PM Healthcare
PROGRESS THROUGH PARTNERSHIP

JOURNAL

Incorporating *The Journal of Pharmacy Management* and *The Journal of Medicines Optimisation*

Autumn 2024 | Issue 10

Highlights:

Contents

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Editorial

In our autumn Journal we have a varied and interesting range of articles, providing us with some fascinating and informative insights – something to cheer and inspire us as the long nights begin to close in.

Danny Bartlett, pharmacist and clinician, reflects upon his journey to develop competence in treating and diagnosing the menopause, describing both the challenges and the rewards. (Navigating Menopause: The Journey of Competence in Treating and Diagnosing Menopause in Pharmacy Clinicians: A Reflection.)

Nazir Hussain, Specialist Respiratory Pharmacist, describes how a one-stop respiratory care clinic in primary care can positively impact services and patient health, especially in areas of health inequalities. (Tackling Inequalities in Respiratory Care - The Impact of a Specialist Pharmacist "One-Stop" Respiratory Clinic in Primary Care.)

Stuart Dark, Deputy Chief Pharmacist and Clinical Pharmacy Manager, and Faiza Khan, Chief Pharmacist, provide a fascinating insight into the implementation of a new operational model, derived from two manufacturing models, into clinical pharmacy services to deliver efficiencies. (Defining an Operational Model for Clinical Pharmacy.)

Nadia Malik, Practice Pharmacist, and Suhrab Sayfi, Highly Specialist Pharmacist, examine the 'epidemic' of recent medicines shortages and what can be done to avert the current crisis in availability. (Are medication shortages the new pandemic?)

And in our sponsored article, Jyotika Singh and colleagues examine the role of pharmacists and pharmacy teams in supporting an integrated care pathway to improve management of eosinophilic esophagitis in adults.

As ever, please contact me with any ideas you have for articles and experiences you would like to share. Also, if there is a subject area that you would like to see covered in the Journal, perhaps in a special edition, do not hesitate to get in touch.

John Chater
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Do you have an idea for an article or an area that you think we ought to be covering in the Journal?

If you have an idea for an article that you would like to discuss then please get in touch to see if we can include it in the Journal.

We are very keen to support healthcare professional who want to write about:

- Their experiences working in pharmacy and the related professions
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- Clinical studies and papers that are of interest to a HCP audience, with a focus on pharmacy
- ICS/ICB-led initiatives in pharmacy, medicines optimisation and management
- System changes and reforms that have improves patient care locally and are capable of being scaled up
- Career development stories that will inspire the next generation of pharmacy graduates
- Opinions and commentary from those delivering services

These are just a few of the areas that are of interest to our readers and that contribute to our objective of bringing you insightful and relevant content that translates into best practice and practical application.

Please contact me with ideas at:

John Chater, Editor – PM Healthcare Journal E: editor@pmpublications.co.uk

Navigating Menopause: The Journey of Competence in Treating and Diagnosing Menopause in Pharmacy Clinicians: A Reflection

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As a Pharmacist and Clinician, embarking on the journey to develop competence in treating and diagnosing menopause has been both rewarding and challenging. Over time, my role has evolved, expanding beyond the scope of traditional pharmacy duties, where medication reviews and blood pressure checks were the norm, to one that involves a more holistic approach in managing menopause in patients. Integrating menopause care into existing workstreams, such as medication reviews and chronic disease management, has been key to ensuring comprehensive and patient-centered care.

Understanding Menopause: A Complex Health Journey

Menopause is a significant life stage for many women, marked by the cessation of menstrual periods and the onset of symptoms such as hot flushes, night sweats, mood swings, and cognitive changes like brain fog. Beyond these classic symptoms, many women experience non-classical signs like joint stiffness, anxiety weight gain, itchy skin and genitourinary syndrome of menopause (GSM). These varied presentations highlight the need for healthcare professionals, especially pharmacy clinicians, to develop robust diagnostic skills and an understanding of the full spectrum of menopause.

From the outset, I recognized that menopause management requires a nuanced approach that is not solely about treating symptoms but about addressing the long-term health implications of oestrogen decline. This realization has shaped the way I approach consultations and the kind of support I provide to patients.

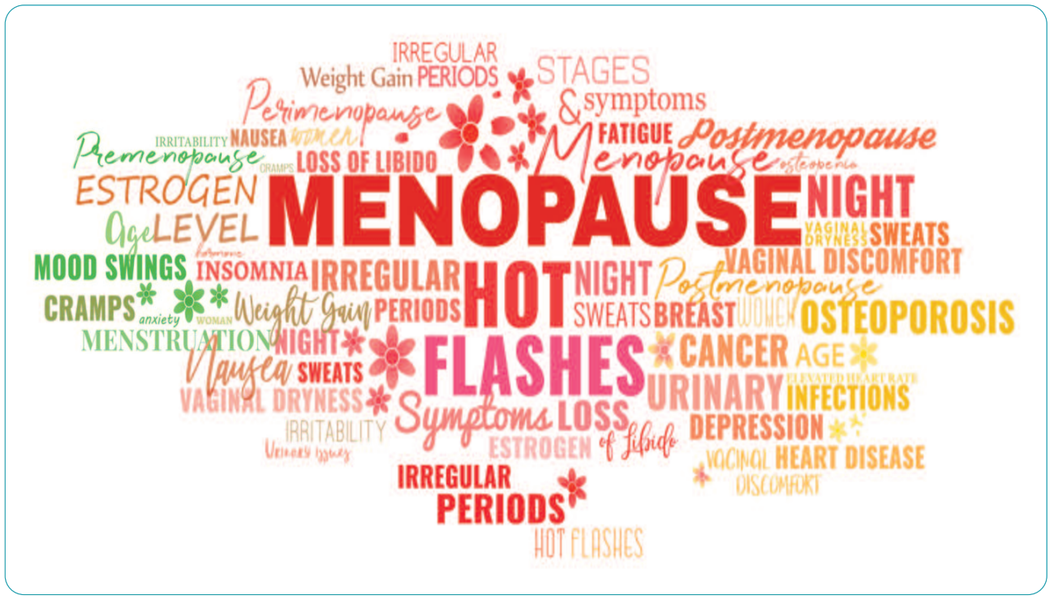
The Importance of Hormone Replacement Therapy (HRT)

Hormone replacement therapy (HRT) plays a pivotal role in managing the symptoms of menopause. It has been shown to significantly reduce the risk of conditions such as osteoporosis and type 2 diabetes in postmenopausal women, whilst reducing overall cardiovascular risk. As a clinician, gaining confidence in prescribing and switching HRT required an in-depth understanding of both the benefits and potential risks. Understanding that transdermal options are accepted as having a lower risk of venous thromboembolism (VTE) and are preferable for women with higher body mass index (BMI) or pre-existing conditions like hypertension has been vital in optimizing patient care.

However, the journey didn't stop at simply knowing the benefits of HRT. It was equally important to familiarize myself with the nuances of prescribing and administering HRT, considering factors such as stock shortages and patient access to medications. The importance of monitoring, particularly for conditions like hypertension, as well as ensuring that endometrial protection is maintained in women with an intact uterus, was something I learned early on.

Developing Diagnostic Skills: A Holistic Approach

One of the key challenges I encountered was the diagnostic aspect of menopause, which requires a holistic and Shared Decision Making approach. Menopause is a retrospective diagnosis, only



confirmed after 12 months of amenorrhea. However, the peri-menopausal phase can be difficult to identify, especially in women who are experiencing non-classical symptoms. As a clinician, I learned to approach diagnosis not just with an eye for clinical history but by asking the right questions. Symptoms like recurrent urinary tract infections, dry skin, and changes in mood were often clues that pointed toward a peri-menopausal state.

The importance of using a patient-centered approach in diagnosing menopause cannot be understated. Understanding the individual needs and circumstances of each patient, including their personal health history, family medical background, and even cultural factors, plays a critical role in ensuring accurate diagnosis and appropriate treatment plans. "How are the symptoms effecting you day-to-day" became a useful tool to gauge exactly which symptoms were the more problematic and pertinent to ease in a patient's experience.

Integrating Menopause Care into Existing Workstreams

As a clinician, one of the most impactful steps in developing menopause expertise has been integrating menopause management into existing pharmacy team workstreams. Whether it's during medication reviews, blood pressure assessments, or chronic disease clinics, I've found many opportunities for opportunistic menopause diagnosis and treatment initiation.

Medication reviews have become a very valuable opportunity to address menopause. Many women in the perimenopausal or postmenopausal stages are already on long-term medications for chronic conditions, such as hypertension , hyptothyroidism or diabetes, which can overlap with menopausal symptoms. During these reviews, I often assess not only the effectiveness of current medications but also whether any new symptoms could be related to menopause. This has also been a chance to review the need for HRT or alternative treatments such as selective serotonin reuptake inhibitors (SSRIs) for women who cannot take HRT. Conversely some patients with mood disturbances caused by the perimenopause may have not needed an SSRI in the first place had their menopause been treated initially.

Similarly, blood pressure reviews have provided a platform for discussions around menopause. High blood pressure is a known risk factor in postmenopausal women, and ensuring regular monitoring has become a routine part of my practice. Incorporating this cardiovascular 'MOT' into menopause consultations has allowed for a more comprehensive care approach.

Pharmacist-Led Menopause Clinics: Overcoming Challenges and Building Competence

In recent years, pharmacist-led menopause clinics have emerged as a critical service for providing dedicated support to women navigating menopause. Setting up such a clinic required not only clinical expertise but also practical knowledge of how to structure services, approach GPs, and engage patients. There were numerous challenges along the way, including time constraints, patient engagement, and ensuring that I had the necessary supervision and support from colleagues.

"Overcoming these hurdles has been an essential part of my professional development. Collaborating with GPs and learning from colleagues with special interests in menopause has helped build my confidence in delivering these reviews. The importance of follow-up appointments cannot be overstated. Ensuring continuity of care through pharmacist-led follow-ups has not only benefited patients but has also been crucial for my own learning and growth as a clinician. "

Cultural Sensitivity in Menopause Care

One of the most enlightening aspects of this journey has been recognizing the cultural differences in how menopause is experienced and treated. Women from different ethnic backgrounds may experience menopause symptoms at different ages, and cultural taboos may prevent open discussions about these experiences. Addressing these inequalities has been an ongoing effort in my practice, ensuring that resources like interpreter services and educational materials in multiple languages are readily available.

I have also learned the importance of approaching these conversations with sensitivity. In some communities, discussions about menopause, particularly around sexual health or HRT, can be difficult. By fostering a safe and supportive environment, I've been able to build trust with my patients, ensuring that they feel comfortable discussing their concerns.

Shared Decision-Making: Empowering Patients

A key principle in managing menopause is shared decision-making (SDM), where patients are actively involved in decisions about their treatment options. This collaborative process ensures that treatments align not only with clinical guidelines but also with the patient's preferences, values, and lifestyle. Flexbility and choice in selecting the most appropriate formulation of HRT for patients is vital, patients are their own experts on which formulation(s) suit their lifestyle.

Through my own experience, I have learned that SDM is particularly valuable in menopause care. The decision to start HRT, for instance, can be fraught with concerns about risks such as breast cancer or cardiovascular disease. By providing patients with evidence-based information and useful resources, addressing their fears, and offering alternatives where appropriate, I have been able to empower them to make informed decisions about their health.

Resources and Continuous Learning

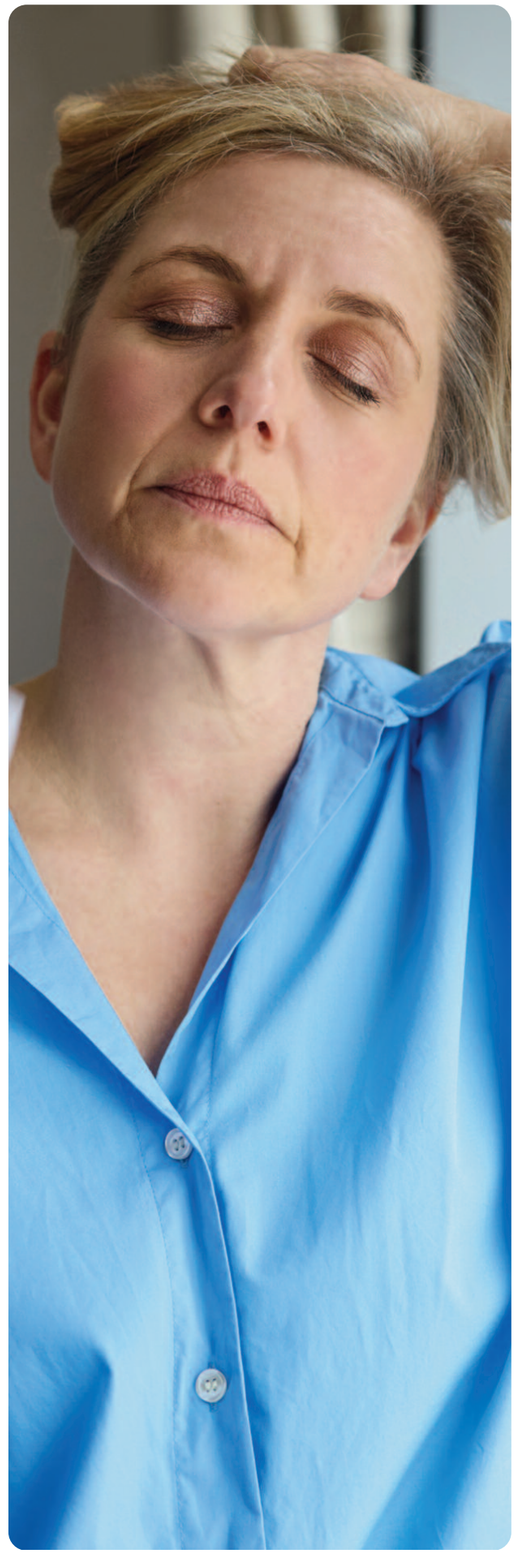
Finally, developing competence in treating and diagnosing menopause has been a journey of continuous learning. Resources such as the British Menopause Society's clinical tools, NICE guidelines, and online training platforms have been invaluable in building my knowledge base. Case studies, like those shared by colleagues, have provided practical insights into managing real-world scenarios, from optimizing HRT to addressing non-hormonal options.

"Learning to adapt to each patient's needs, applying the latest clinical guidelines, and staying updated on available treatments have all been integral to my development as a pharmacist that can conduct menopause reviews as part of routine practice. And as I continue this journey, I am reminded that menopause care is not static—it evolves with every patient, every consultation, and every new piece of research that emerges."

I reflect on being a male clinician when approaching conditions such as menopause, and although I come from a position of lack of experience being a man, I am always keen to approach patients in an open and empathetic way, with an eagerness to hear their experience and see how my knowledge on available options can alleviate some of their symptoms. It is vital in my opinion that despite there being a stigma or barrier to approaching any condition from a place of the opposite gender, we must be confident, understanding and ready to learn and adapt to serve our population as clinicians.

Conclusion

The journey of developing knowledge in treating and diagnosing menopause has been transformative. From integrating care into existing workstreams to building competence through pharmacist-led clinics, this evolution in practice has been marked by challenges, learning, and growth. Through continuous learning, collaboration with colleagues, and an unwavering focus on patient-centered care, pharmacy clinicians can make a meaningful difference in the lives of women experiencing menopause.



