" for clinics operating POCT devices as standalone islands ⁴³). The key is to mitigate cost and lock-in through smart procurement and to mitigate technical issues through strong project governance and support.

Maximizing Middleware Success: Tips for POCT Teams

For POCT managers and laboratory leads, effectively implementing and utilizing middleware requires both technical and operational strategies. Based on NHS best practices, professional guidance, and hard-earned lessons from the field, here are some practical tips to manage, monitor, and improve middleware use:

- **Involve IT and Pathology from Day One:** A successful POCT connectivity project is a multi-disciplinary effort. Engage your IT department early – loop in network engineers, LIS/EPR interface analysts, and cybersecurity officers about the planned middleware. Likewise, ensure your pathology management (clinical leads, quality manager) is on board. NHS England's guidance for new POCT services (like virtual wards) explicitly recommends involving the local pathology lead and digital/IT teams at the design stage ⁴⁴. Together, define the scope: which devices, which data flows, and what success looks like (e.g. 100% of ED troponin POCT results in EPR within 5 minutes). By collaborating early, you can preempt issues such as integration with existing IT architecture and assign responsibilities for ongoing support.
- **Conduct Thorough Validation and Testing:** Treat the middleware go-live like you would a new analyzer validation. Test each device connection and each result type. Simulate various

scenarios: a normal result, a critical high, a failed QC (does it lock the device?), an operator whose certification expired (does it prevent login?), etc. Verify results land in the correct patient record with correct units and reference ranges. It's wise to run devices in parallel with usual practice during a trial phase – for example, run a week where staff use the devices connected to middleware but still do their old recording method too, just to compare that all results are captured. **Perform an end-to-end audit during testing**, checking that for every POCT sample taken, a result is viewable in the LIS/EPR and/or middleware. Any discrepancies should be investigated and resolved before full go-live. Also test downtime procedures: disconnect a device or shut the network port and see if the device stores results and sends later, and how the system alerts you of the outage. This will ensure your team is familiar with what things look like when something goes wrong. Document all the testing – UKAS assessors will be interested in evidence that the interfaces and middleware were validated.

- **Develop Clear SOPs and Training Materials:** Create standard operating procedures that cover middleware use and contingency plans. For example, an SOP should outline: how to enroll new operators into the system, how often to update device configurations, what to do if a device fails to connect, and how to report middleware downtimes or errors (including reporting to the MHRA if it's an adverse incident). The **MHRA recommends** that SOPs include actions to take in the event of device faults or connectivity breakdown, and how to report these issues ⁴⁵. Ensure there's an SOP accessible on every ward using POCT that explains the basic steps: e.g. *"If the device shows 'result not sent', call the POCT office or lab. If middleware is down, record the result manually in the notes and inform the doctor."* Training sessions should be held for all POCT operators to introduce the new middleware (if it's a new rollout). Emphasize any changes in workflow – for instance, scanning a patient's barcode **before** testing if that's new, or the importance of selecting the correct patient from a worklist. Also train them on any user-facing interfaces: some middleware allow ward staff to log in and see their device statuses or QC reports. If you empower users to utilize those features, it can improve compliance (e.g. a ward manager can check if their staff have done IQC that morning). Keep the training practical and role-specific.
- **Monitor Daily and Audit Regularly:** Assign responsibility within the POCT team for **daily monitoring** of the middleware dashboard. This includes checking for any devices that went offline, any results in a holding or error queue, and any operator lockouts or QC failures. Most middleware have summary views or can be configured to send daily emails of exceptions. Jumping on issues quickly can prevent them snowballing – for example, if you see that NICU blood gas analyzer hasn't sent results in the last hour, you can alert NICU before it becomes a crisis. Regularly review operator lists against HR records to remove those who have left and update those with new roles. It's also good practice to **audit the data quality** periodically: pick a sample of POCT results each month and verify the patient ID, result, units, etc., were correctly transmitted and recorded. If you find any anomalies (like a transcription error or missing result), investigate and address the root cause (it might reveal a gap in training or a system mapping issue). Also, review incident reports (Datix) related to POCT every month. Look for patterns – e.g., multiple incidents from one ward might indicate a device placement or training issue; multiple "ID not recognized" incidents might suggest the ADT feed from hospital registration is lagging or the barcode format changed. **Quality indicators** for POCT connectivity can be tracked, such as the percentage of results transmitted successfully within a target timeframe, or the number of incidents due to connectivity per quarter, aiming for continuous improvement ⁴ ⁶.
- **Leverage Middleware Features Fully:** Many middleware systems come with bells and whistles that can greatly enhance POCT management if used. For instance, use the **lockout features** (for expired certifications, for QC failures) to enforce quality – they may seem strict, but they uphold

ISO standards and ultimately protect patients. Utilize built-in reports for audit: middleware can often report on operator performance (who is doing lots of tests, who hasn't done QC in a while), reagent inventory (when lot expires), and compliance metrics. These reports can feed into governance meetings or pathology quality reviews. Some platforms allow rule-based alerts – e.g. automatic email to POCT coordinator if a critical result is obtained or if a device generates an error code. Set those up in line with your clinical risk assessments. **Remote access** capabilities are also valuable: if available, ensure the POCT team can securely log into the middleware from home or via VPN after hours. This way, if a call comes in about a problem at 2 AM, someone can check the middleware status remotely (some issues can be solved without going on-site, like unlocking a user or resending a result). Additionally, if the middleware has an operator training or e-learning module (as some do), consider integrating that into your competency program – it can automate quizzing users and documenting their competency scores.

