Hub and spoke dispensing model: A thematic review from GPhC inspections

October 2025



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About the GPhC

Who we are

We are the regulator for pharmacists, pharmacy technicians and pharmacies in Great Britain.

We are a statutory organisation set up by the UK and Scottish parliaments, and we are independent from government and those we regulate. Our role and functions are set out in legislation called the Pharmacy Order.

We are funded by fees paid by the pharmacists, pharmacy technicians and pharmacies that register with us.

What we do

Our main role is to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy.

We set standards to make sure that every pharmacy provides safe and effective care. And we provide guidance to help pharmacy owners achieve this.

We also inspect pharmacies to assess whether they are meeting our standards and to help them improve their systems and services.

1. Executive summary

This thematic review explores the implementation and regulatory oversight of the current hub and spoke dispensing model across registered pharmacy premises in Great Britain. This review draws on inspection data from July 2023 to August 2025, before legislative changes enabling hub and spoke dispensing across different legal entities came into effect from 1 October 2025.

<u>Changes to legislation</u> include an update to the Medicines Act 1968, section 10 and The Human Medicines Regulations 2012.

In a combined approach across past inspections and a targeted data capture of inspections conducted in August 2025, fifty-five inspection reports were reviewed including both hub and spoke premises.

This review identified five key themes:

- 1. Governance and risk
- 2. Legal and regulatory compliance
- 3. Operational processes
- 4. Staffing
- 5. Patient experience

While many pharmacies demonstrated strong practices, particularly in automation and business continuity, areas such as standard operating procedures (SOP) development, risk assessments, error reporting, compliance with responsible pharmacist (RP) legislation and training require further improvement.

This review provides targeted recommendations to support pharmacy owners and superintendent pharmacists in meeting the GPhC standards for pharmacy premises and preparing for the anticipated expanded use of hub and spoke models across different legal entities. These include ensuring robust governance frameworks, clear defined roles between hub and spoke entities, comprehensive staff training, and transparent communication with patients.

Pharmacies should follow any requirement set out in respective NHS national regulations, for example, The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Miscellaneous Amendments) Regulations 2025 with regards to hub and spoke provision. The requirements are not included within the scope of this review, but they should be considered in addition to the recommendations within this report.

This review aims to promote safe, effective, and patient-centred care through regulatory insight and shared learning.

This report will be shared with key stakeholders including relevant government departments, professional leadership bodies and representative organisations in Great Britain.

Recommendations by theme

Theme 1: Governance and risk

- a. Complete and regularly review risk assessments before and after operationalising hub and spoke models.
- b. Develop robust, tailored SOPs covering all aspects of the hub and spoke process and ensure these are accessible to both the hub and spoke(s).
- c. Establish clear documentation (including written agreements where required by legislation) outlining roles and responsibilities between hub and spoke premises.
- d. Implement formal error reporting systems and promote a learning culture, even in automated environments.
- e. Conduct initial and ongoing audits to assure quality and safety.
- f. Ensure robust Business Continuity Plans (BCP) are in place at both the hub and spoke(s) to cover any failures that may impact upon service provision to patients.

Theme 2: Legal and regulatory compliance

- **a.** Ensure RP regulations are followed at all registered premises, including for hubs that are closed to the public. Maintain accurate RP notices and real-time RP records.
- **b.** Securely transmit patient data using integrated systems that comply with legislative requirements.
- **c.** Review and update indemnity insurance, including to reflect responsibilities across different legal entities where applicable.

Theme 3: Operational processes

- **a.** Risk assess the dispensing of medicines (especially those associated as higher risk) and clearly document responsibilities for clinical checks and counselling.
- **b.** Ensure all team members are aware of higher-risk medicines.
- **c.** Implement SOPs and training for removal of medicines from their original packaging ensuring stability and traceability of medicines.
- **d.** Embed robust checks for all stock, including items outside of automated systems.
- **e.** Establish robust procedures for alerts and recalls, with clear accountability.
- **f.** Ensure that there is a documented process in place for how any changes to prescriptions are communicated prior to the hub and spoke model commencing, and it is consequently adhered to by the pharmacies involved.

Theme 4: Staffing

- **a.** Ensure all staff involved in the hub and spoke supply process are appropriately qualified and enrolled on GPhC-accredited courses as relevant and where available.
- **b.** Provide protected learning time and structured induction and training processes.
- c. Facilitate cross-site (hub-spoke) understanding through training materials and visits.
- **d.** Deliver safeguarding training tailored to the hub and spoke context, even where patient contact is limited.

Theme 5: Patient information and experience

- **a.** Inform patients about the hub and spoke model and ensure they are aware of their choices about how their medicines can be supplied. Display notices in pharmacies and online, where required by legislation.
- **b.** When operating a hub and spoke model across different legal entities, only include the spoke address on medicine labels.
- **c.** Create mechanisms for capturing and reviewing complaints and feedback related to the hub and spoke service.

2. Background

What is the 'hub and spoke' model?

Hub and spoke dispensing is a model where medicines are dispensed centrally by one pharmacy on behalf of another. In this model, a hub pharmacy can provide dispensing services to one or more spoke pharmacies(figure 1). Both the hub and spoke must be GPhC registered pharmacy premises and are therefore subject to the same GPhC inspection processes.

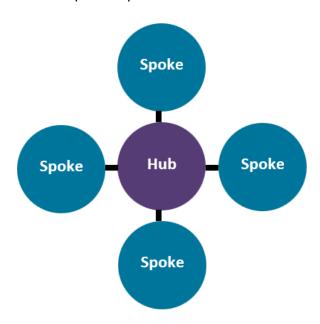


Figure 1: Hub and spoke model diagram

Changes in legislation

Section 10 of the Medicines Act 1968 previously prevented the sale and supply of medicines outside of the same legal entity. This therefore prevented the hub and spoke model being provided by two separate legal entities.