Tackling Inequalities in Respiratory Care - The Impact of a Specialist Pharmacist "One-Stop" Respiratory Clinic in Primary Care

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Nazir is a Specialist Pharmacist in Respiratory Care for The Dudley Group NHS Foundation Trust and an Executive Committee Member of the Primary Care Respiratory Society (PCRS).

He has a real passion for respiratory medicine and was one of the first pharmacists in Primary Care to be accredited as a Pharmacist with a Special Interest (PhwSI) in Respiratory Care. Throughout his career, he has been involved in several innovative projects demonstrating the value of pharmacist prescribing. His pharmacist-led respiratory service offers an alternative model of care to address inequalities in respiratory care.

Nazir has been shortlisted for multiple national awards because of his dedication to improving the lives of respiratory patients. Whenever he gets the opportunity, he loves to share his experiences to inspire others.

The national respiratory challenge

Respiratory health outcomes in the UK rank among the worst in Western Europe, with some of the highest mortality rates related to asthma and COPD.[1] There is also significant variation in care across the UK, regionally, and between general practitioner (GP) practices as demonstrated by national reports such as the National Review of Asthma Deaths (NRAD)[2] and the National Asthma and COPD Audit (NACAP).[3]

Incidence and mortality rates from respiratory disease are higher in disadvantaged groups and areas of social deprivation, with the gap widening, and leading to worse health outcomes. The most deprived communities have a higher incidence of smoking rates, exposure to higher levels of air pollution, poor housing conditions and exposure to occupational hazards.[4]

In regions such as the Black Country and West Birmingham, which are home to some of the most deprived communities in the country, the rates of mortality and hospital admissions due to asthma and COPD are among the highest in the nation.[5] There is also a significant proportion of ethnic minority populations that live in these areas who face additional barriers and challenges in accessing care like poor health literacy and language barriers. A significant challenge is still timely access to good quality care.[6]

Early and accurate diagnosis is crucial to promptly initiating patients on the correct treatment plan.

"Both under and overdiagnosis of respiratory conditions leads to delayed treatment and an increased chance of acute admissions.

Late COPD diagnosis is associated with a higher exacerbation rate and increased comorbidities and costs compared with early diagnosis.[6]"

Individuals experiencing difficulty breathing are having long delays in receiving an accurate diagnosis. A recent study of 12,000 people with lung conditions in the UK revealed that one out of every five respondents had to wait more than a year for an accurate diagnosis of a chronic lung condition.[7]

Routine assessments like spirometry are essential in accurately diagnosing asthma and COPD. Without these simple tests, primary care clinicians are only able to provide some symptomatic treatment instead of being able to accurately diagnose and treat underlying pathology. This can also lead to misdiagnosis and patients started on the wrong treatments. It is also important to remember that diagnosing asthma can in some instances be challenging due to its variable nature with test results often appearing normal. This underscores the need for prompt appropriate investigation when the patient is symptomatic. Along with pressures in Primary Care, this all leads to delays in starting appropriate treatment and a progression of a patient's lung disease, leading to worse long-term health outcomes.[4]

Investment in Primary Care respiratory services

To have a sustainable NHS for the future we have been told by successive governments of the importance of shifting care away from hospitals and into the community. The recent Darzi report indicates the reverse has happened. The NHS budget is not being spent where it should be – too great a share is being spent in hospitals, too little in the community and on preventative healthcare.8 This is particularly significant when it comes to respiratory conditions given that the majority of asthma and COPD cases are diagnosed and managed in Primary Care.[4] The new government will need to redress this balance and make significant investments in Primary Care. Delivery is needed on the promise of the NHS Long Term Plan Implementation Framework, of more funding to deliver improvement in respiratory care with a focus on reducing local health inequalities and improving prevention.[9]

How can we deliver improved respiratory care?

The NHS long-term plan encourages integrated respiratory care to improve respiratory outcomes and mentions the importance of person-centred care and empowering patients to manage their conditions better.[9]

"Integrated respiratory care is patient-centred, proactive and coordinated care delivered through clinical leadership and a multidisciplinary team without walls".

Various models of integrated respiratory care are emerging nationwide, with each approach varying based on the available organisational resources and structures. It would be difficult to expect all Primary Care sites to achieve the same standards when they may have different resources, skills and knowledge. Concentrating expertise and resources in specialist clinics may be a better approach and one-stop clinics have been reported to be the most resource-efficient way of delivering respiratory services while enhancing the overall patient experience. One Stop clinics enable patients to be assessed and diagnosed or reviewed on the same day meaning fewer trips to hospital/community settings and less time spent waiting. This improves access to care and reduces the number of appointments necessary for each patient. Attendance rates should improve with less interactions required and less breakdown of the diagnostic pathway. This means that quality of life and patient satisfaction should also improve. An overall reduction in the number of appointments helps to increase clinic capacity and should lead to a decrease in waiting times for urgent and routine appointments.[10]

There are a number of Community Diagnostic Centres (CDC) located across the country, but they will not be the complete solution and have already encountered issues in delivering services with several teething problems. However, they provide an insight into what is possible and the learning from these may inform the way forward. A situation compounded by the fact that we simply do not have enough respiratory professionals in the NHS.[4]

"What we need is a local solution that can work alongside existing services by upskilling the primary care workforce and clinics that are accessible in Primary Care and surgeries."

New models of care- A Pharmacist-led One Stop Respiratory Clinic in Primary Care

Dudley Integrated Health and Care NHS Trust was legally dissolved on 1 October 2024. It was a first-of-its-kind integrated care trust, integrating primary care across Dudley with community physical and mental health services. The trust had made significant provisions for community services to address local clinical needs and commissioned services, including establishing a One Stop Specialist Pharmacist Respiratory Clinic in Primary Care.

One stop respiratory clinics in the community have been piloted before with large multidisciplinary respiratory teams.[10] However, the pharmacist-led clinic was unique in being a mobile service managed by a single specialist pharmacist with novel ways of working with the wider respiratory team. The clinic was developed as an enhanced respiratory pathway to improve patient access, experience, and outcomes.

The clinic focuses on preventive healthcare to minimise the need for urgent and unscheduled care. Shifting from the current reactive model, it implements a proactive strategy centred on population health. This approach aims to identify practices and patients who would derive the greatest benefit from the services offered. The clinic operates within GP practices twice weekly, rotating among Primary Care Network (PCN) practices every quarter, and it accepts direct referrals from clinicians to address more complex cases.

During the development of the clinic, various stakeholders were involved, including the local Primary Care Medicines Optimisation Sub-Group (PCMOS). This group comprised of GPs, Primary Care Network (PCN) clinical directors, Pharmaceutical Public Health Team Pharmacists, a finance officer, an operational manager, local community pharmacy representatives, and input from local respiratory specialists. Feedback from expert patient representatives in local respiratory groups was also considered.

A systematic approach was taken to evaluate patients, which included comprehensive history taking, physical examinations and performing objective testing. Through this methodical evaluation, potential differential diagnoses were screened for. There was also a focus on identifying comorbidities commonly associated with asthma and COPD that may exacerbate respiratory symptoms, such as nasal disease, breathing pattern disorders, and Obstructive Sleep Apnoea. The assessment of these conditions was conducted using the Total Nasal Symptom Score (TNSS), the Nijmegen Questionnaire (NQ), and the Epworth Sleepiness Scale (ESS) respectively. When deemed necessary, a Radioallergosorbent test (RAST) was utilised to pinpoint patient-specific triggers to be avoided as part of the patient's personalised action plan. The Primary Care Respiratory Service (PCRS) Respiratory Service Framework (RSF) was used to help shape the design and delivery of the clinic.[11]

Inclusion and exclusion criteria were established, accompanied by a defined set of referral guidelines to facilitate the process of directing patients to a respiratory specialist at the local hospital.

The clinic offers a comprehensive range of services, including:

1. Identification and management of respiratory patients at high risk of poor outcomes who are not currently under the care of a respiratory consultant. The list of at-risk patients was established based on a consensus and the results of the NRAD report.[2] Practices that needed the most support were identified by analysing population-level data, and risk-stratification tools used to case-find high-risk respiratory patients who then had a face-to-face consultation with the Pharmacist.
2. Early and accurate diagnosis of asthma and COPD through quality-assured spirometry and Fractional Exhaled Nitric Oxide (FeNO) testing, allowing for the prompt initiation of appropriate treatment plans.
3. Acceptance of referrals from primary care clinicians for more complex respiratory cases that typically necessitate a specialist referral. This approach aims to alleviate long wait times for outpatient appointments, which can extend to a year or more locally, while also reducing the frequency of hospital visits and enhancing the quality of referrals to secondary care.

4. Improving patient safety by identifying and discontinuing treatments that may worsen respiratory conditions.
5. Detection of patients who may have been incorrectly diagnosed with asthma or COPD.
6. Management of coexisting comorbidities in respiratory patients visiting the clinic.
7. Referral of patients to a respiratory consultant when a potential differential diagnosis is suspected or when there is diagnostic uncertainty.
8. Identification of patients who could benefit from specialist asthma biologic treatments. An enhanced referral pathway was created with a joint satellite multidisciplinary team clinic with the regional Difficult Asthma Centre to identify patients suitable for asthma biologics.
9. Correction of poor inhaler techniques to improve disease management.
10. Enhancement of patient education, self-management strategies, access to pulmonary rehabilitation, smoking cessation support, and overall patient experience.
11. Completion of asthma or COPD Quality and Outcomes Framework (QoF) templates in conjunction with medication reviews when applicable.

Inclusion criteria for identifying patients at high risk of worse outcomes:

- High use of Short-Acting Beta2 Agonist (SABA) inhalers (more than 12 in a year).
- High oral corticosteroid use (>2 prescriptions for prednisolone in 12 months).
- On SABA monotherapy without a confirmed respiratory diagnosis.
- Had an unscheduled respiratory-related hospital visit or admission.
- Difficult to treat or deemed urgent by practice clinicians
- In a vulnerable group such as learning disabilities, dementia, mental health issues and drug users.
- Poor health literacy, English is not a first language.
- Not previously engaged with the healthcare system, missed several respiratory appointments.

Reasonable adjustments were made for those in vulnerable groups including longer consultation times and more follow-up appointments.

Service Evaluation

The Research and Innovation Steering Group at the Trust approved the service evaluation, and the effectiveness of the service was evaluated by the following:

Access

- Reduction in outpatient appointments.
- Shortened wait times for diagnostic tests.
- Number of secondary care referrals prevented.
- Number of diagnoses confirmed or excluded.
- Identification of misdiagnoses.
- Improvements in disease management will be evaluated via enhanced symptom scores and reduced reliance on reliever medications.
- Patient safety improvements will be measured by the number of misdiagnoses identified, and inappropriate treatments discontinued.
- Increase in patients' confidence in recognising and managing a deterioration or exacerbation of their condition will also be assessed.

Experience

- Patient experience will be evaluated through a qualitative questionnaire and feedback from patient testimonials.
- Feedback will also be obtained from staff and healthcare professionals involved with the service.

Outcomes and findings of the service

- 376 patients were reviewed over 12 months across 8 GP practices.
- A diagnosis was established by the Pharmacist in all the patients (n=87) identified on SABA monotherapy, without a confirmed diagnosis. 68 were diagnosed with asthma, while 19 were diagnosed with COPD. These patients were commenced on the correct treatment plan and all of them had a post-treatment follow-up within 6 weeks before being discharged from the clinic to ensure the effectiveness of any treatments initiated as well as providing safety netting.
- 100% of patients (n=79) who received 12 or more SABA inhalers over the past year, reported a significant reduction in SABA use and improvement in their Asthma Control Test (ACT) scores following interventions made by the Pharmacist including optimisation of treatment, correction of inhaler technique and management of triggers and comorbidities.
- 100% of patients (n=19) who in the last 12 months had a hospital visit or admission, prescribed oral steroids, or were in a vulnerable group, reported an improvement in symptom control and the ability to self-manage following interventions made by the Pharmacist.
- The difficult-to-treat patients (n=30) referred to the clinic were seen within a few weeks of the referral instead of waiting up to 12 months to see a hospital consultant. The majority were successfully managed by the Pharmacist with only 3 patients requiring an onward referral to a respiratory consultant. This included 2 patients suspected of having Interstitial Lung Disease and 1 patient with Inducible Laryngeal Obstruction. This not only increased access to specialist care but also enhanced the quality of referrals to secondary care, helping to reduce waiting lists and pressure on secondary care.
- Among the 30 patients referred by practice clinicians for diagnostic testing, 22 were diagnosed with asthma, 6 with COPD, while 2 patients were determined not to have either condition. **The time from referral to testing was within 6 weeks which is faster than the local pathway that takes at least 24 weeks. 80% of these patients had a same-day diagnosis, while the rest were diagnosed within 4 weeks of their initial appointment.**
- 19 patients were either incorrectly coded or misdiagnosed with asthma or COPD.
- 3 patients had beta-blocker treatment stopped following a confirmed diagnosis of asthma.
- 1 patient was referred for suspected Nitrofurantoin lung disease and 3 for suspected Obstructive Sleep Apnoea.
- 117 patient records were examined in collaboration with the Difficult Asthma Team to identify suitable patients for asthma biologics. This resulted in 9 patients being initiated on biologic therapies. This not only increased access to specialist treatments but also significantly decreased the local referral-to-treatment timeline from approximately 52 weeks to less than 12 weeks.
- 66% of patients who had a face-to-face consultation felt uncertain about how they would manage worsening respiratory symptoms or a potential exacerbation of asthma or COPD. All these patients reported increased confidence at the end of their clinic visit and each was given a personalised action plan. Their understanding was rechecked in their post-treatment follow-up.
- 7 patients experienced a reduction in high dose inhaled steroid treatments, and one patient ceased oral steroid medication, improving the safety of prescribing by minimising potential side effects.
- 60% of patients seen in the clinic had poor inhaler technique corrected to improve disease control.
- 9 patients were referred for pulmonary rehabilitation and 49 were given smoking cessation advice.
- 69 patients were prescribed treatments to manage their comorbidities such as rhinosinusitis and gastroesophageal reflux disease. 5 patients were sent for a RAST test to identify potential triggers to avoid as part of the management plan.
- 12 vulnerable patients were reviewed in the clinic (learning disability, mental health issues, drug users).

"The pharmacist was ideally positioned to optimise pharmacological treatments-implementing Maintenance and Reliever Therapy (MART) in patients with asthma to reduce Short-Acting Beta Agonist overuse was particularly effective."

Patient Experience

100% of patients rated their appointment at the clinic as either an "excellent" or "good" experience. Patients expressed satisfaction with how quickly they were seen in the clinic for diagnostic testing and said that they felt listened to. They also liked the continuity of care they received with a post-treatment follow-up after 4 weeks.

"I was told that it would take more than 6 months to have a test done to help diagnose my respiratory symptoms. So, when I was told I could have the test at the surgery within a week I jumped at the opportunity not least because I was dreading going into the hospital to have the test. The specialist respiratory pharmacist was great, he took the time to explain everything in a way that I could understand and really listened to my concerns. I was diagnosed with asthma the same day and started on treatment that completely transformed my life! I wish I could have seen him sooner as I was experiencing breathing problems for over 12 months before I was finally diagnosed".

Feedback from staff and clinicians in all GP practices involved was also excellent, with the practices requesting the service to continue.

