Oxford University Hospitals
NHS Foundation Trust

Cover Sheet

Select Meeting: Thursday 12 September 2024

Health Oversight and Scrutiny Committee

Title:	**Management of Medicines Supply Shortages**

Status:	**For Information**
History:	**FINAL**

Board Lead:	**Chief Medical Officer**
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Confidential:	**No**
Key Purpose:	Assurance, Policy

Executive Summary

1. Medicines shortages are a significant global issue, exacerbated by factors like manufacturing issues, changes in NHS contracts, distribution problems, product withdrawals, demand fluctuations, and stockpiling, and can lead to patient harm and increased financial pressures on healthcare systems. The effects range from low impact, where substitutes are available, to critical situations involving life-saving medications, potentially causing treatment delays, errors, and suboptimal care. The Department of Health and Social Care (DHSC) and the Commercial Medicines Unit (CMU) manage supply issues nationally, while local responses involve alternative sourcing, stock management, rationing, collaboration, and communication.
2. In the last 3 years, OUHFT has been affected by 369 supply shortages of which an average of 60 (range 45 to 80) are active at any one time. Examples of current and recent shortages include Creon® capsules, Insulin Humulin S® vials, and Pabrinex® IV injection, semaglutide Ozempic® Injection; each require specific strategies to manage the shortages effectively.
3. OUH Pharmacy Department has a dedicated medicines supply shortages practitioner to identify and manage potential supply issues by working with clinical areas and procurement teams, implementing various strategies to mitigate the impact of the supply shortage on the Trust. The successful management of these shortages have been aided by having a supply shortages database on the Trust intranet where everyone can be kept up to date on each supply disruption. There is a Medicines Shortage Bulletin published regularly to advise prescribers about the agreed alternatives to be used during shortages. The practitioner leads on the local implementation of any national initiatives from DHSC, NHS England and other national bodies. In addition to this, the practitioner chairs a weekly supply shortage meeting where clinicians and other staff affected by shortages can attend to discuss alternatives and monitor progress on any other strategies put in place to manage supply shortages. Future measures to further reduce potential harm from shortages should include investment in the Trust's EPR system so that decision support at the point of prescribing can be utilised enabling increased agility when responding to shortages. Improved coordination of supply problems across the ICB is desirable, particularly for medicines prescribed in both hospital and primary care.

Recommendations

4. This is a briefing paper submitted jointly from OUH and BOB ICB for information and assurance. HOSC are asked to note the content of this paper and support the current arrangements for managing supply problems in OUHFT.

5. HOSC are asked to note the improvements proposed to further reduce potential harm from shortages including:
    a. Investment in the Trust's EPR system so that decision support at the point of prescribing can be utilized enabling increased agility when responding to shortages.
    b. Improved coordination of supply problems across the ICB, particularly for medicines prescribed in both hospital and primary care this is actively being worked on with the ICB and wider SE Region.

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Management of Medicines Supply Shortages

1. Introduction

1.1. Medicines shortages affect healthcare systems worldwide. They can be caused by several complex and interacting factors, and can occur at short notice and change rapidly, making forward planning difficult. In recent years, there has been an increase in shortages due to global issues such as COVID-19 caused a significant reduction in manufacturing capacity, the UK's exit from the European Union affected the distribution supply chain and, recent global conflict has caused further instability.

1.2. The proportion of medicines affected by supply shortages can vary, but it generally impacts a small percentage of the total medicines available. For example, in the UK, disruptions typically affect a very small proportion of medicines in the NHS, and most shortages can be managed without interrupting people's supplies. However, the degree of disruption in normal healthcare provision from a single supply shortage can be extensive and range from inability to provide optimal care to, in certain situations, having to cancel or postpone clinical procedure.

1.3. Supply issues attract regular media coverage. Recent supply issues that have gained coverage include medicines for treating ADHD, diabetes, cystic fibrosis and epilepsy.

1.4. Shortages can arise from various factors and often cannot be attributed to one reason, sometimes a shortage has resulted from the accumulation of several factors. Response to the shortage of one medicine can lead to shortage of the replacement medication. Reasons may include:

1.4.1. Manufacturing issues- these include-difficulty obtaining raw materials or API (Active Pharmaceutical Ingredient), medicine recalls or batch failures, and capacity issues. Problems in production processes quality control failures, and regulatory interventions can disrupt supply.