Following the consultation process in 2022, the Department of Health put forward a proposed legislation change to the Medicines Act 1968 that now allows the hub and spoke model to work across different legal entities. This legislation change is to support the rapidly changing pharmacy landscape and enable greater efficiencies by utilising larger scale automated dispensing processes that hub sites can provide. The Human Medicines Regulations 2012 has also been updated to support implementation of the hub and spoke model across different legal entities. The change in legislation was made on 25 June 2025 and was implemented from 1 October 2025.

The changes will also allow NHS dispensing doctors to act as the 'spoke'.

Additionally, the legislation changes only impact the provision of the hub and spoke model across different legal entities which will include the creation of a new statutory information gateway for transfer of patient data between a hub and a spoke. This will ensure compliance with UK General Data
Protection Regulations when data is transferred across two legal entities.

As part of this legislative change, when the hub and spoke model operates across different legal entities, there is a requirement that there must be a written agreement in place between the hub and spoke.

Additionally, the hub must:

- be a GPhC registered premises
- include the spoke name and address on all medicine labels
- include the date of supply from the hub (not the spoke) on the patient label

and the spoke:

- must display a notice that informs the patient of the hub and spoke model in use this must also be available on the relevant pharmacy or NHS dispensing doctor's website or app, if they provide an online dispensing service
- has control over the final supply and decision-making control over <u>label particulars</u> such as directions for administration.

Other requirements for the hub and spoke model

As both the hub and spoke pharmacy in this model are GPhC registered premises, they are subject to inspection by the GPhC against **the five principles of the standards for pharmacy premises**:

- 1. The governance arrangements safeguard the health, safety and wellbeing of patients and the public.
- 2. Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.
- 3. The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.
- 4. The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.
- 5. The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

Some pharmacies will be subject to NHS national regulation requirements with regards to hub and spoke provision. These requirements are not within the scope of this review but should be considered in addition to the recommendations in this report.

The purpose of this review

In response to the legislation changes, we committed to complete a thematic review of our inspections at hub and spoke pharmacies. The purpose of this review is to support pharmacies that are already operating a hub and spoke model, and those that are considering providing services in this way, including across different legal entities.

The review will provide key themes and learning points from past and current inspections of pharmacies utilising the hub and spoke model, provide examples of good practice and areas for improvement, and recommendations to support compliance with the standards for pharmacy premises.

3. What we did

We captured evidence via three different mechanisms:

- 1. Reviewing past inspection reports over the last two years from July 2023 to June 2025, identifying themes where premises have 'standards met' or 'standards not met'.
- 2. Targeted data capture during inspections carried out over a four-week period in August 2025, focusing on key themes highlighted during the retrospective analysis and current topics being discussed nationally. The data capture took place during routine inspections, re-inspections and new premises application visits.
- 3. Facilitated themed survey based on the above data sets completed by inspectors that are assigned to pharmacies that are known to currently utilise hub and spoke dispensing.

The targeted data capture during current inspections in August 2025 was carried out by completing a MS Word template questionnaire in addition to the usual inspection documentation. The templates were designed to be able to capture quantitative responses quickly and easily, while providing areas for additional qualitative feedback for evidence gathering.

We used similar templates for both the hub and spoke premises, with a slight adjustment in questions where applicable, to highlight differing responsibilities between the hub and spoke. Our inspection team were involved in reviewing these templates to ensure they were suitable for use.

The use of the questionnaire did not impact the approach or completion of the usual inspection process.

Inspections record whether standards are met against the <u>GPhC standards for pharmacy premises</u> and inspectors can complete full or focused inspections based on professional judgement. There is <u>more information about how we carry out inspections</u>, including changes to the inspection process from January 2025 on our website. Inspectors carrying out re-inspections of premises that didn't meet the standards may decide to focus only on the standards that previously weren't met, or to carry out a full inspection.

Homecare premises were not included within this thematic review, as they were the subject of a previous themed review, published in April 2025: **Evaluating service provision: a themed review of registered pharmacies providing homecare medicines services**.

Hub and spoke models vary significantly across companies with a range of automation, manual processes and types of medication supply and services. This thematic review therefore provides generalised examples of good practice, recommendations and improvements.

The analysis of evidence is themed around five key areas:

- 1. Governance and risk
- 2. Legal and regulatory consideration
- 3. Operational
- 4. Staffing
- 5. Patient information and experience.

Inspection reports are published on the **GPhC pharmacy inspections website**.

4. What we found

Review of past inspections: results

Between July 2023 and June 2025, 37 premises were actively registered with the GPhC as dispensing hubs providing the hub and spoke model. Of these, 32 premises were located within England and five located within Scotland.

During the two-year period, 27 inspections took place within these 37 premises. The inspections included:

- six re-inspections of premises where standards were not met at the initial inspection.
- one inspection of a premises which failed on standards unrelated to the hub and spoke model, and so is not included within the 'standards not met' group for this review.

Of the 27 inspections that took place, 20 premises (74%) met the requirements for standards met. For comparison, 84% of all premises types inspected between April to June 2025 (Quarter 1, 25/26) met the standards.

Of the seven premises that did not meet the standards, one was a routine inspection compared to six inspections of newly registered pharmacies. This reflects themes seen within the GPhC Quarter 1 data that shows that the percentage of newly registered pharmacies that met standards dropped to 68% from an overall average of 84%. The standards that were not met during the inspection of the seven premises are shown below in figure 2.