- **Maintain Open Communication with Vendors and Peers:** Keep in touch with the middleware vendor's support team and stay updated on software upgrades or patches. Vendors often release updates to add new device drivers or fix known bugs. Plan for periodic upgrades (e.g. annually or as needed) and test them in a test environment if possible. Also, engage in user groups or forums – many middleware vendors have user meetings or online communities (and organizations like the ACB or IBMS POCT groups may have sessions where people share experiences). Learning how other NHS trusts configured their middleware or overcame specific challenges can be immensely helpful. Networking with other POCT managers can lead to insights like, "how did you integrate that new glucometer?" or "have you enabled two-factor authentication on the middleware for cybersecurity and how did that go?". Given that POCT is a rapidly evolving field, such exchanges ensure you're not solving problems in isolation. The **importance of collaboration** was emphasized by UK POCT leaders – by sharing difficulties and solutions, both users and vendors can improve the products ⁴⁶ ⁴⁷. Provide feedback to vendors on features that would help you. For example, if you find the middleware doesn't easily produce a certain audit report, request it – vendors do listen, especially if multiple customers raise the same need (some now offer direct EQA data uploads, phone app interfaces, etc., thanks to user feedback).

- **Have a Robust Backup Plan:** No one likes to think of worst-case scenarios, but a contingency plan is vital. Define what happens if the middleware goes completely down or if connectivity to a critical device is lost. This might involve having **paper record forms** ready as backup (so ward staff can record results manually and fax to lab, for instance). It could also involve configuring devices to print results locally as a fallback. Ensure that these backups are described in the SOP and that staff know where to find the paper forms or printer. Regularly simulate a downtime (maybe during a slow period) to see if staff follow the manual process correctly – this can be as simple as "today from 2-3pm, LIS connectivity will be off for maintenance, please follow downtime procedure". Also, consider data backup: the middleware database itself should be backed up by IT in line with hospital policies (so that if a server fails you don't lose all POCT records). In a few cases, trusts have had to run for days without their POCT middleware (e.g. during a cyber-attack or major IT outage); having result data cached on devices or having an alternative way to capture results can sustain essential services. After any serious downtime, do a post-incident review to improve the plan.

By implementing these practices, POCT teams can greatly enhance the reliability and effectiveness of their middleware systems. The goal is to **embed the middleware into routine operations** such that much of its work is in the background, silently ensuring quality, rather than firefighting problems. As one IBMS article pointed out, **electronic connectivity and remote management are becoming**

essential to uphold POCT quality in a healthcare system that's increasingly without walls ^{48 49} .
Good middleware management turns that ethos into everyday reality.

Future Trends: POCT Middleware and Digital Governance

Looking ahead, the landscape of POCT middleware is likely to evolve significantly as healthcare digital transformation continues. Some future trends and developments that POCT managers and professionals should watch for include:

- **Greater Integration into Laboratory and Hospital Systems:** The line between “LIS” and “POCT middleware” may blur. LIMS vendors (like CliniSys, Epic Beaker, etc.) are working on more native POCT modules so that separate middleware might eventually be optional. Similarly, hospital EPR systems might offer direct connectivity for certain popular devices via integration brokers. The push for **enterprise digital platforms** means middleware could become more tightly integrated with order comms, inventory management, and electronic health records. For example, we may see POCT results flowing through regional shared care records in real time, not just local EPRs ^{50 33} . This will require middleware to support modern APIs (like FHIR) in addition to HL7, and to handle higher volumes of data exchange. It also means POCT data will be part of big data analytics – trusts might leverage middleware data (through LIS) to analyze usage patterns, outcome correlations, etc. POCT middleware could thereby become a source feeding into population health management tools and decision support systems.
- **Cloud-Based Middleware and Connectivity-as-a-Service:** Just as many IT services are moving to the cloud, we can anticipate POCT data management following suit. Instead of installing servers on-premises, hospitals might subscribe to cloud-hosted middleware platforms. This is already starting – some vendors offer **cloud connectivity solutions** where devices send results over the internet to a secure cloud database accessible to the lab. Cloud middleware could ease the IT burden on local teams (with vendors managing updates and uptime) and facilitate multi-site connectivity (ideal for integrated care systems or pathology networks consolidating POCT oversight). Of course, it raises data governance questions (NHS policies on cloud data, patient confidentiality), but if done securely, it could be advantageous. Cloud solutions might also use modern web interfaces that are more user-friendly and accessible on mobile devices, which could increase clinician engagement with the data. The NHS will need to weigh the benefits against risks; however, smaller institutions or GP federations might adopt cloud POCT services more readily if they lack onsite IT support.
- **Interoperability and Standards Development:** Standards like **CLSI POCT1-A2** (the POCT device communication standard) have been around since 2006 ⁵¹ , but not all devices fully implement them. The future likely holds more rigorous adoption of interoperability standards. The advent of **HL7 FHIR** (Fast Healthcare Interoperability Resources) could lead to new standard APIs for sending POCT observations directly into EPRs with richer context. There's also talk of standardizing operator identity management across systems (so that a single staff ID can be used universally). Regulatory and accreditation pressures will encourage vendors to ensure their systems don't operate in silos – **connectivity will be a must-have, not an afterthought** for new POCT devices. We might even see regulators requiring that a POCT device sold into a hospital environment must support a standard connectivity protocol (much like how lab analyzers must output results electronically). All this points to an ecosystem where adding a new POCT device is more plug-and-play with existing middleware, reducing the time “to interface” new tests.