1.4.2. Changes in NHS contract or pricing strategies.

1.4.3. Distribution issues - Importing/exporting bans or restrictions, wholesaler ordering process delays.

1.4.4. Withdrawal or discontinuation – competitors may withdraw/discontinue products causing strain on other medicines in class.

1.4.5. Demand Fluctuations: sudden changes in prescribing practices due to change in guidance or practice, pandemics or switching products as result of shortages elsewhere can lead to shortages.

1.4.6. Stockpiling or panic buying - This often happens because of a rumoured shortage or shortage with similar products. This is actively discouraged within NHS Trusts.

2. Impact of Medicines Supply Shortages

The effects of a shortage on patients and clinicians could range from a low impact, where a cost-neutral suitable substitute medicine can easily be substituted, to a critical situation, involving potentially life-saving medication where harm to the patient is likely if an alternative is not readily available. Response will vary depending upon medicines involved, duration and extent of the issue, and the suitability of alternatives. Therefore, a wide range of risks is possible.

2.1. Risk of patient harm due to unavailability of essential medicines:

2.1.1. Lack of available treatment or alternative, leading to potential treatment failure or deterioration in condition due to delays.

2.1.2. Errors due to unfamiliarity with alternative treatment options (prescribing, administration or advice)

2.1.3. Medications delayed or suboptimal treatment options

2.1.4. Decision support rules and safety alerts built into EPR may not be available for alternative agents.

2.1.5. Continuation of care in community may be affected, and patients may be referred into secondary care who were previously cared for in primary care and stabilised on treatment.

2.2. Financial pressures:

2.2.1. Alternatives may be significantly more expensive leading to cost pressures

2.2.2. The Trust may have to cover the cost for importing unlicensed alternatives

2.3. Risk of redirection of clinical resources:

2.3.1. Clinical resources may be redirected from direct clinical care to support the practicalities of reviewing and introducing alternative products.

2.3.2. Alternatives may require additional monitoring or clinic visits.

2.3.3. Increased training and counselling may be required to understand any changes made.

2.3.4. Increased workload for clinicians and Pharmacy services.

3. National tool and resources to support the local response

3.1. The Department of Health and Social Care (DHSC) Medicines Supply Team are responsible for supporting management of supply issues nationally and many shortages are now listed on the Specialist Pharmacy Service (SPS) Medicine supply tool online. This tool was launched in 2022 in response to increasing shortages and includes some of the known supply issues, potential impact and recommended actions.

3.2. The Commercial Medicines Unit (CMU) on behalf of NHS England are responsible for negotiating the regional contracts of thousands of medicines each year. Manufacturers are required to inform them if they anticipate any potential supply issues with their contracted products. CMU are informed of anticipated shortages, timeframes and reasons for delay and this information is shared with the NHS Trusts monthly.

3.3. Shortages deemed higher risk or those that are expected to have the most impact are communicated specifically, in the form of a Medicine Supply Notification (MSN) or National Patient Safety Alert (NatPSA).

3.4. Other information sources that may identify a shortage include wholesalers, clinicians, purchasing colleagues working across the NHS, primary care representatives, professional clinical groups, order failures or from patients themselves.

3.5. In general, there is not one individual source that can provide the panacea to aid supply management, and various information sources must be used. Issues will vary from Trust to Trust and region to region. Although these tools are useful, the advice and recommendations can quickly become outdated, and recommendations have to be reinterpreted before they can be implemented within the context of the local Trusts. Contradictions between the measures put in place in hospitals and what is being advised in primary care may sometimes create confusion. For example, in some situations, patients are encouraged to visit the hospital for a supply of medicines in short supply (example national shortage of GLP-1 receptor agonists including semaglutide for type 2 diabetes). This could confound the hospitals strategy to restrict limited stock for the most critically ill patients. Better coordination between hospital and primary care is required.