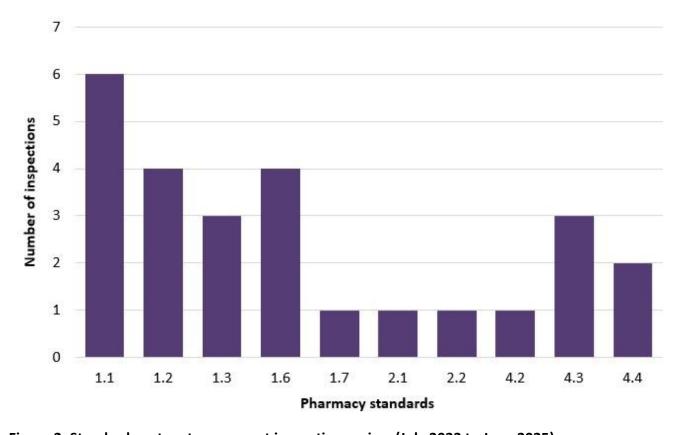


Figure 2: Standards not met across past inspection review (July 2023 to June 2025)

Review of planned inspections: results

During August 2025, 11 hubs and 17 spokes (28 pharmacy sites in total) were inspected and inspectors collected responses using the data capture tool. Inspections included a spread of models and pharmacy types. For example, pharmacies of different sizes and dispensing volumes across Great Britain, and those dispensing original packs and medicine compliance systems.

Three hub responses were collected virtually with pharmacy groups that utilise the hub and spoke model. One hub inspection was a new premises application inspection.

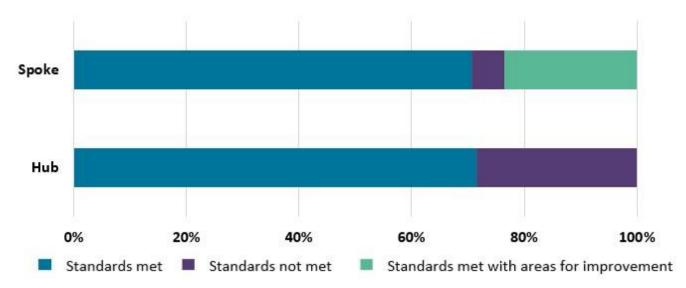


Figure 3: Inspection outcomes of August 2025 data capture

Figure 3 shows that 94% of spoke premises met the standards and 71% of hubs inspected met standards. 'Areas for improvement' is where pharmacies have met standards, but still have areas for improvement within a standard or standards.

Themes across all inspections

This is a summary of themes found throughout the analysis of the past and August inspection reports, highlighting general themes relating to what went well and areas for improvement, plus some overarching recommendations.

Theme 1: Governance and risk

Standard Operating Procedures (SOPs)

All seven hubs that failed to meet standards during the review of past inspections failed to meet standards within principle 1 (governance). All seven had concerns raised regarding inadequate SOPs being place. Across the 27 inspections completed during the last two years, most pharmacies had SOPs in place, but some were outdated, lacked specificity, or were not signed as being read by all team members or lacked a process for recording associated training. Some SOPs were tailored to hub and spoke models, but others were generic or missing key processes.

During the August inspection capture, as seen in figure 4, 89% of premises had written arrangements or specific procedures relating to the process for hub and spoke. As a whole, the majority of pharmacies had SOPs in place to cover most elements of the hub and spoke model but there was variation as to whether these were read by only the individuals involved in either the hub or spoke part of the model, or by the whole teams across the pharmacy group. Some pharmacies used SOPs issued by the Patient Medication Record (PMR) supplier. One company provided videos of the spoke process to be watched alongside reading the SOPs.

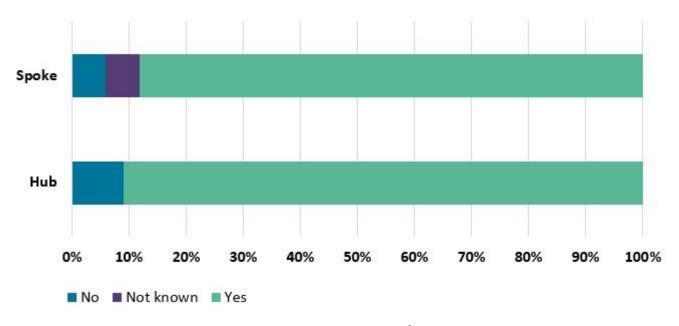


Figure 4: Does the pharmacy have written arrangements and/or specific procedures relating to the process for hub and spoke? (August 2025 data capture)

Roles and responsibilities

Roles and responsibilities were generally well understood across the teams in the past inspection review. Some pharmacies had clear accountability structures, however, the documentation of roles and responsibilities varied. Some team members were unaware of the roles and activities that could be carried out in the absence of the RP. One pharmacy was unable to demonstrate any documentation to show the differing roles between the hub and spoke or the lines of accountability.

Within the August data capture, 86% of pharmacies had procedures that defined clear accountability for each step of the process and were able to demonstrate records of checks completed at each change. Most pharmacies had electronic systems that recorded these checks, which included the clinical check, and any clinical interventions made and the details (including GPhC registration number) of the pharmacist completing them.

One spoke pharmacy had a process for recording if the RP needed to open a sealed bag from the hub to check the contents to ensure a clear accountability and audit trail. Another spoke pharmacy had an agreed process that if the bag of medicines delivered from the hub arrived at the spoke damaged, the spoke would be responsible for removing the items, re-checking them against the prescription and putting them into a new bag.

Risk assessments

Four premises within the two-year period review highlighted that they had completed risk assessments before becoming operational, enabling them to highlight potential risks and problems before opening. Areas of review included types of medicines suitable for hub supply, IT infrastructure reliability and environmental risks. One premises had a risk register that they were able to review regularly and implement relevant mitigations. The majority of hubs had risk assessed and were not involved in supplying items requiring cold storage or those assessed as greater risks such as certain controlled drugs. Some pharmacies had no documented risk assessments or only provided them post-inspection. Risk assessments sometimes failed to address high risk areas such as medicines being removed from original packaging.

During the August capture collection, as seen in figure 5, 45% of hubs but only 24% of spokes were aware of a completed written risk assessment for hub and spoke arrangements. Even if a risk assessment was in place, the majority of the individuals present during the inspection were not aware of whether one had been completed or couldn't refer to it.