Barriers and challenges in developing and delivering the service

The main challenge was to provide respiratory services to 43 GP practices in Dudley, covering 6 PCNs, with the service only being available for 2 days per week. To overcome this, the clinic rotated between practices, covering 2 practices from 2 different PCNs each quarter. Therefore, the service was offered to a set number of practices at a time.

Due to time constraints and the uncertainties brought about by the COVID-19 pandemic, the clinic was unable to conduct workshops with patients and service users before launching the respiratory service as originally planned. However, changes were made based on patient and practice feedback once the service became operational. An early example of this was the recognition that training needed to be provided to practice staff and clinicians to ensure that the right patients were scheduled for the correct duration, including providing pre-test advice to patients to prepare for diagnostic testing.

Looking ahead

The cost-effectiveness of the pharmacist-led model and the impact on usage of healthcare resources needs evaluation. The potential for learning to be shared vertically across the system is being assessed, and wider system partnerships are being developed to further support patients. This includes collaborating with a local COPD virtual ward.

There are also plans to scale the respiratory clinic in Dudley by training more clinical pharmacists and establishing a Hub and Spoke care model. The Dudley clinic has already inspired a Primary Care Network (PCN) in a different Integrated Care Board (ICB) to initiate a pilot program for a pharmacist-led diagnostic respiratory hub, led by Nazir as part of a General Practice Locality Quality Improvement Scheme. This initiative is being disseminated nationally and is recognised as a best practice case study by the NHS Confederation Primary Care Network.[12]

Summary

We need to change the way we provide respiratory care in the UK if we are to tackle unwarranted variation and improve respiratory outcomes. We cannot operate with the existing systems and models and expect differing outcomes.

One Stop Specialist Primary Care respiratory clinics offer a great opportunity to improve respiratory care and improve the patient journey, particularly in areas where there are significant health inequalities. By providing specialised, proactive, and preventative care under "one roof", these clinics can be at the centre of a truly integrated approach leading to improvements in patient health outcomes, reduction in hospital appointments, and ensuring patients are seen in the right place, at the right time, according to clinical need. These clinics can support more collaborative working between primary and secondary care. Their role in the healthcare system underscores the importance of integrated, community-based care models in achieving sustainable and efficient healthcare.

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Defining an Operational Model for Clinical Pharmacy


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Introduction

Like many NHS Trusts, the clinical pharmacy service at Frimley Health NHS Foundation Trust (FHFT) is facing rising demands and a lack of funding. An efficient operational model is required to deliver a quality service to the wards with minimal resources.

There is little literature or discussion on the details of an operational model to deliver a clinical pharmacy ward service. Consequently, a new pharmacy operational model was proposed for an NHS trust, comprising of two sites (Site A and Site B, both district general hospitals [DGHs] with full A&E departments), derived from two manufacturing models – the *Theory of Constraints* (ToC) and a model known as *Delayed Product Differentiation* (DPD).

While yet to be fully implemented, the final proposed model has led to the creation of new roles and is helping to determine staffing levels and free resources for more services.

This article aims to share the experience of the difficulties of attempting to re-engineer clinical services while still delivering a full service, and to hopefully start a discussion about other, hopefully more efficient, future service designs.

Literature review

Review of Pharmacy Operational Models

A literature review focused on operational healthcare models, particularly in clinical pharmacy. Mahdavi et al. (2013) defined such a model as a formal description of operations to deliver health services, aiding operational decision-making.

UK literature shows strong evidence for individual clinical pharmacy services (e.g. Medicines Reconciliation reduces length of stay and morbidity, NICE 2016) but lacks operational details. Bednall (2021) developed a Clinical Pharmacy Workforce Calculator (CPWC) to standardise ward activity times and calculate manpower needs. However, it predates many hospitals' Electronic Patient Record (EPR) systems. Medicines Reconciliation (MR) is noted as the most time-consuming task for clinical pharmacists- at 30 minutes per patient. NICE (2015) recommends MR for all "people taking 1 or more medicines" in the acute setting- although most hospitals do not reach that target.

"Most pharmacy models found were strategic/tactical, lacking daily operational details. For instance, Woods et al. (2011) describe three US pharmacy practice models, with the patient-centred integrated model resembling UK practice butlackedoperational specifics. Similarly, Jacobi et al. (2016) discuss US models without detailing operational methods."

In summary, despite the evidence for various individual clinical pharmacy activities, there is no model for linking these activities together efficiently. As an article by Onatade et al (2018) stated, there is a "lack of information to support the most efficient use of available resources".

As a result, industrial operational models were considered.

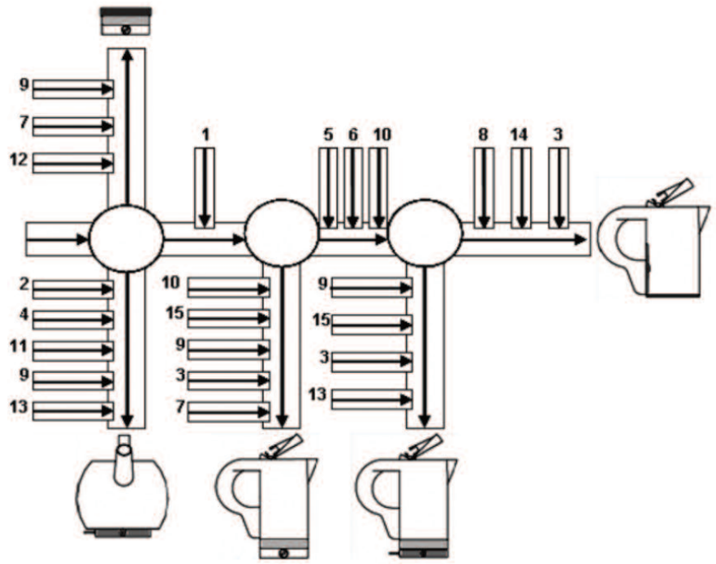

Diagram 1–Assembly Line for a range of kettles (AlGeddawy & ElMaraghy 2009)

Delayed Product Differentiation (DPD)

This manufacturing theory states for a family of products, the generic, common parts should be produced first, with product differentiation occurring later in the process. Examples include clothing initially produced in white and dyed into various colours based on customer demand, or car manufacturing where cars of the same model may receive different accessories, such as leather or vinyl seats, at a later stage.

Compared to having multiple assembly lines, DPD offers these advantages:

- Stock management (Lee and Tang, 1997, Jewkes and Alfa 2009)
- Reducing complexity of the manufacturing processes (Lee & Tang, 1997)

Al-Geddawy & El-Maraghy (2009) showed a DPD model in which the production of a family of kettles (Diagram 1) can be represented as a flowchart (Diagram 2- reminiscent of clades in biological evolutionary trees with common ancestors) enabling common processes to be easily identified.

DPD is not generally applied to service and healthcare industries, but within the clinical pharmacy service there are certain functions –

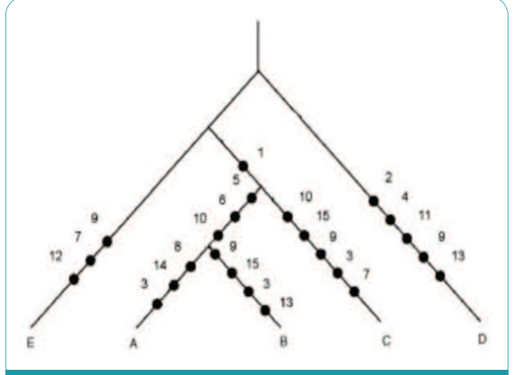

Diagram 2 – Cladistic View of an assembly line
(AlGeddawy & ElMaraghy 2009)

such as Medicines Reconciliation- that are ubiquitous to every patient, and other services (such as the antimicrobial pharmacists) that are delivered only to certain patients.

The services provided by expert pharmacists, whether on dedicated wards (e.g. ITU) or for specialist medications (e.g. anticoagulation) are a version of the product differentiation on DPD. Although clinical pharmacy does not manufacture physical items, staffing could be considered the raw material.

Theory Of Constraints

The Theory of Constraints (ToC), developed by Eli Goldratt (1990), is a management philosophy focusing on a single 'constraint' limiting a process's throughput. The core principle is the bottleneck, the process part where demand exceeds capacity (Goldratt 1990, Wu 2019). The main bottleneck is identified as the constraint, which is addressed using five steps (Rattner, 2006; Goldratt 1990):

1. Identify the constraint
2. Exploit it
3. Subordinate other processes to it
4. Elevate it through investment
5. Repeat as necessary

ToC has shown positive results in healthcare (Bacelar-Silva et al., 2022; Young et al., 2004; NHS 2021) and ToC often yields results with minimal investment, unlike Lean Theory, which can require initial costs (Bacelar-Silva 2022). Fourie (2015) noted that the success of ToC, which creates spare capacity, could be mistaken for waste. In the cash-strapped NHS, there is a concern that freeing up staff might be seen as an opportunity to reduce staffing numbers rather than redeploying them to improve other services.

For clinical pharmacy services, Medicines Reconciliation is a key bottleneck, taking longer than other ward tasks and absorbing the most manpower. Improving throughput in this process could free up staff for other services.

Application to clinical pharmacy

Current model

Clinical pharmacy currently operates on a ward-based paradigm similar to the unit-based model described by Woods and Al-Jazairi; pharmacy staff are sent to the wards to complete MR for newly admitted patients, screen and order new inpatient medications and discharge prescriptions. Staff are usually sent in the morning and are usually given around 4 hours per day for clinical work, with the rest of the day for other duties (e.g. dispensary or clinics). Where pharmacy teams work together, they are built around a single specialty (e.g. ITU).

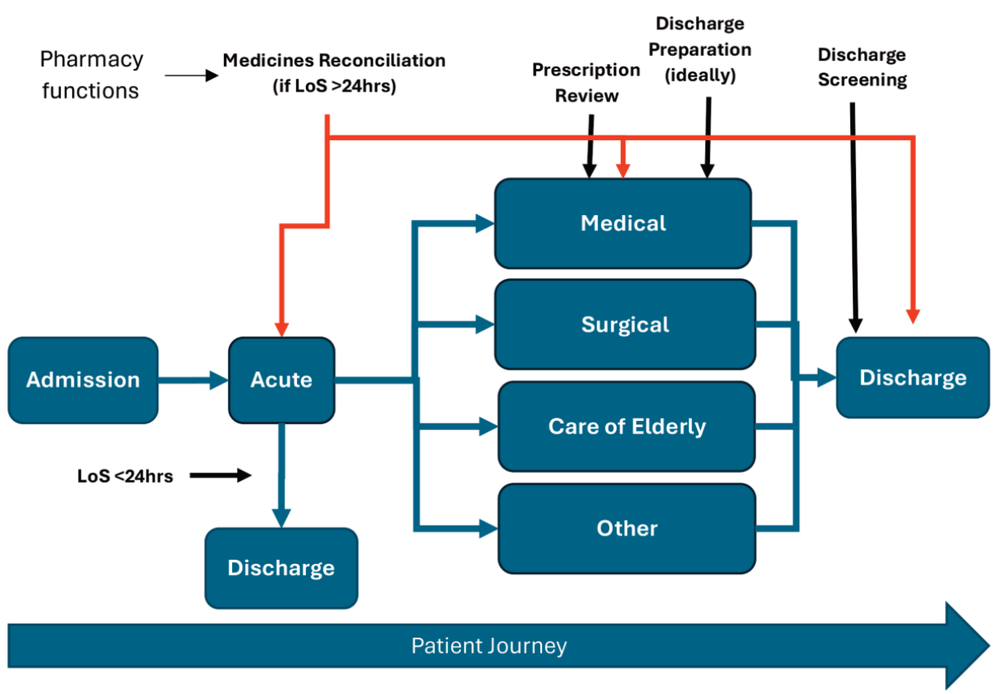

Diagram 3 – Current pharmacy model (simplified)

Diagram 3, below, is a simplified map of the pharmacy model – each specialty is further divided into individual wards, each visited by a peripatetic pharmacy practitioner.

> **"Ideally, the pharmacy team working in the acute wards should perform the majority of MR, but staff shortages and discharge pressures often mean that MR is completed on the wards or even at the point of discharge when screening discharge prescriptions. "**

The individual patient journey is more complex, with potential visits to theatres, ICU, etc, complicating the picture.

Medicines reconciliation

Medicines reconciliation is the process of gathering an accurate list of a patient's drug history, comparing to the current hospital prescription, and clinically screening it.

Medicines reconciliation can be broken down into four tasks:

1. Collecting information from the first source – usually electronically via GP (referred here as level 1 drug history)
2. Comparing with a second source – often by discussing with the patient, or checking the medications the patient brought in with them
3. Reconciling any differences or changes since admission (level 2 or 'full' MR).
4. Clinically screening the prescription

Traditionally, tasks 1-3 are viewed as a single act and can be performed by a qualified technician or pharmacist. A full MR is usually attempted only for patients with a length of stay (LoS) of greater than 24 hrs. However, good practice would suggest that patients with a LoS of <24hours would at least need the first source collected. In the current model (Diagram 3), these rapid turnaround patients are often not attempted.

Application of DPD

Reconsidering MR through the lens of DPD, the admission workflow of pharmacy is redrawn as:

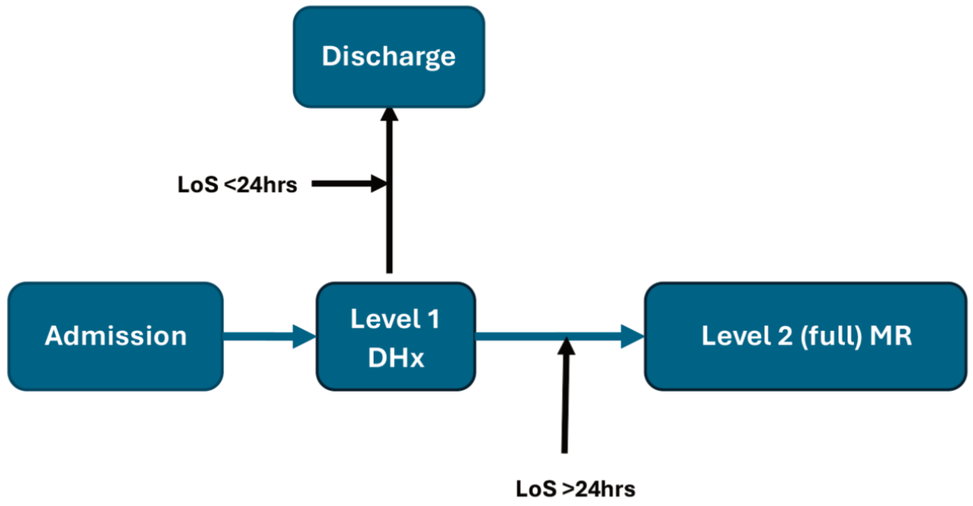

Diagram 4 – Admission as DPD Process

	No. patients /day	No patients /hour	Man-hours required	WTE /day	Cost (inc Oncost) x WTE per AfC banding			
					Band 3	Band 5	Band 7	Band 8a
Current Model	73	2	36.5	4.9	-	£220,226	£293,192	£324,276
Proposed Model								
Level 1 drug history	73	5	14.6	1.9	£61,252			
Level 2 MR	73	4	18.25	2.4		£110,113.00	£146,596.00	£162,138.00
	Total cost (Band 3 + Band 5/7/8a)					**£171,365**	**£207,848**	**£223,39**

Table 1 – Costs of Current vs Proposed Model

Here, the commonality is the transcribing of the GP record. A full MR requires a pharmacist or technician, whereas transcribing (level 1) can be delegated to a Band 3 pharmacy assistant.