- **Advanced Analytics and Automation:** As middleware accumulates troves of data (patient results, QC trends, operator performance), there is an opportunity to apply advanced analytics or AI. For instance, middleware could automatically detect a device that is drifting out of calibration by analyzing QC/ EQA data over time and then alert the POCT team to service it – *predictive maintenance*. Some systems already have rules for out-of-range results; future versions might integrate clinical decision support – e.g. if a POCT result is critical, automatically cross-check if a lab confirmation was done or if clinical action was taken, essentially closing the loop. Also, expect better **dashboards and visualization** for POCT data: heatmaps of device utilization, benchmarking of wards' compliance, etc., to guide management decisions. Digital governance will extend to ensuring data from POCT is used effectively to improve services (for example, identifying that a certain clinic rarely connects their device and thus needs retraining or maybe a better connectivity solution).
- **POCT in Community and Home – New Connectivity Challenges:** The expansion of POCT into community settings (pharmacies, care homes, patient's homes for virtual wards) introduces new connectivity needs. Instead of hospital LANs, devices might use cellular networks or patients' home Wi-Fi to transmit results. Middleware will have to accommodate intermittently connected devices and ensure data security across the internet. NHS programs like virtual wards are already piloting sending results from patients' homes to hospital systems via middleware and Bluetooth hubs ⁵² ⁵³. We will likely see **middleware apps** on tablets or phones that act as intermediaries – for example, a nurse's tablet that gathers results from a portable POCT device via Bluetooth and then uploads to the cloud/EPR. Governance here is critical: verifying the identity of the patient and quality of testing done in non-traditional settings. The middleware might need additional checks (like confirming GPS location of a community test or logging chain-of-custody if patients self-test). This will broaden the remit of POCT middleware beyond hospital walls even more. England's Integrated Care Systems (ICS) may implement regional POCT middleware that multiple organizations share, to support care pathways that cross traditional boundaries. This raises data sharing and **data governance** considerations – ensuring that results are visible to all who need them (with patient consent) and stored in compliance with regulations.
- **Cybersecurity and Resilience:** As with all digital health solutions, future POCT middleware will place a stronger emphasis on cybersecurity. We can expect features like encryption of data at rest and in transit, two-factor authentication for system access, and audit logs of not just patient tests but any data view or export (to prevent unauthorized access). Cyber incidents (like ransomware) could impact middleware, so systems might evolve to have quick read-only modes or offline data access in case of IT emergencies. NHS Digital's push for robust IT contingency (per the Patient Safety Strategy) means POCT data systems must be part of disaster recovery planning. Perhaps future devices will have more autonomy to function and batch-send results once systems are restored, minimizing impact on patient care during downtimes.
- **User-Centered Design and Reduced Complexity:** Finally, we anticipate middleware interfaces becoming more intuitive and user-centric. The current generation of systems often has a utilitarian design; future versions might take cues from modern software UX to simplify tasks. This could include context-sensitive help, guided troubleshooting (e.g. the system might highlight: "Device X has not communicated in 30 minutes – possible causes: check network cable or see error log here"), and more natural integration with clinical workflows. If middleware can integrate with staff communication tools (like sending a secure message to a clinician's phone that "patient's POCT result is ready"), it can further streamline processes. The next generation of healthcare professionals will expect seamless tech – middleware should ideally become as

invisible as possible, quietly ensuring the right data is in the right place without users having to think about it.

In conclusion, POCT middleware systems are now a cornerstone of delivering high-quality point-of-care testing services in the NHS. They bring order, oversight, and reliability to what could otherwise be a chaotic proliferation of devices and data. As we have discussed, they are not without challenges – from technical hiccups to human factors – but with diligent management these can be overcome. The direction of travel is clear: increasing connectivity, integration, and intelligence in how we manage POCT. A well-implemented middleware not only **helps meet today's requirements** (like ISO 15189:2022 accreditation and rapid result communication), but also positions a trust for **future innovations** in diagnostics. By investing in strong digital governance now – essentially, treating POCT middleware as seriously as any critical lab system – NHS organizations will be ready to harness the next wave of point-of-care testing advancements for the benefit of patients and clinicians alike. The end goal is a fully connected diagnostic pathway where no result is ever missed, no quality concern goes unnoticed, and POCT truly delivers on its promise of **immediate, safe, and integrated care at the patient's side**.

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