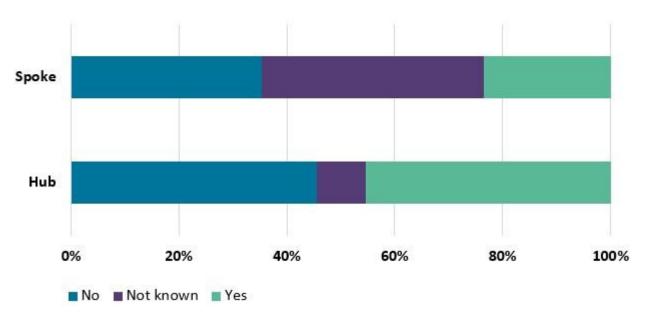


Figure 5: Has a risk assessment been carried out? (August 2025 data capture)

Error reporting and learning

Six of the hubs during the past inspections had inadequate error documentation processes for recording near misses and having suitable processes to learn and improve from errors. In general, recording of near miss errors within the hub premises were inconsistent. This seemed to link to the use of automation and very low error rates, despite most hubs having some element of manual process. Some pharmacies relied on the automatic systems to detect errors but lacked a formal review process or root cause analysis when errors were found.

A lack of documentation resulted in the inability to provide assurance that there was an adequate learning culture. Some stated they discussed errors but had no formal reporting system. Sharing of dispensing errors between hub and spoke was inconsistent, with a reliance on the spoke managing them and often the hub was not aware of any dispensing incidents happening.

During the August data capture however (see figure 6), 93% of pharmacies stated that either the hub or spoke shared details of the dispensing mistakes. Of the two spoke pharmacies that stated they wouldn't, one used an online system to report these and the other highlighted they had yet to receive a reported incident and wasn't aware of a written process to follow. However, the majority of the pharmacies had a process in place for sharing errors (via online, phone, messaging service, or email, for example) and using established systems such as Datix[®].

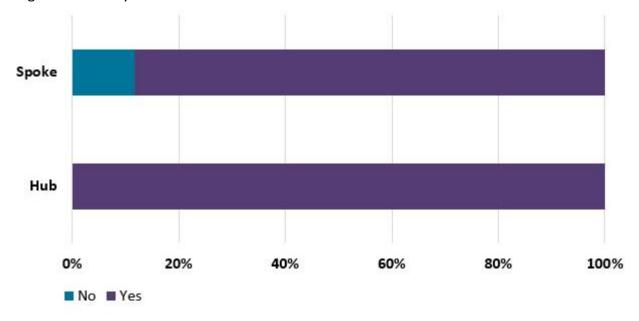


Figure 6: Is there sharing of dispensing errors between the hub and spoke(s)? (August 2025 data capture)

Audits

Audits were not commonly seen across the past inspections review, but three pharmacies had actively created audits to review their processes. One pharmacy audited all prescriptions with a pharmacist check during the first week a spoke pharmacy came on board. The August data (figure 7) capture showed similar results with only 36% across all pharmacies stating they carried out audits on their hub and spoke model. Sixty-four percent of hub premises did complete audits compared to 18% of spokes, but there was a lack of clarity by the team regarding what these included. Several pharmacies had completed audits when the hub and spoke model was initially set up which included accuracy of prescription and contents of final bagged product but, many of these had since stopped.

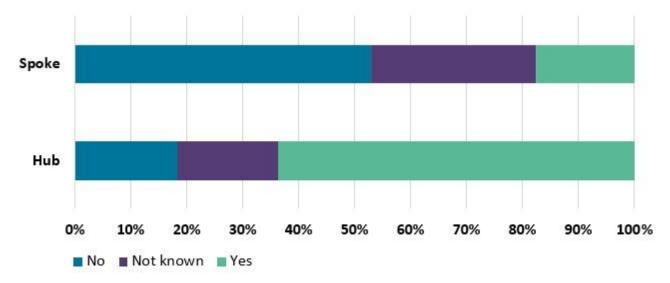


Figure 7: Does the pharmacy carry out audits on hub and spoke? (August 2025 data capture)

Business continuity

Three pharmacies within the past inspection review highlighted they had business continuity plans (BCPs) in place. Many pharmacies with automated equipment had service contracts and backup systems in place. Examples included back-up generators and separate network options to maintain internet connectivity such as additional Wi-Fi, LAN or mobile networks. Most hub pharmacies worked a period of time ahead of when medications were needed to enable additional flexibility and to create a 'buffer', to prevent any delays to patients. Most pharmacies had good feedback mechanisms in place to report concerns back to IT manufacturers. Regular servicing of robots and automated systems was standard practice with some pharmacies having on-site engineers or remote support.

During the August data capture, 86% of premises had considered business continuity arrangements in the event of failure at the hub and spoke with many planning to revert to local dispensing models or move work to other pharmacies within the group. However, this mitigation may not be as easy with the recent legislation change enabling the hub and spoke model across other legal entities. Therefore, a clear plan is required to be built into BCPs, with defined accountabilities, before hub and spoke models become operational. One spoke was able to access a digital software platform that highlighted any stock or technical issues within the business, which they checked daily. This enabled them to be aware and proactively plan for any potential situation that would interrupt supply of medicines to patients.

What worked well

- SOPs relating to both the hub and spoke being available on the company's intranet. This
 enabled team members easy access to up-to-date documents and allowed them to refer to the
 roles and responsibilities of both the hub and spoke and support with accountability.
- Risk assessment being completed before hub and spoke model becomes operational. Risk
 registers in place that are regularly updated and managed after opening. Digital copies of the
 most up to date written risk assessment were readily available.
- A best practice document being available to the team, which set out how to manage prescriptions from start to finish.
- Clear records of checks being made at various stages of the supply process.
- Error reflection forms being used to explore the root cause of the incident and relevant mitigations put in place.
- Weekly communication to the whole pharmacy group sharing errors that had occurred during the week at both hub and spoke.
- Audits for all new spoke pharmacies where 100% of the prescriptions submitted were checked in the first week of integrating with the hub. After the first week a representative sample of prescriptions, proportionate to the volume of dispensing being undertaken for each spoke pharmacy were checked.