A full MR includes patient counselling requiring pharmacy staff to be present on the ward. Each full MR takes roughly 30 minutes (Bednall 2021), i.e. 2 MRs completed per hour.

In the new model, rapid turnover patients (who are not usually provided with a MR) are now potentially receiving a Level 1 MR as a minimum.

A proof-of-concept internal audit demonstrated that the level 1 drug history can be performed remotely and that an assistant can produce 5 level1 drug history/ hour. The remaining tasks to convert a level 1 to a level 2 (full) MR are expected to take around 15mins (i.e. 4 patients/hr).

Cost Analysis

The costs for each model were calculated for a single site, based on the WTE needed to deliver a 100% service. As of July 2024, Site A sees 73 admissions/day requiring full MR. Table 1 shows the service delivery costs for the current model, with full MR every 30 minutes, including costs for various staff bands.

The costs of 1 WTE of each banding (taken at midpoint and including on-costs):

- Band 3: £31,465 pa
- Band 5: £45,252 pa
- Band 7: £60,245 pa
- Band 8a: £66,632 pa

A DPD-based model, using a pharmacy assistant for Level 1 drug history and higher-banded staff for conversion to level 2, delivers the same output at significantly lower cost and WTE.

This, combined with the lessons of ToC, suggest that not to invest and staff properly the admission stage of the patient journey is a false economy and should be resisted.

Prescription Review

Before resources are deployed to review prescriptions the location and nature of the workload needs to be understood.

Where/what is the prescribing workload?

Data was pulled from the trust EPR system, identifying where inpatient medications were prescribed. As shown in table 2, nearly half of all prescribing occurs in ED.

Site	ED	SAU	Surgical	AMU	Medical	CoE	Misc
FHP	7637 (42.4%)	465 (2.6%)	4677 (25.9%)	1034 (5.7%)	3328 (18.5%)	728 (4.0%)	157 (0.9%)
WPH	7117 (46.4%)	55 (0.4%)	2806 (18.3%)	930 (6.1%)	3660 (23.9%)	762 (5.0%)	2 (0%)

Table 2 – Prescribing across different ward groups

There are currently no staff deployed to either ED *specifically* to work with prescribing (there are staff for completing MR, stock, etc). The current model of delivering the clinical services on the wards and not in ED clearly does **not** fit.

Specialisation/Generalisation

As noted in Diagram 3, pharmacists are split across multiple wards, differentiated by specialty. Most hospitals handle these different wards in a similar manner to how an industrial plant may treat different assembly lines with staff dedicated to individual lines (or to several similar lines, if working in teams).

The medication prescribed across the medical and surgical wards was grouped together and arranged in order of prescribing (with fluids being the most common item prescribed). The top 10 across the two sites constituted roughly 50% of all inpatient prescribing.

Table 3 demonstrates that similar medications are prescribed across the various specialties, regardless of site. The significant difference between the surgical wards and medical wards is the presence of two anti-emetics, Cyclizine and Ondansetron in the surgical wards and Insulin pen prescribing in the medical wards.

This prescribing similarity does not justify differentiating generalist pharmacists by specialty. The bulk of the medication groups are 'simple meds' that can be screened remotely by a generalist. Indeed, one medication group – IV Abx – which does justify a specialist pharmacist, is found across medical & surgical specialities, implying that the differentiation of 'medical' and 'surgical' has little impact on the needs for certain specialists.

Specialisations based on patient type & location (e.g., ITU, Cystic Fibrosis) would still be required, as would also differentiating by medication type (e.g., TPN).

Using DPD to build a pharmacy operational model focusing on the commonalities would:

- Reduce the stress on pharmacists by widening the pool of staff covering any gaps (the "Improve stock management" advantage of DPD)
- Make staff rotas and deployment easier and simpler ("Reducing Manufacturing complexity")

Site	Site A		Site B	
Ward Group	Medical	Surgical	Medical	Surgical
1	Fluids	Fluids	Fluids	Fluids
2	Paracetamol & Co-analgesics	Paracetamol & Co-analgesics	Oral Supplements	Ondansetron
3	Oral Supplements	Ondansetron	Paracetamol & Co-analgesics	Paracetamol & Co-analgesics
4	Loop Diuretics	Cyclizine	Abx: All other IV	Cyclizine
5	Abx: Simple	Opiates: Weak Oral	Loop Diuretics	Opiates: Weak Oral
6	Simple Laxatives	Opiates: Injectable	Abx: Simple	Opiates: Injectable
7	Insulin Pens	Oral Supplements	Simple Laxatives	Simple Laxatives
8	Ondansetron	Simple Laxatives	Insulin Pens	Oral Supplements
9	Opiates: Weak Oral	Abx: Simple	Nebs & Inhalers	Abx: All other IV
10	Glucocorticoids: Oral	VTE Prophylaxis	VTE Prophylaxis	VTE Prophylaxis

Table 3 – Comparison of prescribing across ward groups

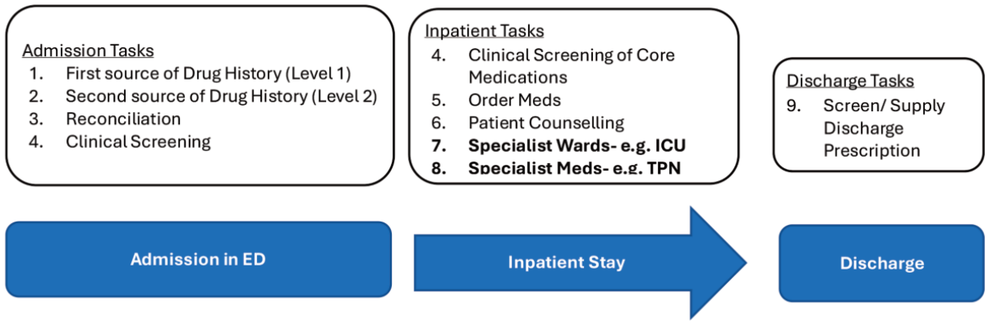

Diagram 5 – current model as task

(Normal text indicates core tasks required for all patients. **Bold text** is for specialist/differentiated work.)

Application of ToC would mean that this screening should be on an ongoing basis to prevent bottlenecks – most EPR systems now indicate when new items have been prescribed, and pharmacist should screen them ASAP, rather than waiting for the next ward visit.

Ordering Medication

The next step after screening medication is ordering and supply. Since this task does not require clinical input – because the medication has already been screened – it can be handled by a technician. This is a standard task that does not require differentiation and, according to DPD, should be regarded as common. With EPR now implemented, this function (ordering, not dispensing) can be performed remotely.

Discharge

Discharging patients can require a separate model in its own right – from simple discharges to complex ones with MDS, patient counselling, transfer of care and DMS referrals. This is beyond the scope of this paper, but it should be noted that ordering medication is part of the discharge process – supplying medications as 'one-stop' is known to expedite the process and must therefore be written into the model. In the proposals that follow, there will be a simple reference to the discharge prescriptions, but no further discussion.

Proposed Operational Model

Diagram 5 shows the current model broken into tasks. Tasks are separated as core or specialist. Diagram 6 places these tasks in a cladistic tree, similar to DPD.

This workflow is similar to the DPD model in Diagram 2. Although some patients may have multiple specialists (e.g. a patient in ICU requiring TPN), the above plan is simplified for easier visualisation. Tasks shown in circles with a dark background can be performed remotely, while those in white circles require the physical presence of a pharmacist or MMT.

Since patients do not follow a linear progression like an assembly line (e.g., they may move to/from ICU or start specialist medications at different stages), a more practical model is proposed in Diagram 7. This model replaces multiple decision branches with feedback loops.

By dividing reconciliation into two tasks (1 and 2) that can be completed in parallel or at different times, the 'constraint' has been leveraged effectively.

Remote completion of "common" patient care tasks allows for staff pooling across specialty boundaries, easing staffing pressures. The efficiency of remote work is comparable to the efficient use of raw materials in DPD. By identifying and performing basic tasks remotely, time and resources are freed up for specialised work and new services.

Using this model, a manager can calculate the average number of tasks per day (e.g. number of items for ordering or screening). The number and banding of staff needed can then be determined using Bednall's CPWC. This approach also helps managers understand changes in demand and request additional resources accordingly.

In this simplistic view, the tasks are placed in a flow chart.

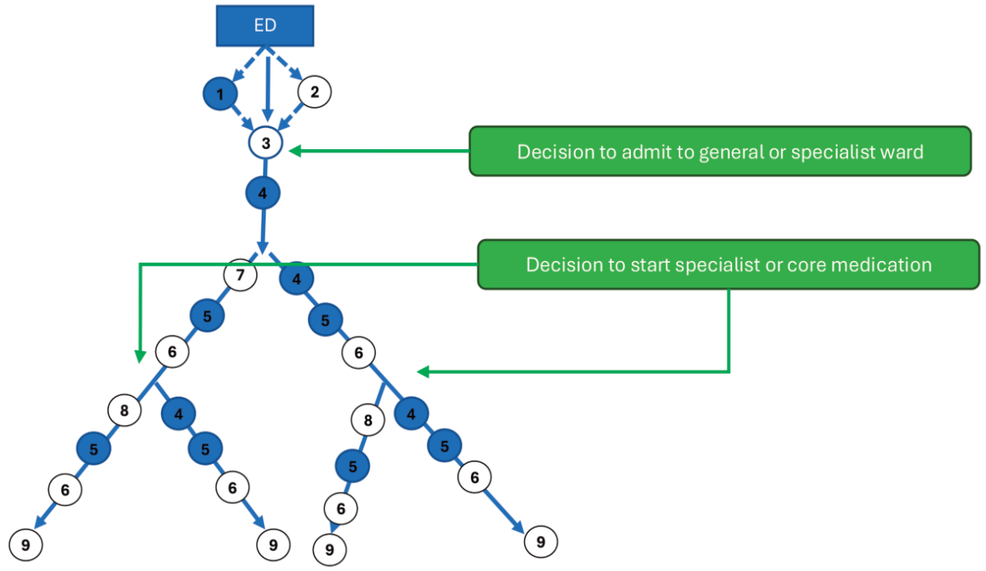

Diagram 6

(Key: Each number refers to the tasks in Diagram 5. Blue circle - tasks that can be completed remotely; White circle - tasks required in person.)

Model operational rules

1. **Continuity:** Each task that can be performed remotely should be done continuously throughout the day, not just during allotted ward times:
   - The task does not need to be done by the same individual; it can rotate among different staff members, provided someone is scheduled
   - Assistants should continually monitor the ED remotely and complete the level 1 drug history as soon as the system notes a patient to be admitted
   - Pharmacists should review all newly prescribed items and screen them
   - Technicians should continually monitor order requests from the wards
2. **Clinical Review:** Ward pharmacists and technicians should visit wards to counsel patients (task 6 in the models) and perform holistic clinical reviews:
   - With routine tasks completed continuously, staff will have more time for meaningful interactions with patients and staff during ward visits
3. **Rules for differentiation:** With significant similarity in medication prescribing across specialties, early differentiation into specialties should be reconsidered:
   - Pool pharmacists across multiple specialties for 'core' tasks
   - Establish clear rules for referring patients – beyond the usual anticoagulation/antimicrobial specialties – to Lead Pharmacists for Gastroenterology, Surgery, etc.
4. **Output monitoring:** The operational delivery of pharmacy services should be monitored:
   - This depends on what the different EPR systems can monitor and report
   - Tracking the number of patients reviewed would help demonstrate improvements in clinical delivery

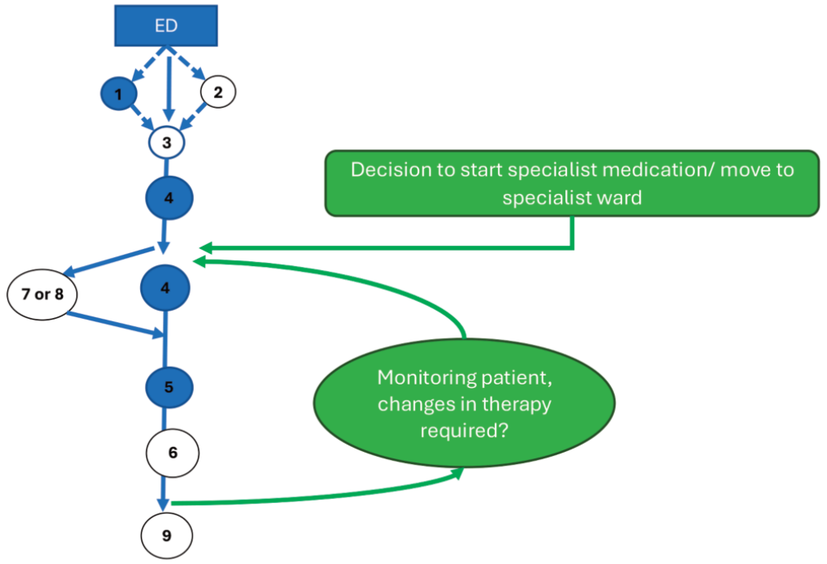

Diagram 7 – abbreviated model

- Tracking the number of patients seen in clinics would indicate that resources are being effectively reallocated to provide additional services

Limits and Flaws of the Model

Any theoretical or idealised model will have gaps where the reality of service provision does not align perfectly with expectations. These gaps need to be acknowledged and understood. The working hours of most hospital pharmacy services do not match the 24/7 activity of a hospital; therefore, when staff start in the morning, there will be medication orders that have not been screened, or on Mondays, a large number of patients without drug histories (as most hospitals do not run a full MR service on weekends).

These flaws do not invalidate the model but require managers to implement systems to mitigate them. For example, staff could be instructed to clear all newly prescribed items first thing in the morning.

Individual medication screening risks missing more complex issues. Therefore, a full chart review, or holistic screening of a patient's prescription, must be incorporated into the model. This is embedded into the second rule above.

It is important to note that this model is limited to the delivery of clinical services and does not include other roles a pharmacist may have on the wards, such as governance or prescribing advice.

Implementation

The implementation of a new operational model has been haphazard and challenging. Constraints from staffing budgets, vacancies, slow EPR system transformation, doctor strikes, resistance to change, and other factors have hindered progress. The primary obstacle, however, has been the need to maintain service delivery while transforming the service.

Unlike manufacturing, where new factories can be purpose-built with assembly lines organized according to DPD, ToC, or other operational models (e.g., Lean), pharmacy must evolve while still providing medicine to take away (TTAs), patient counselling, and other services.

The burden of the current model impacts our ability to implement changes—TTAs require time for screening due to inadequate history-taking, but staff cannot focus on drug histories because they are busy completing TTAs. Similarly, moving staff from the wards to screen prescribing in the ED is difficult as they are occupied with unscreened medications on the wards.

However, recent winter pressure funding allowed us to develop a 'proof-of-concept' model with Band 3 assistants taking level 1 drug histories. The posts are now permanent and are currently being advertised. As noted in Table 1, this is a more efficient use of resources, with funding for these full-time posts coming from unfilled pharmacist positions. These new roles, Medicines Management Assistants, have garnered support from stakeholders, including acute consultants and senior nursing staff.

Medication ordering has also been revamped, with teams of technicians and pharmacists- often pooled across specialties- (as per the new operational rules)- working throughout the day to screen and process the orders. This has resulted in faster return of medications to ward areas and less stressful dispensary late shifts.