4. OUH experience and processes for mitigation

4.1. In the last 3 years, OUHFT has been affected by 369 supply shortages of which an average of 60 (range 45 to 80) are active at any one time. Further details about these supply problems are provided in Figures 1 to 4 below.

4.2. Since 2020, the pharmacy department have operationalised a medicines supply shortages practitioner working as part of the Medicines Effectiveness Team. The role of the practitioner is to support identifying and managing any potential supply issues. They lead the OUH Pharmacy response by liaising with clinical areas, taking appropriate actions in advance and ensuring transition to a suitable alternative is effective and communicated in a timely manner.

4.3. Once an issue has been identified, the required action will vary depending on the potential impact on the Trust, these may include:

4.3.1. Ensure all potential information regarding the shortage is gathered– reason(s) for the shortage, anticipated resupply date and potential impact to the Trust

4.3.2. Checking availability of different strengths, manufacturers, suppliers to source a direct alternative.

4.3.3. Working with procurement colleagues within the region to support each other and help share knowledge.

4.3.4. Managing current supplies – putting in place potential short-term restrictions, remove from clinical areas stock lists.

4.3.5. Identifying and sourcing unlicensed imports or UK specials to help support demand – ensuring all required paperwork is prepared and completed in preparation.

4.3.6. With the support of clinical teams ensure appropriate communication or guidance is in place to aid colleagues who may be affected by the shortage.

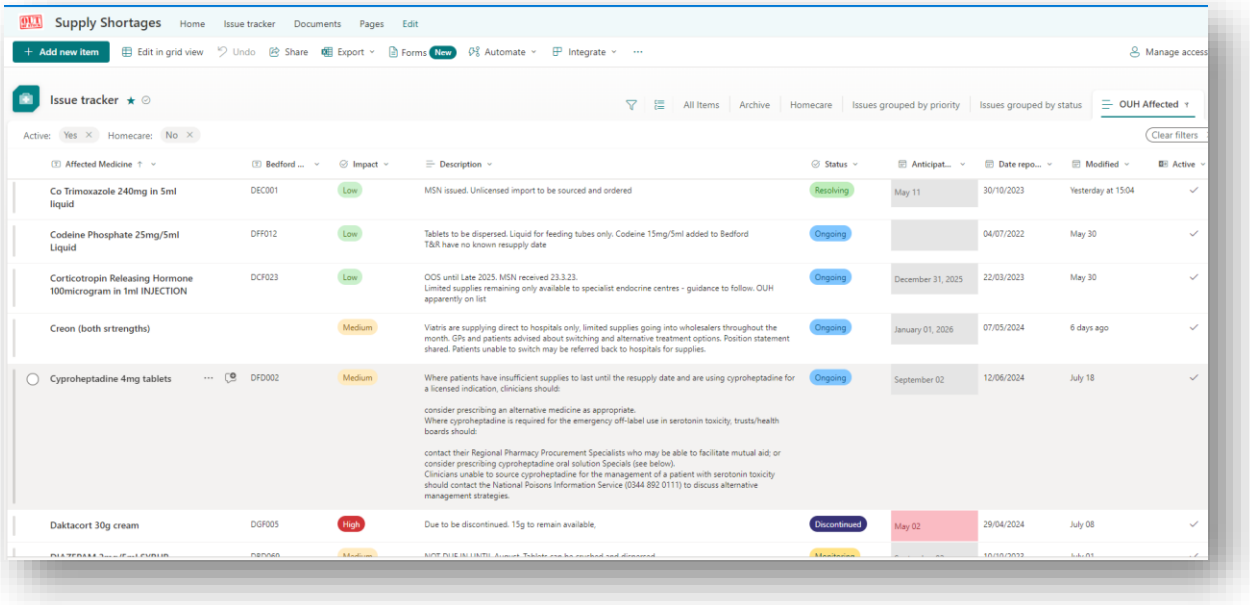
4.3.7. Responding to an MSN (Medicines Safety Notice) or NatPSA (National Patient Safety Alert), ensuring any action points recommended by these are adhered to and recorded via Ulysses (the Trust incident reporting system).