Areas for improvement

- SOPs kept off-site at another local branch or utilising SOPs provided by the Patient Medication record (PMR) company that had not been adapted to be specific to the individual hub / spoke.
- Failure to consistently report and document near misses (even if a low error rate due to automation).
- No formal way of feeding back errors and enabling the team to learn from them.
- Risk assessments and relevant actions not being documented, missing high risk areas, or not being completed at all.

Recommendations for governance and risk

- 1. Risk assessments need to be completed before the hub and spoke model becomes operational. There should be a process for regular review and audit to ensure that mitigations are still appropriate. Risk assessments should focus on suitability of medicines being supplied, risks of medicines being removed from the original packaging, infrastructure reliability, limitations of technology, risks of delays to patients and how patient information is securely transferred. Risk assessments should be available for all team members, both at the hub and spoke, to refer to and support risk awareness and understanding of the relevant mitigations in place.
- 2. All hub and spoke premises are required to have sufficient and appropriate **SOPs** in place to cover all elements of the hub and spoke model. This needs to include a robust governance programme for approval and regular review via an appropriate person. All SOPs should clearly outline roles and responsibilities for each task and an audit trail of team members who have read these also

- needs to be in place. Both hub and spoke should have access to up-to-date copies of these to ensure full oversight and understanding of the processes in place at both premises.
- 3. There must be **written agreements** (for example a service level agreement SLA) in place when the hub and spoke model operates across different legal entities. It is important that the roles and responsibilities between the hub and the spoke are clear: although this is not a legal requirement for existing hub and spoke models (within the same legal entity), this should also be considered to similarly ensure defined accountability. These should include as a minimum, but not limited to:
 - Responsible Pharmacist (RP) roles and responsibilities at both sites, including who is
 responsible for each element of the supply process for example, clinical checks, dispensing
 and transfer between sites, and the defined roles and responsibilities for when changes to
 prescriptions are made at the hub
 - error reporting and management process for all errors
 - the process for data submission, transfer of data and how to manage a data breach in line with the General Data Protection Regulations (GDPR) and the Data Protection Act
 - criteria for which medicines are suitable for hub processing
 - the process for responding to medicine recalls and alerts at each classification level, and which person or organisation is responsible for them.
 - a point of contact for escalations for communication between both the hub and spoke including how it will be communicated, for example by phone or email
 - a point of contact for patients to escalate concerns to including the complaints management process
 - a process for highlighting and addressing performance and quality concerns of the hub and spoke service between the two organisations such as delays in supply back to the spoke, patient feedback, and prescribing quality
 - timeframes for the turnaround of the dispensing service.
 - business continuity plans for service disruption, including the process for safely terminating the hub and spoke model to minimise service disruption and supply to patients
 - any additional requirements for compliance with NHS national regulations where applicable

These written agreements need to be in place before the model starts operating.

- 4. A positive learning culture should be established by ensuring a robust process for documenting near misses and dispensing errors is in place, even when automation is used. This should include a 'no blame' culture and a process for shared learning and development for the team and a review and change of technology used where appropriate. Documentation of errors and any relevant changes or improvements should be kept, to monitor key themes and to be able to review their effectiveness.
- 5. Initial and recurrent **audits** should be carried out, and review and follow up on recommendations from these should provide ongoing assurance of quality and safety of the of hub and spoke.
- 6. Ensure a robust **BCP** is in place at both the hub and spoke to cover any failures that may impact service provision to patients and consider regular maintenance plans for all areas of automation to minimise future service disruption. Spokes should specifically have a robust method to continue

service provision for patients if the hub can no longer deliver the service due to either temporary or permanent (termination of contract) service failure. This should also include relevant due diligence checks on the pharmacies before implementing any new service or contract.

Theme 2: Legal and regulatory compliance

Responsible Pharmacist (RP) regulation

A failure to meet the requirements of <u>The Medicines (Pharmacies) (Responsible Pharmacist)</u>
<u>Regulations 2008</u> was seen in five hubs during the review of past inspections. This is because RP notices weren't displayed appropriately, or RP records were incomplete or missing. Some pharmacists retrospectively signed in, breaching RP regulations.

During the August inspection data capture, 100% of hubs displayed a RP notice. One hub had gaps in records where it was unclear when the RP started and ceased working and one hub had made amendments to records due to previous errors made.

Information governance and GDPR

Most pharmacies in the past inspection review used patient medication record (PMR) systems that were password protected, but some lacked individual logins or used default logins provided by the IT supplier. One pharmacy used biometric login for some equipment and smart cards were predominately used securely. Three pharmacies stated they were registered with the Information Commissioner's Office (ICO) and most pharmacies had processes in place for training team members on information governance or had relevant SOPs or confidentiality agreements in place. Physical access to all hubs were secured appropriately to prevent unauthorised access.

The majority of the spoke pharmacies in the review of past inspections transmitted prescription data electronically to the hub using either integrated Patient Medication Record (PMR) systems or secure software platforms. However, one pharmacy used a mainly paper based system with no electronic communication between the hub and spoke.

In the August data capture (figure 8), 86% of pharmacies had considered how data is securely shared between the hub and spoke, with pharmacies using integrated systems for data transmission, and the majority of pharmacies used sealed containers when delivering medicines between premises.