Another practice change has been the gradual implementation of recording and monitoring the full chart reviews through the EPR system. This not only demonstrates the pharmacy department's workload to the trust but also helps identify areas of low performance within the department.

Output Monitoring

One of the challenges identified with developing an operational model was the lack of data on clinical pharmacy performance.

Key questions include:

- How much of a pharmacist's time is spent on ordering?
- How much time is allocated to band-appropriate work (e.g. is a band 8a pharmacist routinely screening medications like senna)?
- How many patients are seen in the clinic? How many patients have their charts screened?

The absence of this data reflects poorly on operational management. In other industries, professionals typically complete worksheets for time spent with clients, or workers receive daily job sheets. As part of the implementation process, clinical 'output' measurement has been introduced, focusing on the number of individual patients or prescriptions handled by pharmacy staff. Pharmacists are not accustomed to justifying their workload, so logging patients reviewed, or clinic numbers, represents a cultural shift for many. However, this change is beginning to increase awareness within the trust of the pharmacy department's workload and capacity to deliver.

Conclusion

The creation of a new operational model at the Trust is not without benefit and controversy. By clearly stating what tasks are required, instructing

what staff is needed and where, it is possible to have informed discussions about best use of resources – such as the benefit of Medicines Management Assistants in increasing the number of patients receiving level 1 drug histories – and improving patient care.

Benefits have also been noted by applying the same ideas to medication ordering, and the efficiencies are allowing the department to consider new services and even allow regular working from home for clinical staff. It is hoped that as output monitoring improves, we will be able to demonstrate an increase in clinical reviews and patient counselling. Longer term staff and patient satisfaction would be scrutinised through the various annual satisfaction surveys.

Despite the ongoing challenges in implementing a new operational model, this exercise has yielded new ways of thinking about clinical service delivery. Utilising industrial theories such as DPD has enabled us potentially to increase efficiencies while improving patient care and reducing staff burden. The lack of useful operational data in the NHS makes it difficult to calculate efficiencies accurately- but adjusting how we work has enabled the workload to be better shared and become more manageable for the team.

The idea that many pharmacy tasks can be delivered remotely, and differentiation between historic specialties should be reduced, is one with implications for pharmacist training and how we differentiate 'core' from 'specialist' roles.

Historically there has been a lack of debate on the operational rules for delivering clinical pharmacy services to ward areas. It is hoped that this paper may generate discussion on how to deliver services, and that further articles will provide further thought on how to effectively deliver services with an efficient use of staff and resources.

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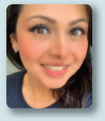

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One would assume that with advances in technology, medicine shortages would be a thing of the past or that robustness in the healthcare system would prevent impact on patient care.[1] The Department for Health and Social Care (DHSC) says that it has: 'Well established processes to manage the small number of supply problems that may arise', however, ongoing medicine shortages have plagued health systems across the country.[2,3]

The occurrence of medication shortages is influenced by a multitude of factors, including Brexit, the repercussions of the Covid-19 pandemic, and broader economic instability, all of which have been identified as significant contributors.[4,5] This situation is further compounded by the growing number of prescribers and, in certain instances, the increased adoption of private medical clinical teams. The daily management of shortages is thus posed with considerable challenges.

NHS England (NHSE) and DSHC's document titled *A Guide to Managing Medicines Supply and Shortages* offers support in the form of issuing serious shortage protocols (SSPs) and price concessions, which enable pharmacists to provide specific alternatives to scarce medicines and to cover the price differences.[6]

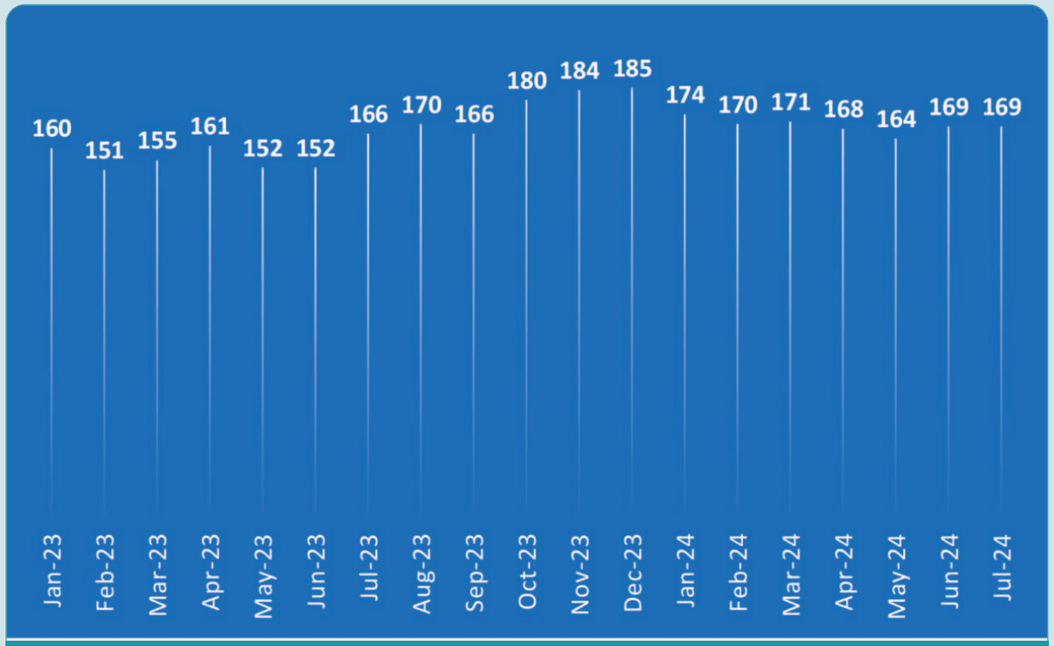

Table 1 – Number of drug shortages reported by MIMS between January 2023 and July 2024

Department of Health and Social Care (DHSC) oversees the management of medicine supplies and coordinates with other stakeholders, including manufacturers, suppliers, NHS bodies, and pharmacies, to monitor supply levels. They gather reports of supply disruptions, through Supply Disruption Alerts (SDAs), which are issued by manufacturers when they foresee or experience a shortage.

The DHSC can officially declare a drug shortage when it concludes that the supply of a particular medicine is insufficient to meet demand. They also oversee the Serious Shortage Protocols (SSPs). **The Medicines and Healthcare products Regulatory Agency (MHRA)** monitors reports from manufacturers regarding potential shortages or disruptions and plays a key role in verifying whether a shortage is genuine, especially if it involves regulatory issues such as quality control problems, recalls, or manufacturing issues that affect supply.

NHSE's 'Monthly supply report summaries' provide an overview of all current supply issues, and shortages and are circulated using various channels e.g. the Pharmaceutical Services Negotiating Committee, PresQIPP and The Specialist Pharmacy Service.

"Drug shortages have a significant impact on patient health and the health service.[5] Recent drug shortages include medications for conditions including cancer, diabetes, attention deficit hyperactivity disorder (ADHD), epilepsy, hormone replacement therapy (HRT) and Adrenaline (used to treat severe allergic reactions and anaphylactic shock)."

There can be a significant impact on patients who are unable to receive their treatments in time, both physical and mental, possibly requiring additional reviews and causing concerns as to when their next repeat prescription will be available. There is also an impact on pharmacists and pharmacy staff, often unaccounted for on job plans or schedules, who often must react quickly to minimise the impact for patients.

Increased workload and stress

Pharmacists across primary care, community, and hospital settings are on the front lines of this crisis and bear the brunt of the logistical challenges posed by drug shortages.

Challenges include:

- **Finding alternatives** – A significant number of resources are required to address shortages, Community Pharmacy England (CPE) reports than 'on average an extra 11 hours per week' is spent sourcing alternatives and managing patient expectations and concerns.[7,8]
- **Patient counselling** – Additional time is needed to counsel patients on changes in their medication regimens, including potential side effects and efficacy of substitutes. Ensuring compliance with regulatory guidelines when substituting medications adds another layer of complexity.
- **Ethical dilemma** – Pharmacists face ethical dilemmas when prioritising which patient receives limited supplies of a drug.
- **Reputation management** – Maintaining the pharmacy's reputation becomes challenging when patients are dissatisfied due to drug unavailability.

These challenges are additional to existing responsibilities, without extra staffing resources to account for the time spent on managing shortages.

Currently, community pharmacists are legally

required to either contact the prescriber or refer the patient back to the prescriber to seek an alternative, unless an SSP is in place (7).

For the 169 medication shortages reported in July 2024 as shown in table 1, there are only four SSPs in place, meaning that patients affected by the remaining 165 shortages may face delays in obtaining their medication.[4,10] For the remaining medications, contact with the prescriber is needed, causing further delay and increased workload, adding pressure to clinics. Additional resources and appointments are required to identify and manage alternative treatments including the associated cost of training and educating healthcare staff to ensure medication safety when prescribing an alternative agent to preserve patient care.[16]

These persistent shortages contribute to job-related stress and burnout among pharmacy and primary care staff, affecting their overall well-being and job satisfaction. Primary care staff have reported exposure to rising levels of abuse from patients unable to access their medication.[17]

This also adds pressure to clinics as contact with the prescriber is needed, causing further delay and increased workload taking time away from essential services.[7]

Patient care and safety

The Pharmaceutical Journal identified that, worryingly, 57% of pharmacists (working across all sectors) answered 'yes' when asked if 'In the past six months, have medicines shortages put patients at risk?'[9]

"A MIMS survey of 2,028 UK adults conducted between 15 and 17 May 2023 revealed that 30% of respondents attempted to locate their medicines from multiple pharmacies, of which 17% who were unable to obtain supplies went without medication. This highlights the very real impact on patient outcomes and health inequalities.[1,4]"

Multiple studies have shown that medication shortages can lead to an increase in medication errors, especially when alternative drugs have different dosages or administration schedules. Changes in medication regimens can impact patient adherence, especially if new drugs have different side effects or require different administration routines.[11,12,13,14]

Evidence suggests that better patient engagement leads to improved outcomes.[14] However, drug shortages can lead to communication breakdowns between clinicians and patients who are counselled on a certain therapy, only to be told that their drugs are unavailable. Patients are often unaware of the complexities of the supply chain and regulatory factors that may contribute to delays, and this may make patients feel disheartened and engage with healthcare providers less.[15]

Case study example – Diabetes in primary care

There are currently around 3.8 million people living with diabetes in the UK, with the current cost of direct patient care for those living with diabetes estimated to be £9.8 billion. Intentions to treat holistically have led to a higher demand for treatments such as GLP-1 receptor agonists (GLP-1RAs).[16]

This class has attracted significant media attention for its weight loss properties leading to persistent shortages and intermittent supplies due to off-label use for weight management. A National Patient Safety Alert (NPSA) in January 2024 meant that due to the shortage, patients prescribed GLP-1RAs were switched to tablets and new initiations were prohibited.[19] In an attempt to ensure prescriptions are fulfilled in a timely manner this would undoubtedly put pressure on pharmacy teams across the country. The Medicine Supply Report 2024 stated that 99% of community pharmacies surveyed reported encountering at least one shortage per week and 72% facing multiple shortages per day.[20]

Case study example – secondary care (Phosphate Sandoz®)

This challenge of drug shortages is shared in secondary care where patients are admitted with complex health needs and require urgent treatment. Acute shortages often mean that unlicensed products must be purchased at a premium charge.

"One example is the shortage of Phosphate Sandoz® in December 2023. Given the absence of an alternative licensed oral phosphate replacement, secondary care providers were required to purchase an unlicensed alternative for £120 for 100 dose units compared to £19.39 for Phosphate Sandoz®.[21] Any such overspends on unlicensed products, caused by medicines shortages, can only contribute to the financial challenges endemic in the healthcare system."

Additional resources and appointments are required to identify and manage alternative treatments, including the associated cost of training and educating healthcare staff to ensure medication safety when prescribing an alternative agent to preserve patient care.[16]

Possible solutions

Drug shortages in the UK continue to pose significant challenges to patient care and the healthcare system. The complexity of the NHS's organisational structure often makes it difficult to swiftly implement ideas from decision-makers down to front-line pharmacists.

Pharmacists, being on the front lines, often encounter these shortages first hand and are integral to finding solutions. Recently, the Centre for Pharmacy Education (CPE) and the Royal Pharmaceutical Society have been advocating for policy changes that would empower pharmacists to amend prescriptions and provide alternative medications when stock issues arise.[7] As more

pharmacists obtain independent prescribing qualifications and community pharmacies become increasingly accessible, there is potential for these expanded roles to help alleviate delays in the current prescribing system.[18]

One proposed solution is the development of an enhanced collective reporting system that enables community pharmacists to report drug shortages. Pharmacists frequently experience or anticipate supply difficulties before they are acknowledged by industry stakeholders or wholesalers. By capturing these early signals, a robust reporting system could serve as a crucial tool in mitigating the impact of shortages, allowing for quicker interventions and adjustments.

Additionally, the establishment of Integrated Care Board (ICB)-wide shortages steering groups could play a pivotal role in managing drug shortages. These groups would facilitate collaboration and communication among healthcare providers, ensuring a coordinated response to supply issues. Through the sharing of resources and strategies, these steering groups can effectively manage and distribute limited supplies, thereby minimising disruptions to patient care.

Moreover, these ICB-wide steering groups would enhance the ability to track and predict shortages, allowing for proactive measures to be taken. They also strengthen relationships between primary and secondary care providers, which can streamline patient referrals and improve continuity of care. The overall benefits of these groups include improved resilience, optimised resource utilisation, and enhanced patient safety and outcomes during periods of drug shortages.

The collective efforts of pharmacists, healthcare providers, and policymakers are essential to address the ongoing issue of drug shortages. By empowering pharmacists with the ability to amend prescriptions and implementing robust reporting and collaborative systems, the healthcare system can improve its response to supply challenges, ultimately ensuring better patient care and safety.

Conclusion

Drug shortages in England have created a significant crisis with far-reaching consequences for patients, healthcare providers, and pharmacists. Patients are at increased risk of health complications due to delays or unavailability of essential medications, while the healthcare system faces mounting costs and complex logistical challenges that strain resources and operational efficiency. Pharmacists, who play a pivotal role in managing these shortages, are burdened with increased workload, stress, and ethical dilemmas, often operating without adequate support or recognition for the additional efforts required.

Addressing this issue demands a comprehensive and coordinated response involving healthcare providers, pharmacists, policymakers, and the government. Implementing Integrated Care Board (ICB)-wide shortage steering groups presents a strategic solution by enhancing communication, facilitating resource sharing, and enabling a cohesive response to supply disruptions across the healthcare continuum. These groups can proactively manage and distribute limited resources, thereby safeguarding patient care and minimising the negative impact of shortages on health outcomes.

Furthermore, empowering pharmacists with the authority to amend prescriptions and provide alternatives during shortages would significantly reduce delays and improve the efficiency of medication management, directly benefiting patient care. This expanded role for pharmacists not only leverages their expertise but also strengthens the overall resilience of the healthcare system.

As the healthcare landscape continues to evolve, it is imperative to adopt proactive, innovative, and collaborative strategies that prioritise patient safety and system robustness. By enhancing the capacity of pharmacists and fostering integrated approaches to shortage management, the healthcare system can better navigate these challenges, ensuring that patients receive the timely and effective care they deserve. The collective efforts of all stakeholders are crucial in creating a more resilient, responsive, and patient-centred healthcare environment that can withstand the pressures of ongoing and future medication shortages.