4.4. Ongoing work throughout the month includes weekly procurement meetings with colleagues across the region, weekly OUH pharmacy meetings with clinical and procurements leads to discuss potential issues arising, monthly shortage summaries sent to all pharmacy colleagues and maintaining an internal medicine supply shortage database. In addition, a

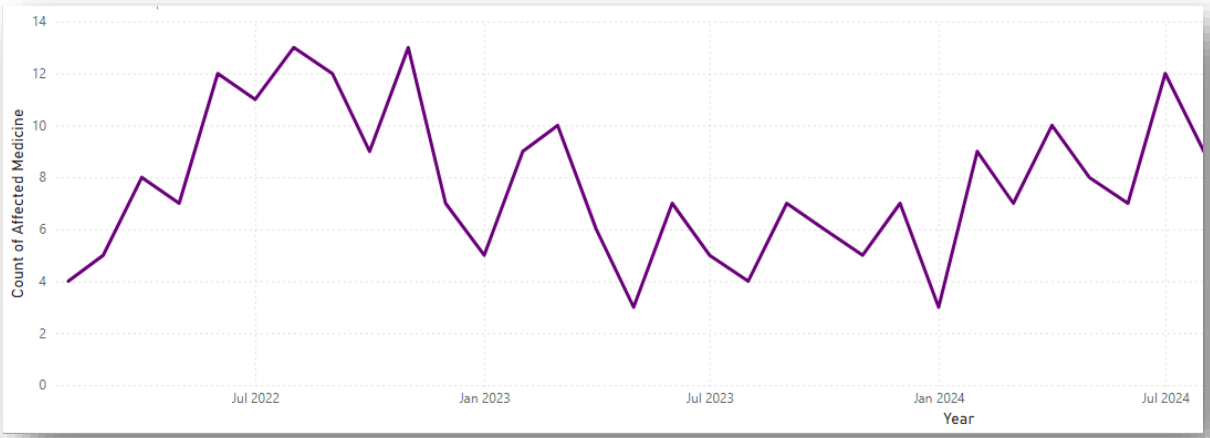
supply shortage update is presented at the Trust's monthly Medicines Management and Therapeutics Committee (MMTC) meeting.

4.5. The Medicines Supply Shortage database is updated by the medicines supply shortage practitioner with the support of procurement colleagues. As of 07/08/24, OUH Pharmacy is currently monitoring and managing 61 active supply shortages, and a further 25 are being managed within Homecare services.

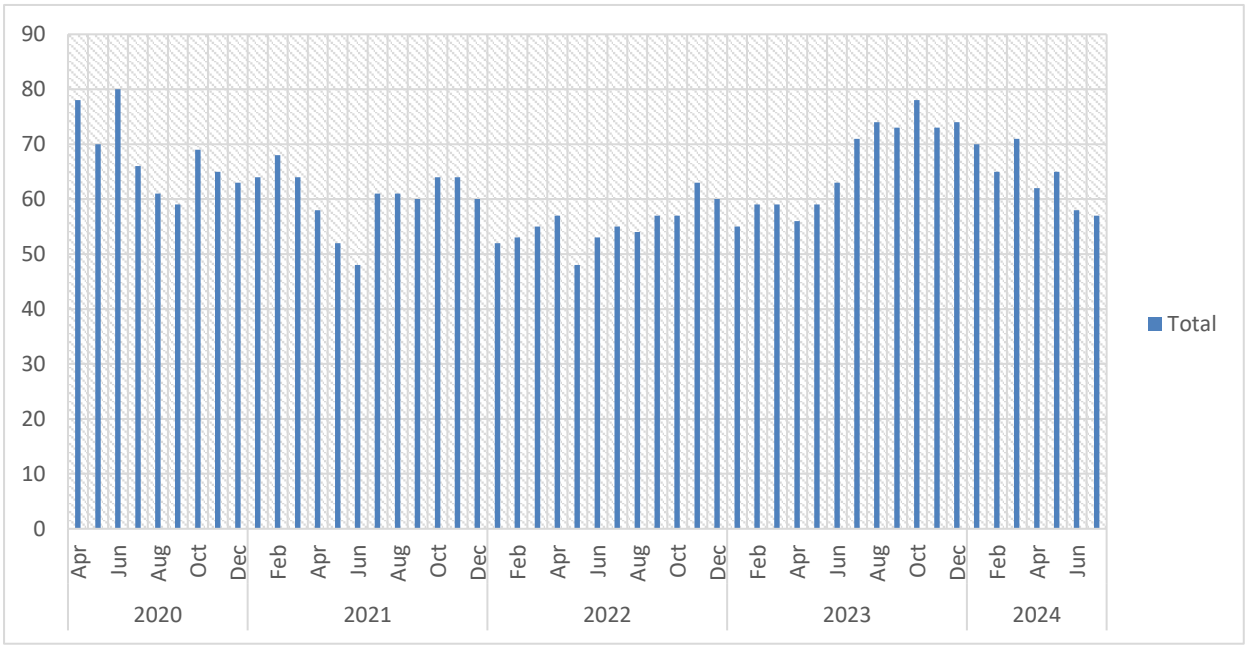
5. Figure 1. Medicines Supply shortage database available to Trust colleagues