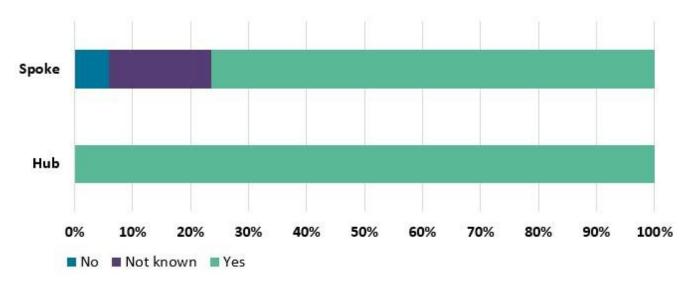


Figure 8: Has the pharmacy considered how data is shared securely between hub and spoke? (August 2025 data capture)

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Indemnity insurance

All the inspection reports over the two-year period showed all premises having appropriate indemnity insurance in place. It is important to note that indemnity cover for the pharmacies covered within this review was within the same pharmacy company (hub and spoke) and this will need to be considered now legislation has changed to include hub and spoke supplies across different legal entities.

What worked well

- The majority of pharmacy teams were aware of the role of the RP and what they could and couldn't do when they were absent. The best examples had this documented within SOPs that clearly outlined roles and responsibilities of all staff groups.
- Where there were individual logins with varying restrictions for team members this ensured accountability and protected access to patient information.
- Secure electronic transfer of patient data between spoke and the hub.

Areas for improvement

- One premises had no pharmacist on site despite compliance devices being dispensed. One
 pharmacy had no RP notice or evidence of completed RP logs as they believed it wasn't
 required in a closed hub.
- Smart cards were left unattended in one pharmacy and two pharmacies used generic, original logins since the system was installed.

Recommendations for legal and regulatory compliance

- All hub and spoke premises, including those that are closed to the public are required to abide by the legal requirements for **responsible pharmacists** as set out within The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. All premises must ensure an accurate RP notice is displayed, and RP records are maintained in real time and kept up to date.
- 2. Pharmacies need to ensure patients' data is transmitted securely between hub and spoke pharmacies in line with legislation.
- 3. Pharmacies are required to have appropriate indemnity insurance in place to cover the roles and responsibilities they have within the hub and spoke model. Insurance arrangements need to provide clarity on what is covered when working with other legal entities.

Theme 3: Operational processes

Automation

The majority of hubs within the past inspections were using automated dispensing systems. These included robots, barcode and QR-code scanning, photographic verification of packs, and conveyor belts for both original pack and compliance aid provision. There were varied models in use with differing levels of automation, integration, and audit trails. Some had robust systems with barcode scanning and electronic tracking; others relied on manual processes, and some provided error detection which would flag anomalies and missing items. Across the past reports the use of automation was used well with low error rates.

During the August data capture, 82% of hubs used automation in the dispensing process. These included dispensing robots and barcode accuracy scanning.

Higher-risk medicines

Most hubs in the past inspection review were not involved in the supply of controlled drugs or fridge items to minimise risk, and supply of these items was managed by the spoke. Some hub pharmacies did dispense higher-risk medicines (such as methotrexate, sodium valproate, finasteride and lithium) and when hub teams were asked, it was assumed that counselling for these medicines was conducted by team members at the spoke. Some hub pharmacies supplied higher-risk medicines in original packs, however some pharmacies lacked appropriate risk assessments for when higher-risk medicines were required to be removed from original packs at the request of the spoke. There was a mixed response as to whether teams were aware of additional dispensing requirements for higher-risk medicines and automated processes sometimes covered warning labels on the medication packaging.

During the August data capture, 73% of hubs dispensed higher-risk medicines. The majority of hubs did not dispense fridge lines, or schedule 2 or 3 controlled drugs.

Removal of medicines from original packs

Dedicated spaces for dispensing from original packs were common across pharmacies, but SOPs and stability considerations were often lacking. Some pharmacies used photographic identification and batch tracking, however there was evidence in two hubs in the past inspection reports, where concerns were raised regarding stability risks and a lack of specific SOPs. These two hubs were observed to not be following the requirements for labelling medicines that were requested to be removed from the original pack by the spoke. This included missing expiry dates and batch numbers when removed from the original packaging. This also impacted on the ability to action medicine recalls where applicable.

During the August 2025 data capture, 55% of hub pharmacies stored medicines out of the manufacturers original pack, which all related to compliance aid dispensing. Unlike with the past inspection review, when medicines were removed from the original packaging prior to being used in compliance packs, 100% were stored with appropriate labelling. This included ensuring containers had product name, batch number and expiry stated, and some pharmacies used barcode technology that linked back to the original product and packaging.

Stock expiry date checking

Within the past inspection reports, most pharmacies had an expiry date checking process in place, often as part of their SOPs or monthly routines. Those that used automated systems had the most robust systems in place as they utilised the robot's house-keeping functionality for tracking batch number and expiry dates, and automated removal of the medicines from the robot. However, if stock was managed manually there was a need to incorporate a manual date checking process too. One hub failed to meet standards as the stock that was kept out of the automated dispensing system was not checked and the inspector found several items out of date. This was due to a reliance of the automated system to highlight medicines with short expiry.

Cold storage

From past inspection reports, fridges were not routinely in use by hub pharmacies as they did not often hold medicines that require refrigeration. Some pharmacies failed to monitor fridge temperatures when fridges were not routinely in use.

Alerts and recalls

The past inspection reports showed varied processes for managing alerts and recalls for medicines and devices. Some pharmacies had robust systems and audit trails; others lacked documentation or received alerts indirectly. Three hubs were unable to provide documented evidence of action for recalls or patient safety alerts and were lacking a robust process for actioning these. Often recalls were managed and documented within the main office of the pharmacy group rather than within the individual pharmacies.

During the August 2025 data collection, 91% of operational hubs had a process in place; only one pharmacy team was unsure of their procedures. Processes for both actioning and documenting alerts and recalls varied, but compliance of these processes was unclear and highlighted areas for improvement.