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The writing of this article was funded by Dr Falk Pharma

The role of pharmacists and pharmacy teams in supporting an integrated care pathway to improve management of eosinophilic esophagitis in adults

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Abstract

The role of pharmacists and pharmacy teams in supporting an integrated care pathway to improve management of eosinophilic oesophagitis in adults

Mrs Jyotika Singh,[1] Dr Hasan Haboubi,[2] Mr Rupesh Thakkar,[3] Dr Jason Dunn,[4] Ms Jemma S. Carter,[5] Professor Anjan Dhar,[6] and Professor Stephen Attwood.[7]

Introduction

Eosinophilic oesophagitis (EoE) is a chronic condition characterised by solid-food dysphagia and food bolus obstruction due to eosinophilic infiltration of the oesophageal epithelium and submucosal fibrosis. Suboptimal management includes delayed diagnosis, inappropriate referral, and ineffective treatment, leading to repeated food bolus obstructions and hospital attendances, increased resource use, and impaired quality of life.

Methods

Expert group meetings were convened to discuss how to optimise the diagnosis and management of EoE in the UK.

Results

An integrated care pathway was developed. Hospital and community pharmacists can support this pathway by identifying patients with persistent oesophageal symptoms which could be suggestive of EoE, such as patients with episodes of acute food bolus obstruction, persistent difficulty swallowing while eating and adaptions to eating habits.

Pharmacists can also help ensure PPIs are stopped prior to endoscopic biopsies being taken and directing prescribers towards use of appropriate licensed treatments for induction and maintenance of remission, particularly budesonide orodispersible tablet, developed specifically to treat EoE; and ensuring budesonide orodispersible tablet is accessible for induction and maintenance of remission, with follow-on prescribing ideally through primary care.

Discussion

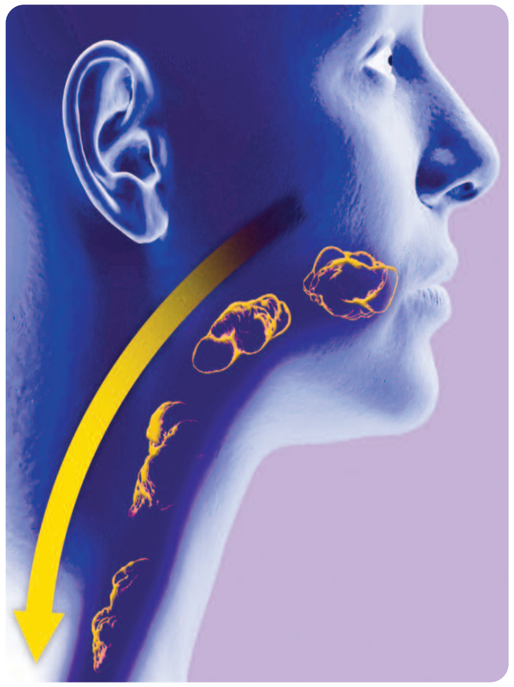
Pharmacists have an important role ensuring that patients with EoE receive optimal care and treatment and can contribute at multiple points in a new integrated care pathway to ensure patients are diagnosed more quickly and receive and continue appropriate treatment.

Conclusion

Supporting the pathway will facilitate optimal diagnosis and management of EoE, improve therapeutic outcomes, prevent complications, reduce emergency attendances, and improve quality of life.

Key words

budesonide orodispersible tablet, dysphagia, eosinophilic oesophagitis; food bolus obstruction; guidance



Introduction

Eosinophilic esophagitis (EoE) is a chronic progressive inflammatory condition of the oesophagus in which eosinophils infiltrate the oesophageal epithelium.[1–7] Although eosinophils are the hallmark of the inflammatory reaction, mast cells, dendritic cells, T-cells and activated fibroblasts are also involved.[8] Inflammation in the oesophagus leads to a swollen, oedematous mucosa and oesophageal dysmotility, which causes dysphagia.[1–4,6,7,9–11] Submucosal fibrosis develops as inflammation progresses, and the oesophagus becomes non-compliant, which can lead to strictures, narrow bore oesophagus, food bolus obstruction, and swallowing-/non-swallowing-related chest pain.[1,4,6,7,9,11]

Although EoE can present at any age, the incidence rises during adolescence and peaks in early adulthood.[4,8,11] It is more common in men, white people, and people with an affected first-degree relative.[4,8,9,11] Pooled estimates of global annual incidence and prevalence are 5.3 and 40/100,000 population, respectively,[4] but US and European prevalence rates are much higher at 79–118/100,000 population.[5,7] EoE is the second most common inflammatory oesophageal disease and causes >50% of food bolus obstructions, which are one of the most common gastrointestinal emergencies.[4,6,8–10] Two-thirds of patients have other atopic diseases such as asthma, rhinitis, and eczema.[9,11]

Patients typically have EoE for many years and become used to being aware of food travelling down their oesophagus.[4,10] They may adapt their eating to avoid these sensations – for example, drinking large amounts of water or only eating foods known to travel smoothly down the oesophagus.[10] Patients are prolonged chewers, slow to eat, and last to finish meals, so they avoid eating out, resulting in social isolation, anxiety, and reduced quality of life.[4,9,11]

After endoscopy with biopsy evidence of eosinophilia meeting the diagnostic threshold for EoE, patients require treatment to induce remission. Before budesonide orodispersible tablet (ODT) – a corticosteroid formulation with oesophageal delivery – was licensed for EoE in the UK in 2018,[12,13] numerous poorly effective approaches were used to manage symptoms, including elimination diets, off-license proton pump inhibitors (PPIs) and asthma corticosteroids, and investigative biologics targeting type 2 inflammation.[9] Currently, budesonide ODT is the only licensed treatment for EoE in the UK and is preferred unless patients with mild and intermittent symptoms opt to trial dietary restriction or PPIs. It is also licensed and available across Europe, the Middle East, Australia, New Zealand, Canada, and many other countries. As EoE is chronic and recurs quickly after treatment is withdrawn, lifelong maintenance treatment is essential.[8,14,15]

Management of EoE in the UK is suboptimal throughout the pathway due to lack of awareness in primary and secondary care. This leads to delayed diagnosis, repeat food bolus obstructions and hospital attendances, inappropriate referral and treatment, increased healthcare resource use, and impaired quality of life. Two expert group meetings were convened to discuss how management of EoE in the UK can be improved and new evidence since guidelines were published.[8,11] Figure 1 and Table 1 summarise the integrated care pathway for diagnosis and management of EoE developed following these meetings.[16] This paper focuses on where pharmacists can contribute to improving management of EoE in this pathway.

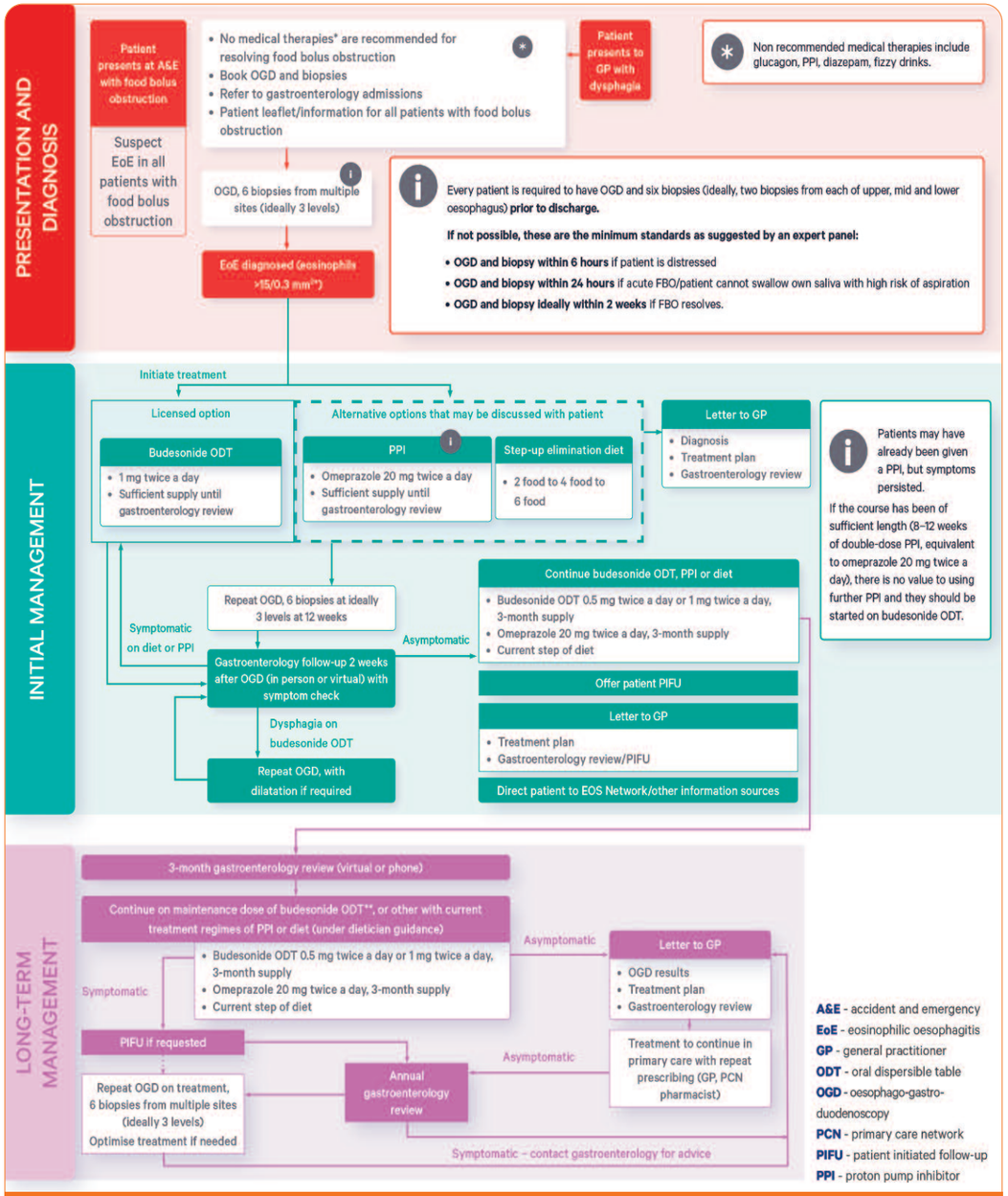


Figure 1. Integrated care pathway for management of eosinophilic oesophagitis (EoE).[16] A&E, accident and emergency; ENT, ear, nose, and throat; GP, general practitioner; ODT, oral dispersible tablet; OGD, oesophago-gastro-duodenoscopy; PCN, primary care network; PIFU, patient-initiated follow-up; PPI, proton pump inhibitor

Step of pathway	Recommendations
Presentation of EoE	• Consider EoE in all patients with dysphagia or food bolus obstruction.[8]
Acute management of food bolus obstruction	• Perform chest x-ray only in patients in distress and chest/abdominal computed tomography only if patients have surgical emphysema or oesophageal perforation is suspected.[8,17] • Clear food bolus obstruction endoscopically. · Perform immediate dilatation if indicated.[8] • Do not start PPIs or conservative treatments such as baclofen, glucagon, salbutamol, diazepam, or fizzy drinks.[8,9]
Referral for suspected EoE	
Emergency department	• Do not discharge patients with food bolus obstruction without arranging further investigation or follow-up, even if obstructions resolve spontaneously.[8,9,18] • Refer urgently to gastroenterology.[8,9] • Before the patient leaves the emergency department, request esophago-gastro-duodenoscopy, including oesophageal biopsies: - within 6 hours if patients are distressed - within 24 hours if patients have acute obstruction or cannot swallow their own saliva due to the high risk of aspiration - within 2–4 weeks if obstruction resolves to ensure EoE is diagnosed before another event. • Avoid PPIs if biopsies cannot be obtained during acute management to avoid masking eosinophilia at later biopsy.[19]
Primary care	• Refer patients with symptoms of airways blockage, difficulty breathing, distress, or continuous coughing as an emergency or to the ear, nose, and throat department. • Refer all patients with dysphagia describing symptoms of food stuck in their oesophagus to gastroenterology for further investigation and endoscopy. • Book esophago-gastro-duodenoscopy within 2–4 weeks at a service that performs biopsies. • Do not start PPIs.[8] · Stop PPIs 2–3 weeks before endoscopy to avoid masking eosinophilia.[8,19] • Give patients an information leaflet to explain the suspected diagnosis of EoE and that it is treatable, so they expect follow-up and understand the importance of endoscopy, even if the obstruction resolves.
Diagnosis of EoE	• Diagnose EoE through esophago-gastro-duodenoscopy with biopsies, even if the oesophagus looks normal.[4,9,11,18] • Take ≥6 biopsies from multiple sites (ideally 3).[4,9,11,20] • EoE is confirmed by 15 eosinophils per 0.3 mm² of oesophageal epithelium.[4,9]
Induction of remission	• Discuss the efficacy and limitations of all treatment options for EoE with the patient. • Budesonide orodispersible tablet was developed specifically for EoE.[13]

Table 1. Recommendations for the management of eosinophilic oesophagitis

Step of pathway	Recommendations
Induction of remission	• Systemic steroids, swallowed fluticasone, and other immunosuppressants are not recommended.[8,10,11] • PPIs have variable efficacy, and their use is off-licence.[8–11] • Dietary approaches are lifelong, of limited efficacy, burdensome for patients, and involve multiple endoscopies.[8–11] • Monoclonal antibodies and biologics are reserved for clinical trials and not routine practice for EoE in the UK.[8,11]
Budesonide ODT	• Budesonide orodispersible tablet offers reliable efficacy and should be recommended in patients with frequent, daily symptoms. • If a patient opts to try budesonide orodispersible tablet, prescribe sufficient supply for 1 mg twice daily until gastroenterology follow-up. • Initial repeat esophago-gastro-duodenoscopy is not required in patients taking budesonide orodispersible tablet. • Arrange gastroenterology follow-up at 14 weeks to assess response and symptoms. • Arrange repeat esophago-gastro-duodenoscopy for patients with persistent dysphagia and obtain consent for dilatation if required.
PPIs	• PPIs usually fail and should be first-line treatment only in patients with mild, intermittent symptoms and according to patient preference. • If patients opt to try PPIs, prescribe double the usual dose (equivalent to 20 mg omeprazole twice daily) for 8–12 weeks[8] with sufficient supply until gastroenterology follow-up. • Book esophago-gastro-duodenoscopy 12 weeks after treatment is started. • Arrange gastroenterology follow-up at 14 weeks to assess response and symptoms. • Switch patients with persistent symptoms after an 8–12-week trial of double-dose PPI to budesonide orodispersible tablet and arrange gastroenterology follow-up.
Diet	• Diet usually fails and should be first-line treatment only according to patient preference and with consideration of the burden in patients with mild, intermittent symptoms. • If patients opt to try diet: - Recommend a step-up approach (2-food to 4-food to 6-food).[8,21] - Arrange dietician support for elimination/reintroduction.[10] - Arrange esophago-gastro-duodenoscopy 6–12 weeks after each food reintroduction.[8] • Book esophago-gastro-duodenoscopy 12 weeks after treatment is started. • Arrange gastroenterology follow-up at 14 weeks to assess response. • If the patient has persistent symptoms, switch to budesonide orodispersible tablet and arrange further gastroenterology follow-up.
Maintenance of remission	• Budesonide is licensed for maintenance therapy in patients with EoE achieving remission on budesonide orodispersible tablet.[13] - The recommended dose for maintenance of remission is 1 mg budesonide as one 0.5-mg tablet in the morning and evening or 2 mg budesonide as one 1 mg tablet in the morning and evening.[13] - 1 mg budesonide twice daily is recommended for maintenance in patients with long-standing disease or high oesophageal inflammation in acute disease.[13] - Duration of maintenance therapy is determined by the treating physician.[13] • Send a letter to the general practitioner to confirm esophago-gastro-duodenoscopy results, treatment plan, patient-initiated follow-up is in place, and timing of next gastroenterology review. - Repeat prescribing of budesonide orodispersible tablet should be undertaken by general practitioners if possible or via gastroenterology if not. - General practitioners should manage repeat prescribing of PPIs. • Patients should have annual follow-up with gastroenterology: - Continue budesonide orodispersible tablet, PPI, or diet in asymptomatic patients:[8] • Provide 3-month supply of budesonide orodispersible tablet 0.5 mg twice daily or 1 mg twice daily or PPI. - Continue with current step of diet. • If doctor and patient agree not to use maintenance therapy, review the patient after 3 months due to the risk of recurrence.[22,23] • Repeat esophago-gastro-duodenoscopy annually if symptoms persist or recur or if treatment withdrawal is planned.