6. **Figure 2. Graph show that there are between 4 and 12 new shortages added to the database each week.**



7. **Figure 3. Graph show that we have an average of 60 (range 45 to 80) active supply shortage at any one point in time.**



8. Figure 4. Status of all shortages added to databse since 2021.

Status	Count of Issue tracker
Resolved	225
Discontinued	28
Ongoing	27
Need Update	25
Long Term	21
Monitoring	15
New	14
Resolving	11
Short Term	3

9. Examples of some of the current & recent shortages impacting OUH

Example 1: Creon® capsules

Supply shortage ongoing until at least 2026. This is due to unavailability of the API and an increase in demand. Indicated for the treatment of pancreatic exocrine insufficiency such as in cystic fibrosis, pancreatic cancer and pancreatitis. There is no clinical alternative.
Limited supplies are available in the community setting; GPs are being advised to switch patients where appropriate. Those that cannot switch are referred to secondary care for review to determine ongoing supplies. These teams are looking at alternative options as to how best to provide for these patients.

Example 2: Insulin Humulin S® vials

Went out of stock between May and June 2024. The preparation is also used to manufacture a variable dose insulin syringe special from Portsmouth specials manufacturing unit. To support Portsmouth manufacturing, the action was to send out all remaining Humulin S vials to Portsmouth to support the manufacturing process and ensure they could continue to manufacture the variable dose syringes. Routine use was switched to Actrapid® vials.

Example 3: Pabrinex® IV injection

Became out of stock for an unspecified length of time. Is used for treatment of Wernicke's encephalopathy, alcohol dependence and refeeding syndrome. Collaboration between clinical colleagues across the Trust ensured a suitable alternative (Unlicensed Thiamine) was sourced and all communication, electronic

prescribing and decision support pathways (Power Plans) were prepared and ready in advance of the shortage.

10. Conclusion

The management of medicines shortages in the NHS requires a coordinated and proactive approach involving multiple stakeholders. By implementing robust strategies and maintaining effective communication, the NHS aims to mitigate the impact of shortages and ensure that patients continue to receive the necessary treatments. Whilst the coordination of these supply disruptions at national levels have helped create a more uniform approach across the NHS, interpretation in the local context is an important prerequisite before they can be implemented at a local Trust level. Having a dedicated senior pharmacy technician working as medicines supply practitioner has helped OUHFT to put effective systems in place. Having a named officer to manage supply problems is a standard that could be adopted for all acute healthcare providers as it avoids moving clinical staff away from patient-facing duties to manage supply disruptions.

Some suggested improvements to further reduce potential harm from shortages include:

Investment in the Trust's EPR system so that decision support at the point of prescribing can be utilized with more agility to respond to shortages.

Improved coordination of supply problems across the ICB, particularly for medicines prescribed in both hospital and primary care: this is actively been worked on with the ICB and wider SE Region.

11. References

[1]: A Guide to Managing Medicines Supply and Shortages - NHS England [2]: A Guide to Managing Medicines Supply and Shortages [3]: Medicines shortages: regulatory processes to manage supply disruptions