Changes to the original prescription request received by the hub

The August 2025 data showed that 27% of hubs would make changes to the prescription request sent by the spoke and 18% of the spokes concurred. Examples of changes made included limited label changes such as abbreviations from 'PRN' to 'when required', contacting the spoke pharmacy to offer the choice of partial dispensing or return, providing amended documents to spokes or GPs and using a flagging system to the spoke when a product couldn't be added. One pharmacy hub stated they would not accept any prescription if there were errors on the label and would mark the request as an error and would not dispense it. The spoke pharmacy for this hub were responsible for rounding quantities for non-controlled drugs to the nearest whole pack to enable supply from the hub at the spoke pharmacist's discretion (within the legislative allowance).

What worked well

- Use of short-dated zones within fridges and use of automation and barcoding to alert teams to expired or short dated stock.
- Fridge temperature monitoring with alert systems in place.
- Photo identification of medicines removed from original packaging.
- Use of automation for flagging anomalies and errors.
- Segregation of areas for different dispensing processes (e.g. separating whole pack dispensing and when medicines are required to be removed from original packaging).
- Reputable resources used for checking suitability of products for compliance aid dispensing.

Areas for improvement

- Items kept out of automated systems not being checked for expiry due to reliance of expiry checking ability of the automated system.
- Expired stock being outputted from an automated system but with no records of how and what medicines were destroyed.
- Lack of documentation of medicines and devices recall actions.
- Lack of consideration for medicines requiring special warning labels (such as sodium valproate) within automated labelling systems.
- Lack of appropriate labelling and consideration of stability of medicines removed from original packs.

Recommendations for operational processes

- Ensure appropriate risk assessments are in place for the dispensing of higher-risk medicines, including how automation may impact dispensing guidance related to higher-risk medicines. To include documented roles and responsibilities for clinical check, dispensing and counselling of patients.
- 2. Ensure all team members are aware of higher-risk medicines and use **reputable sources** for referral such as the World Health Organisation (WHO) <u>Medication safety in high-risk situations</u> publication and any relevant MHRA guidance associated with dispensing them.
- **3.** Implement a robust risk assessment for removing medicines from original packs: consider stability of products when removed from original packaging and appropriate labelling for identification, date checking and to support drug alert and recall actions. This requires a written SOP and appropriate training for team members.
- **4.** Embed a robust process for checking all medicines (whether kept within or outside of automated systems) are fit and safe for purpose.
- **5.** Ensure a robust and documented process is in place for actioning medicine and devices alerts and recalls with clear accountability for who is responsible for actioning these, including contacting the patient when required.
- **6.** Ensure that there is a documented process is in place for how any changes to prescriptions are communicated prior to the hub and spoke model commencing, and it is consequently adhered to by the pharmacies involved.

Theme 4: Staffing

Staffing Levels and contingency

During the past inspection review, most pharmacies had adequate staffing across various staff groups, with contingency plans for leave. It was common for pharmacies to use relief staff and locum pharmacists, but also to rotate team members (both GPhC registrants and support staff) between different pharmacies. When team members from the spoke pharmacy were requested to support hub teams, additional training was required to be able to understand the automation and hub specific processes. One pharmacy organisation had a system where the spoke pharmacy team and hub

pharmacy team could cover each other's roles when required once they had received appropriate training. The flexibility to use team members within the same organisation will not be the same when hub and spokes operate across different legal entities, therefore additional mitigations will be needed for hubs in this scenario.

Training

When reviewing the past inspection reports, two hubs had team members dispensing without appropriate dispensing qualifications. This was due to the team not being aware of the requirement to have the qualification before 'stepping in' to support when required. Some pharmacies had various options for supporting team members with training and new learning and were also supporting team members through their pharmacy technician qualification. One pharmacy sent their hub pharmacist to observe and shadow the spoke process to be able to understand how the hub and spoke processes aligned. The same hub planned an ongoing training programme which included the on-site engineers too. They also provided the spoke pharmacy with resources packs regarding the hub processes, SOPs and relevant training several weeks before the hub went live. Protected learning time was inconsistently provided, and induction and training records were often informal or undocumented.

The August data capture showed that:

- 82% of team members at the hub were trained for the duties they carry out
- 100% of team at the spoke received specific training for hub and spoke arrangements
- 53% of team members at the spoke were aware of what automation is used at the hub

It was evident that the majority of pharmacies had clear training processes in place, but some spoke teams showed gaps in understanding of the full process that happened at the hub, including how and what automation was used. One hub pharmacy had sent their hub team to the spoke pharmacy to provide training face to face.

Safeguarding

Within the past inspection reports, safeguarding training was often completed, but not always across all team members. Some pharmacies lacked clarity on safeguarding responsibilities due to limited patient contact within the hub settings. In general, the Superintendent (SI) or Responsible Pharmacist (RP) had completed safeguarding training, and the teams were aware of how to manage safeguarding concerns and had appropriate points of contact to signpost to. Some companies had yearly safeguarding training in place for all teams but whether all teams had this very much depended on whether the pharmacy was accessible to patients.

Support and communication

In general, across past reports, there was evidence showing pharmacy teams had regular team meetings and appraisals. However, some pharmacies lacked formal review mechanisms or communication handovers.

Performance targets

It was evident within the past inspection reports that performance targets were not in place with regards to productivity. Two pharmacies highlighted they had targets however they were not enforced, with emphasis on safety over productivity.

The August data capture showed that 24% of spoke pharmacies had incentives for the team members to move patients to dispensing via the hub. These did not appear to be financial incentives but focused on how movement of work to the hubs would support spoke time for other activities.

What worked well

- Supporting the team with learning opportunities and visits to spoke sites to see 'spoke perspective' and provide training on hub processes, and vice versa.
- Information sent to the spoke in advance of the hub going live with relevant information regarding hub model.
- Performance targets did not impact patient safety, as staff were encouraged to prioritise patient safety.

Areas for improvement

- Lack of documentation of training and induction processes.
- Lack of protected time to complete training.
- Training not in place for team members involved in hub dispensing process.
- Lack of awareness of safeguarding training requirements.