Table 1. Recommendations for the management of eosinophilic oesophagitis

Presentation, referral, and diagnosis of EoE

Presentation

In about one-third of patients, acute food bolus obstruction requiring emergency hospital attendance is the first presentation of EoE.[4,8] In the remainder, dysphagia is of slower onset, with progressive dysphagia and repeat episodes of milder, self-resolving food bolus obstruction.[2–4,8]

Potential role for pharmacy teams

- Be alert for patients repeatedly prescribed or requesting over-the-counter medicines for upper GI symptoms, including dysphagia that is worsening or has persisted over a long period of time (which can be years), particularly in combination with drugs for allergic conditions.
- Be aware of dysphagia symptoms, particularly if the patient is asking to change medication formulation – for example, from tablet to capsule or liquid preparation.
- Enquire about symptoms that could indicate EoE, particularly if they have been ongoing for years, and suggest a GP consultation:
  - Ask if the patient had hospital attendances due to a food bolus obstruction.
  - Ask if symptoms are ameliorated by changing diet or eating habits such as increasing frequency of chewing and fluid intake with meals.

Referral

Awareness of EoE is increasing among general practitioners, who may refer patients with a feeling of food stuck in their throat to gastroenterology for endoscopy. However, other conditions may be suspected initially due to the nature of symptoms. Partial symptom relief with PPIs in some patients may compound misdiagnosis.

Patients may present in the emergency department, and clinicians often do not refer to gastroenterology or for endoscopy, especially if food bolus obstructions resolve spontaneously.[24] They may assume the obstruction is in the throat and refer to ear, nose, and throat services, which are not set up to diagnose EoE.[9] This can delay diagnosis, leading to repeat emergency attendances. Further food bolus obstruction typically develops in untreated patients within 3 months[25–29] and failure to follow-up predicts recurrence.[30]

Potential role for pharmacy teams

- Be alert for patients still experiencing upper GI symptoms that may indicate EoE despite ongoing prescriptions for PPIs.
- Review the prescribing of PPIs in patients suffering with food bolus obstruction or suspected EoE, as PPIs may mask or dampen the symptoms.

Diagnosis

Diagnosis of EoE requires >15 eosinophils per 0.3 mm^2 (formerly per high-power field) in the oesophageal squamous epithelium.[2,4,8,9,11,31,32] Patients with suspected EoE or food bolus obstruction therefore require esophago-gastro-duodenoscopy with biopsies to confirm diagnosis.[4,8,9] Use of PPIs prior to endoscopy can mask eosinophilia and compromise diagnosis.[8,19]

Potential role for pharmacy teams

- Ensure that patients referred for esophago-gastro-duodenoscopy for suspected EoE stop PPIs at least 3 weeks before endoscopy to avoid masking eosinophilia.[8,19]
- Counsel patients on when to stop PPIs prior to esophago-gastro-duodenoscopy.

Acute management of food bolus obstruction

Endoscopic removal has success rates >95% with minimal complications and is recommended for all patients within 24 hours to increase the chance of removal and decrease complications; it is urgently required in patients unable to swallow their own saliva.[33] Drug and conservative therapies (e.g. baclofen, glucagon, salbutamol, benzodiazepines, and fizzy drinks) are not recommended, as they do not reliably resolve food bolus obstruction and risks may outweigh benefits.[8,9,19]

Potential role for pharmacy teams

- In the A&E setting, ensure that any patients with food bolus obstruction and suspected EoE are not prescribed PPIs or conservative treatments such as baclofen, glucagon, salbutamol, diazepam, or fizzy drinks[8,9,19] but are fully investigated for EoE.

Induction of remission

After diagnosis of EoE, the efficacy and limitations of all treatment options should be discussed with the patient (table 1).

Potential role for pharmacy teams

- Ensure prescribers understand the efficacy and limitations of all treatment options for EoE. Budesonide ODT was developed specifically to treat EoE.
- Pharmacists are critical for patient education on how to take budesonide ODT properly.

Corticosteroids

As in other allergic diseases, EoE is relatively responsive to corticosteroids.[24] Topical corticosteroids have also been shown to reduce oesophageal remodelling.[22] Trials using different agents, delivery systems, and dosages show at least partial symptomatic response in about 60–87% of adults and complete histological response in a similar proportion.[13,14,22,34–36] Use of systemic steroids, e.g. prednisolone, is not recommended because of lack of efficacy and adverse effects.[24]

Fluticasone propionate inhalers have often been prescribed off license for administration by swallowing the spray, so the drug gets into the oesophagus. Although this has some effect in about 50% of patients,[36] many struggle with swallowing the inhaled dose. GPs and pharmacists are reluctant to prescribe off-license, which requires specific considerations, or do not understand that the drug needs to be swallowed and prescribe and dispense as an inhaled dose. With budesonide ODT now licensed and effective for EoE,[13,14] fluticasone inhalers should no longer be used in patients with EoE.

Budesonide is a non-halogenated glucocorticosteroid that primarily acts through an anti-inflammatory action via binding to the glucocorticoid receptor.[13] Budesonide ODT allows targeted delivery of budesonide for patients with EoE, with high topical anti-inflammatory activity and low systemic effects.[14] It was developed on the basis that a mild effervescent reaction initiated by water would allow direct oral application of a tablet placed on the tip of the tongue.[14] This activates in-situ disintegration of the tablet, so the dosage form disperses in the mouth.[14] After swallowing, budesonide-loaded saliva lines the mucosa of the oesophagus and delivers active substance to the site of action.[14] A surfactant in the formulation that facilitates fusion of layers and enables bioadhesion holds the active substance in the oesophagus and increases the contact time.[14]

In the treatment of EoE with budesonide ODT, budesonide inhibits antigen-stimulated secretion of proinflammatory signal molecules such as thymic stromal lymphopoeitin, IL-13 and eotaxin-3 in the oesophageal epithelium, significantly reducing the oesophageal eosinophilic inflammatory infiltrate (Figure 2).[14] Budesonide ODT is not an immediate-release form as there is no rapid systemic absorption from the lower gastrointestinal tract after being swallowed.[14] The small amounts of budesonide ODT that are absorbed are 90% metabolized through each pass of the hepatic circulation, so the systemic side-effects of steroids have not been seen with its use. Budesonide ODT therefore has high topical anti-inflammatory activity and low systemic effects.[14]

Budesonide ODT is the most effective steroid therapy currently available for EoE.12 In the EOS-1 trial, 57.6% of patients achieved clinico-histological resolution with budesonide ODT after 6 weeks compared with none taking placebo ($p<0.0001$) and 93.2% achieved histological resolution (Figure 3).[37] In the EOS-2 trial, 69.6% of patients achieved clinico-histological remission (histological 90.1%, clinical 75.1%) after 6 weeks of induction with 1 mg budesonide ODT twice daily (Figure 3) and mean peak eosinophil counts decreased by 89.0%.[38] In patients in EOS-1 who did not achieve clinico-histological remission after 6 weeks or dropped out at ≥4 weeks due to lack of efficacy, prolonging treatment to 12 weeks of led to clinico-histological remission in 84.7% of patients (Figure 3).[37]

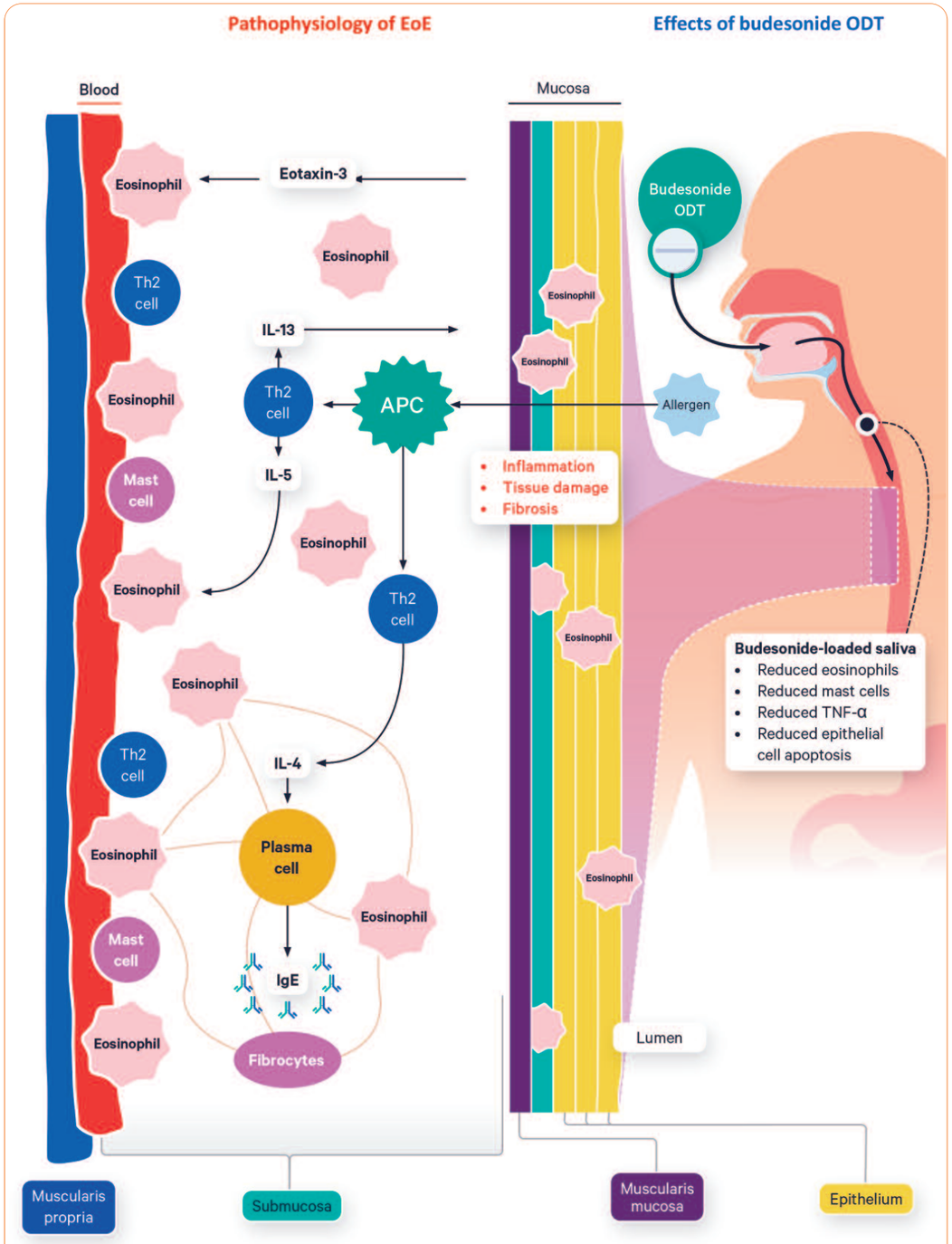
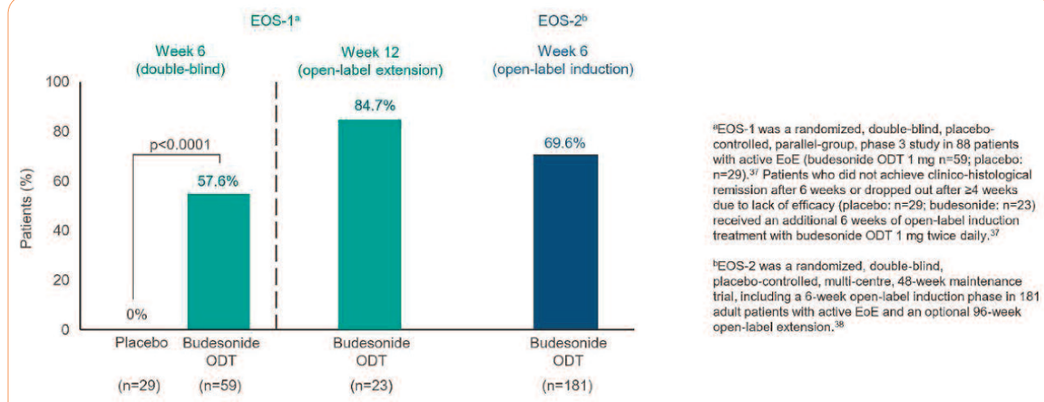


Figure 2. Pathophysiology of eosinophilic esophagitis and the effects of budesonide orodispersible tablet (ODT). APC, antigen-presenting cell; IgE, immunoglobulin E; IL, interleukin; TGF-β, transforming growth factor beta; Th2, T-helper 2; TNF-α, tumour necrosis factor alpha



[a]EOS-1 was a randomized, double-blind, placebo-controlled, parallel-group, phase 3 study in 88 patients with active EoE (budesonide ODT 1 mg n=59; placebo: n=29).[37] Patients who did not achieve clinico-histological remission after 6 weeks or dropped out after ≥4 weeks due to lack of efficacy (placebo: n=29; budesonide: n=23) received an additional 6 weeks of open-label induction treatment with budesonide ODT 1 mg twice daily.[37]

[b]EOS-2 was a randomized, double-blind, placebo-controlled, multi-centre, 48-week maintenance trial, including a 6-week open-label induction phase in 181 adult patients with active EoE and an optional 96-week open-label extension.[38]

Figure 3. Induction of remission with budesonide orodispersible tablet (ODT) in patients with eosinophilic oesophagitis (EoE): clinico-histological remission at Weeks 6 and 12 in EOS-1 (A) and at Week 6 in EOS-2 (B). Adapted from Lucendo *et al*[37] and Miehlke *et al*[38]

Accordingly, although the licensed treatment duration is 6–12 weeks,[13] usual duration of induction in clinical practice is 12 weeks. In June 2021, the National Institute for Health and Care Excellence (NICE) in the UK recommended budesonide ODT to induce remission of EoE in adults.[39] Box 1 describes how budesonide ODT should be used for EoE.

Induction of remission

- Budesonide ODT should be initiated by a gastroenterologist or physician experienced in diagnosis and treatment of EoE.[13]
- Recommended daily dose: 2 mg budesonide as one 1-mg tablet in morning and one 1-mg tablet in evening.[13]

Maintenance of remission

- Recommended daily dose for maintenance of remission depends on individual patient requirements.[13]
  - 1 mg budesonide as one 0.5-mg-tablet in morning and one 0.5-mg-tablet in evening

  or
  - 2 mg budesonide as one 1-mg-tablet in the morning and one 1-mg-tablet in the evening.
    - * Recommended for patients with long-standing disease history and/or high extent of oesophageal inflammation in acute disease state.[13]
- Duration of maintenance therapy determined by treating physician.[13]
- No studies on intermittent bolus therapies for EoE, only continuation of maintenance therapy.[22,23]
- If patient and doctor choose not to have maintenance therapy, review patient after 3 months because more than 50% will have recurrence.[22,23]

Administration of budesonide ODT

- Take immediately once removed from the blister package.[13]
- Place on tip of tongue and gently press against top of the mouth, where it disintegrates over 2–20 minutes.[13]
- Should not be taken with liquid or food.[13]
- ≥30 minutes before eating, drinking or performing oral hygiene.[13]
- ≥30 minutes before or after oral solutions, sprays or chewable tablets.[13]
- Should not be chewed or swallowed undissolved.[13]
- Should be swallowed little by little while the ODT disintegrates.[13]

Box 1. How to use budesonide ODT for EoE

Potential role for pharmacy teams

- Ensure that patients are not prescribed unlicensed suboptimal therapy such as systemic steroids and swallowed fluticasone.
- Ensure prescribers and patients understand that budesonide ODT was developed specifically for EoE.13
- Ensure patients understand how to use budesonide ODT, including not to wash mouth/drink water after swallowing.
- Ensure budesonide ODT is accessible and can be continued regardless of whether repeat prescriptions are issued via the GP or hospital.
- Ensure patients are aware that they do not need to stop/interrupt budesonide ODT treatment if they are prescribed nystatin for budesonide ODT-induced oral/oesophageal candidiasis.

PPIs

PPIs inhibit eotaxin-3 and/or reduce acid in the 10% of patients with EoE and symptomatic gastro-oesophageal reflux disease.[8,9,40] They are ineffective in maintaining remission in patients with histological response8 but may improve reflux symptoms. In a cohort study involving 600 patients, primary treatment with PPIs resulted in histological remission (<15 eosinophils/hpf) in 49% of patients and deep histological remission in 38%, with some improvement in 71% of patients.[41] In patients who do achieve histological response, PPIs are ineffective in maintaining remission.[8] In a long-term study in 389 patients with newly diagnosed EoE, 138 (35.5%) had an initial response to PPIs, with only 22% of the initial responders having a long-term histological response.[42] PPIs have no proven effect on fibrosis and only partially improve symptoms in non-fibrotic EoE.[8] Box 2 describes how to use PPIs if patients opt to trial these drugs.

Induction of remission

- Double the usual dose of PPI, equivalent to 20 mg omeprazole, twice daily, for 8–12 weeks.
- If patients have already trialed a course of 8–12 weeks of double-dose PPI, equivalent to omeprazole 20 mg twice daily, there is no value to using further PPI and they should be started on budesonide ODT.

Maintenance of remission

- Continue double-dose PPI, equivalent to 20 mg omeprazole, twice daily for as long as patients remain asymptomatic.

Box 2. How to use PPIs for induction and maintenance of EoE

Potential role for pharmacy teams

- Be alert for long courses of double-dose PPIs beyond 12 weeks in patients with EoE.

Dietary intervention

As EoE is thought to occur when the oesophageal mucosa reacts to environmental antigens, mostly in foods,[6,8–11] dietary intervention seems logical (Box 3)[8,41] but is variably effective. Intensive support from experienced dietitians is required during elimination and reintroduction, with endoscopies at baseline and after each reintroduction.[8,43] Diets must be maintained lifelong to maintain remission, but long-term adherence is poor.[8]

The six food types most commonly associated with allergy are milk, wheat, eggs, soy, nuts, and seafood.[21] Milk and wheat are the most frequently implicated and eliminating these (2-food elimination) has a 30% success rate. In a randomized trial, neither 1- nor 6-food elimination diets restored normal histology or relieved symptoms of EoE.[43] Six-food elimination resulted in higher histological remission rates than 2- or 4-food elimination but with lower compliance and more endoscopies.[8,21]

Induction of remission

- Request support from an experienced dietitian
- Step up from eliminating 2 foods to 4 foods to 6 foods21
  - 2-food elimination: milk and wheat
  - 4-food elimination: eggs and soy
  - 6-food elimination: nuts and seafood
- OGD before eliminating foods
- OGD after each individual food is reintroduced

Maintenance of remission

- Continue step of diet that was effective to achieve remission for as long as patients remain asymptomatic

Box 3. How to use elimination diets for EoE

Biologics

Investigative biologics targeting type 2 inflammation showed initial promise, but results have been disappointing.[8,11,44] A systematic review that included nine studies comparing biologics with placebo for induction of remission found that:[44]

- Biologics compared to placebo may not lead to clinical symptom improvement when reported as a dichotomous outcome and may lead to an increase in clinical symptom improvement as a continuous outcome (table 2).
- Biologics lead to a large increase in histological improvement when reported as a dichotomous outcome, but their effect is uncertain when reported as a continuous outcome (table 2).
- Biologics may not increase endoscopic improvement (dichotomous outcome), but their effect is uncertain when measured as a continuous outcome.
- Withdrawals due to adverse events as a dichotomous outcome may occur as frequently with biologics as with placebo.

No biologic is licensed for treatment of EoE in the UK but some are used in the UK to manage co-existent atopic disease. More recent data have shown some improvement in histological parameters leading to license approval in the US, but biologics are still limited by the fact that patients need to self-inject, the risk of reaction at the injection site, and lower histologic remission rates to budesonide ODT.[45]

Potential role for pharmacy teams

- Be alert to prescriptions for biologics to treat patients with EoE, as these drugs should not be routine practice in the UK and should be reserved for clinical trials.

Maintenance of remission

Maintenance therapy is recommended to reduce the risk of recurrent food bolus obstruction[8,24] as relapse is common after treatment stops.[8,14,15] In one study, the overall recurrence rate following cessation of inhaled fluticasone propionate and oral viscous budesonide was 57% within 1 year, with median time to symptom recurrence of 224 and 263 days for fluticasone and oral viscous budesonide, respectively.[22] In a study comparing two doses of budesonide ODT and placebo, median time to clinical relapse following treatment cessation was >350 days with budesonide ODT 1.0 mg bd, >354 days for budesonide ODT 0.5 mg bd and 87 days for placebo.

After 48 weeks of treatment in EOS-2, 73.5% and 75% of patients receiving budesonide ODT 0.5 mg and 1.0 mg twice daily, respectively, were in persistent remission compared with 4.4% of placebo patients ($p<0.001$ for both budesonide doses versus placebo) (Figure 4).[22] After 96 weeks of treatment in patients still in remission after 48 weeks and relapsing patients in whom clinical remission was re-induced by 6 weeks of budesonide ODT 1 mg twice daily, 86.1% of patients receiving maintenance budesonide ODT 0.5 mg twice daily maintained clinical, histological, and endoscopic remission (Figure 4) and 78.8% of patients who received an optional biopsy were in deep histological remission (no eosinophils in any

Drug class	Number of Studies	Participants Total	Participants Biologic	Participants Placebo	Events Biologic	Events Placebo	Risk Ratio (95% CI)	p value
Clinical improvement at study endpoint								
All drugs	5	410	281	129	169	129	1.14 (0.85–1.52)	0.38
Anti-IL-13[a] and anti-IL-4r[b]	3	172	106	66	66	25	1.37 (1.02–1.85)	0.04
Anti-IL-5[c]	2	238	175	63	103	40	0.92 (0.73–1.15)	0.45
Histological improvement at study endpoint								
All drugs	8	925	586	339	394	39	6.73 (2.58–17.52)	0.0001
Anti-sialic acid-binding Ig-like lectin 8[d]	1	276	184	91	166	10	8.30 (4.61–14.93)	<0.00001
Anti-IL-13[a] and anti-IL-4r[b]	5	421	228	184	124	9	9.01 (4.88–16.62)	<0.00001
Anti-IL-5[c]	2	237	174	63	104	20	1.75 (0.36–1.66)	0.003

Table 2. Biologics for induction of remission in eosinophilic oesophagitis (EoE): Clinical improvement and histological improvement subgrouped by mechanism[44]

[a]RPC4046 (cendakimab); AQX576 (dectrekumab). [b]Dupilumab. [c]Mepolizumab, reslizumab. [d]Lirentelimab.

biopsy) (Figure 4).[23] No loss of efficacy or increase in side-effects was observed up to 3 years.[23]

The development process for NICE technology appraisal began in 2018[46] following initial licensing of budesonide ODT for induction of remission of EoE in the UK.[13] Although TA708[39] was published after maintenance of remission was licensed in March 2021,[13] it does not include a recommendation for maintenance of remission as that was not part of the original scope. Until NICE undertakes a new appraisal of budesonide ODT for maintenance and offers its opinion, the NHS in the UK is obligated to provide access to the only product licensed for EoE in the UK in line with its approved indication of induction and maintenance of EoE.[13] Budesonide ODT is also licensed for maintenance across all Europe, Australia, New Zealand, Canada, Brazil, and many countries in the Middle East. Given the unreliable control achieved with PPIs and diet, gastroenterologists managing patients with EoE will increasingly prescribe budesonide ODT, and shared care protocols are in place in many systems to ensure that patients have continued access to treatment.

Potential role for pharmacy teams

- Ensure prescribers are aware that NICE recommends budesonide ODT for induction of remission and that, in the absence of NICE opinion on maintenance use of budesonide ODT, patients in the UK should have access to this product in line with its approved indication of maintenance of EoE.[13]
- If accessing or continuing treatment is an issue, ensure that shared care protocols are in place for your locality.
- Highlight when unlicensed suboptimal treatments are being used for patients with EoE.

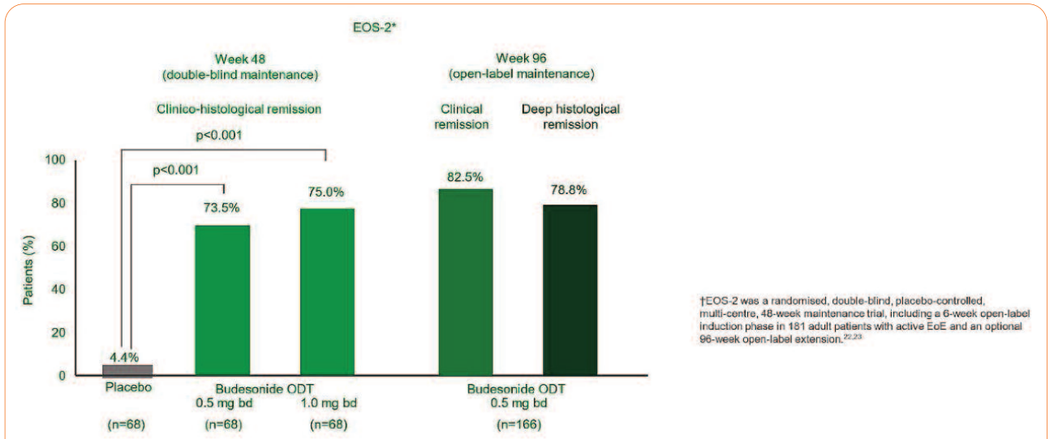


Figure 4. Maintenance of remission with budesonide orodispersible tablet (ODT) in patients with eosinophilic esophagitis: clinico-histological at Week 48 (A) and clinical and deep histological remission at Week 96 (B) of EOS-2. Adapted from Straumann *et al*[22] and Schlag *et al*[23]

Patient support and information

Patients should be signposted to resources to educate them on EoE, such as those provided by the EOS Network or patient information leaflets developed locally. Such additional information and support will help patients understand that EoE is lifelong but treatable, so they understand the importance of attending endoscopy and follow-up and the need for continued treatment, even when feeling well.

Potential role for pharmacy teams

- Signpost patients to the EOS Network to increase their understanding of the condition.
- Provide locally developed patient information leaflets to guide them on their journey with the condition through the local system.

Discussion

Pharmacists have an important role ensuring that patients with EoE receive optimal care and treatment. We encourage them to become familiar with our integrated care pathway,[16] which will improve awareness of EoE and optimise its management in primary and secondary care by ensuring patients are diagnosed more quickly and receive and continue appropriate treatment. Pharmacists should be alert for patients with diagnosed or suspected EoE, encourage prescribers in the UK to initiate and maintain appropriate treatment in line with licensed treatments and NICE guidance, and discourage use of suboptimal therapies. We also encourage pharmacists in the UK to use and disseminate our templates for shared care protocols to facilitate repeat prescribing of budesonide ODT by primary care and formulary applications for budesonide ODT as maintenance, which are available at https://know-eoe.co.uk/.[16] This will allow patients to obtain their treatment in primary care rather than through repeat visits to hospital. Our pathway has been developed for the NHS in the UK, but the underlying principles can be applied to healthcare systems elsewhere.

Acknowledgements

The authors wish to recognise Kumar Basu, Joseph Cooney, Amir Jehangir, Helen Morgan, Maxton Pitcher, Marion Sloan, and Terry Wong for their contributions during the expert group meetings and Kieran Brown of HSJ Advisory for project management support.

Funding

Development of the integrated care pathway for EoE was funded by Dr Falk Pharma and developed by an expert clinical group with the support of HSJ Advisory (formerly Wilmington Healthcare). Medical writing support by Jemma S. Carter was funded through HSJ Advisory (formerly Wilmington Healthcare) by Dr Falk Pharma and Jyotika Singh is a pharmacist and an employee of HSJ Advisory (formerly Wilmington Healthcare).

Declaration of interests

The integrated care pathway for EoE has been independently developed by the expert group members with the support of HSJ Advisory (formerly Wilmington Healthcare). The expert group members received honoraria from Dr Falk for their involvement in the development of the integrated care pathway. SA has been a member of advisory boards of Dr Falk Pharma, AstraZeneca, Regeneron/Sanofi, MSD, BristolMyersSquibb, and Eupraxia. KB has received fees for advisory boards for Dr Falk Pharma. JSC's work on this paper was funded by Dr Falk through HSJ Advisory (formerly Wilmington Healthcare). JC has received speaker fees from Dr Falk Pharma. AD has received honoraria from Dr Falk Pharma for advisory boards and speaker fees. JD has received honoraria from Dr Falk Pharma for advisory boards. HH is a clinical advisor for Dr Falk Pharma. AJ has received honoraria for speaker meetings from GlaxoSmithKline and AstraZeneca and advisory boards from Dr Falk. MP received honoraria for advisory boards from Dr Falk. MS received honoraria for advisory boards from Dr Falk. TW has received lecture fees and advisory board fees from Dr Falk Pharma. JS is an employee of HSJ Advisory (formerly Wilmington Healthcare).

Author contributions

The authorship of this paper includes members of two expert groups convened to discuss the pathway, a senior principal consultant from HSJ Advisory (formerly Wilmington Healthcare), who facilitated the process, and an independent medical writer, who drafted this article. An initial pathway was developed based on discussions of an expert group at a first meeting and desk research. The draft pathway was then discussed at a meeting with a second expert group. Feedback from both groups was incorporated into the pathway and supportive information. The process was facilitated by HSJ Advisory (formerly Wilmington Healthcare).

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