Recommendations for staffing

- 1. Pharmacy teams need to be aware of **qualifications** required for each role and ensure all team members are on appropriate GPhC accredited courses (where applicable).
- 2. There should be **protected time** for team members to complete training and relevant learning to support appropriate development of the pharmacy team.
- 3. Spoke teams should fully understand the hub process by either visits, videos or **detailed training** packages. This will enable the team to have full understanding of the process and be able to answer patient queries regarding the journey their medications follow and vice versa for the hubs. Both hub and spoke teams should support the provision of this training for each side.
- 4. Appropriate and tailored **safeguarding training** needs to be in place for all members of the team involved in the hub and spoke model to ensure awareness of safeguarding issues and vulnerable patients who may be using the service.

Theme 5: Patient information and experience

Patient experience

In the past inspection reports, communication with patients was mostly only with spoke pharmacies. Patient information leaflets were inconsistently supplied, with some pharmacies using QR codes or websites instead; however, these were provided on request and predominately linked to compliance aid dispensing. There was no clear trend on which address was included on the medicine label, with some using the spoke and some pharmacies using both the hub and spoke address. No examples were seen of just the hub address being present on the medicine label.

The August data capture showed that 57% of medicine labels included both the hub and spoke details in various formats. No pharmacies included just the hub details.

Urgent requests

During the past inspection reviews, urgent requests for medicines after information was transmitted to the hub was managed by the spoke pharmacies. Some pharmacies lacked clear processes for urgent supplies. However, the majority had robust processes for managing these and ensuring that dispensing information was cancelled at the hub, or that medication would be flagged on receipt at the spoke to prevent duplication of supply.

In the August data capture it was found that 100% of spokes and 91% of hub pharmacies had a procedure to deal with urgent requests made by people for prescriptions already transmitted to the hub.

The majority of pharmacies had processes to pull back or cancel prescriptions electronically from the hub with a relevant audit trail and barcode technology to prevent duplication at handout or delivery. Some pharmacies were required to call the hub to cancel the order.

Patient choice

It was unclear in the past inspection reports whether patients were actively informed about the hub and spoke arrangement or whether they could opt out of these.

The August data capture however showed that 59% of spokes actively informed people about the hub and spoke arrangements and 94% of spokes provided patients the option to opt-out of hub and spoke arrangements.

Many patients were informed verbally or via leaflets when the service was first initiated. Some patients provided verbal consent only which wasn't documented. There was no evidence that patients were regularly informed about their medicines being dispensed via the hub and no pharmacies had signage to indicate this. One pharmacy indicated that they didn't need to ask permission from patients but that they were aware their medicines were dispensed off site. To opt out of the service, patients would need to verbally request this, and it would be marked on their patient record.

Complaints and feedback process

During the past inspection reports, nine pharmacies stated they had a complaints process or procedures in place. Low numbers of complaints were received at the hub and often complaints were initially directed to the spoke pharmacy as hubs often had limited patient contact.

During the August data capture, only 27% of hubs received feedback from the people who have their medicines dispensed at the hub. This included sustainability concerns due to high plastic usage and having to wait a set period of time for their medicines to be dispensed. Sixty-five percent of spokes provided feedback to the hub from people who have their medicines dispensed at the hub. This included patient concerns related to the ability to use compliance aids or wanting their medicines dispensed locally instead. One spoke had a self-service hub and spoke portal on the intranet for reporting issues back to the hub which would then be allocated to the relevant individual.

Service expectations

There was limited evidence of performance targets in the past inspection reports, with the only targets seen around compliance aid turnaround times.

The August 2025 inspection data showed 64% of hub pharmacies have an SLA or agreement for dispensing time, with KPIs such as time to deliver medication from initial submission of data. Examples ranged from 24 hours to nine days, though these were sometimes based on informal agreements.

What worked well

- All pharmacies had a method for responding to urgent requests after information was transmitted to the hub.
- Having a hub and spoke 'self-service' portal on the intranet for raising concerns.

Areas for improvement

- Unclear whether hubs having low complaint numbers was reflective of service level or lack of visibility of these if not kept informed by the spoke pharmacy.
- Methods for informing patients of their medicines being supplied by a hub.

Recommendations for patient information and experience

- Patients need to be kept regularly informed of their choices when having their medicines
 dispensed via the hub and spoke model. This includes ensuring patients always have a point of
 contact for concerns or questions regarding their medicines and being able to remove their
 consent to the service at any point. If operating across two legal entities, a notice must inform
 patients that their medications will be dispensed via a hub pharmacy.
- 2. When operating a hub and spoke model across different legal entities, only include the **spoke** address on medicine labels.
- Hub and spoke pharmacies need to have a mechanism in place for regular oversight and prompt actioning of any complaints made about the hub and spoke model to support safe practice and service development.

Conclusion

This thematic review examines the current use of the hub and spoke dispensing model across Great Britain, based on past and current inspections conducted between July 2023 and August 2025.

With legislative changes which allow the hub and spoke model across legal entities, having taken effect on 1 October 2025, this review provides timely insights for pharmacy owners, superintendent pharmacists and their pharmacy teams.

It identifies five key themes:

- 1. Governance and risk
- 2. Legal and regulatory compliance
- 3. Operational processes
- 4. Staffing
- 5. Patient experience

While many pharmacies demonstrated strong practices, particularly in automation and business continuity, other areas such as SOP development, risk assessments, error reporting, compliance with RP legislation and training require further improvement.

The review compared findings from past inspections to those that were undertaken more recently (August 2025). This highlighted similar trends in some areas, but in other areas there were distinct improvements in the most recent data capture. This could indicate the development and progression of hub and spoke models over time as they become more commonplace, or correlate to the development of pharmacy automation.

The review concludes with actionable recommendations to support alignment with GPhC standards and the expanded use of hub and spoke models across different legal entities.

This report will be shared with key stakeholders including relevant government departments, professional leadership bodies and representative organisations in Great Britain.

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