

PM Healthcare

JOURNAL

Summer 2022 | Issue 01





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Ref: 1. NHS BSA. Drug Tariff. <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff> Accessed: October 2022. **2.** UK General Practice Prescribing Data July 2021 - June 2022. <https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>. Carbon Footprint Limited. Life Cycle Assessment Report 2022. Data on File. **4.** Certifications of carbon neutrality for Luforbec 100/6 & 200/6 pMDI. **5.** MIMS: Inhaler Carbon Emissions. <https://www.mims.co.uk/inhaler-carbon-emissions/respiratory-system/article/1739635>. Accessed: October 2022. **6.** Luforbec 100/6 pMDI. Summary of Product Characteristics (SPC). Lupin Healthcare UK Limited. **7.** Luforbec 200/6 pMDI. Summary of Product Characteristics (SPC). Lupin Healthcare UK Limited. Fostair[®] is a registered trademark of Chiesi Ltd

Now is the hour

Author

Ted Butler, *Chairman of the Editorial Board, PM Healthcare Journal.*

Throughout time there have always been moments when a set of circumstances collude to create a change.

Delivering healthcare in all countries of the world is demanding as populations grow older and the requirement for services reflects that situation. But add to that scenario a pandemic across the globe and all health systems show signs of being under ever-increasing pressure.

Having contributed an outstanding performance in vaccination, all healthcare professionals (HCPs) are now experiencing another surge of patient needs as medical conditions that could not be treated during lockdown emerge in practices and hospitals.

Most governments across the world will be reviewing the provision of services to support their communities, as the financial burden on the state created by Covid is like nothing seen before. What are the most appropriate medicines for conditions? Where should care be delivered? Who has which role in the new world? Nothing will be 'off the table'.

The actions of some HCPs during the pandemic have unquestionably raised their profile in relation to maximising their input to patient care. Of particular relevance are the many anecdotal stories that have been received of community pharmacies remaining open and providing patient advice whilst it became increasingly difficult to obtain a face-to-face appointment within general practices.

In England we are seeing probably the biggest reorganisation of the NHS since its inception. The creation of Integrated Care Systems (ICSs), with responsibility for budgets across primary and secondary care, will move the system into alignment with the health board approach that we have seen in the Celtic nations for many years.

This massive change will challenge HCPs to communicate more effectively across the divide and will demand closer working between professionals who may not have had a working relationship together in the past.

Communication skills and project management will undoubtedly top the list of skills required. That, however, is simplifying the number of elements for the new way of working that will face HCPs in the future.

As well as increased demand on the service, we will now experience in England a major change of system working. Skills that are entrenched in the business world will rise to have a greater value for cooperation between the NHS and the commercial world.

The Celtic nations should not be overlooked as challenges exist in maintaining service delivery as significant numbers of general practitioners decide to retire or leave the service. Much has been achieved in Scotland already by greater integration of community pharmacy into the delivery of patient care in health boards, and a new Community Pharmacy Contract in Wales is surely trail-blazing in its aims.

It is within this context that our new PM Healthcare Journal will seek to provide practical and timely support for NHS colleagues facing new ways of working and engaging with new colleagues.

Make no mistake – the pandemic has opened Pandora's Box for new ways of working and it is unlikely that there will be a return to the past in many aspects of service delivery.

Where will care be delivered? Who or which professions will undertake which role in patient care? How will the funding-flow for services operate? These are some of the questions we will help answer.

PM Healthcare Journal will be an integral part of our portfolio of support for HCPs through this period of change.

Stay tuned to learn about our Conferences around the UK and our Management Skills Programmes which are designed specifically for NHS Healthcare Professionals.

Welcome to the first edition of the PM Healthcare Journal

The Journal comes to you at a very challenging time in UK healthcare. Currently, it is difficult to say anything about the NHS without slipping into hyperbole – we are all very familiar with the eye-watering backlog of procedures that are a consequence of Covid and an ongoing staffing crisis affecting all care sectors. Despite the heroic and ongoing efforts of healthcare practitioners the system is very much in shock and looking for solutions.

Also, in England, we have seen the long-anticipated transition from the world of clinical commissioning groups to their replacement, integrated care systems (ICSs), the latest in what can sometimes seem to be an endless spiral of reform. This transition may have passed in the media with not so much a bang as a whimper (we do have other things to occupy us at the moment) but for those involved in the provision of healthcare the change is a significant one. Now, we see newly established ICSs very much caught up in the process of change, trying to plan and deliver services in what has become the most challenging period in the NHS's long history.

There has never been a more urgent need for the sharing of best practice, never a greater need for practical advice, professional development and education.

And this is what the Journal is all about – sharing your experiences with colleagues across the UK, providing examples of how you make things work, and promoting initiatives that support colleagues and benefit patients. This is really our aim – we want to do everything we can to help you navigate and overcome the challenges that are endemic in the system.

As well as continuing our excellent and diverse clinical content, for this edition we have some fantastic insights to share with you. A hands-on description of what the ICS structure means for pharmacy services, how one ICS implemented the Discharge Medicines Service to enhance referrals to community pharmacy, the benefits of pursuing a clinical academic career within the pharmacy profession, and a personal perspective on delivering respiratory services in a post-Covid NHS.

Of course, we can't do this without you, and the Journal can only work if we work together to create a publication that is of practical use. For this reason I would like to invite you to get in touch with me directly to share ideas for articles that you think would be of interest to our readers (in pharmacy but also wider) and also your opinions, enthusiasms and fears for the future.

If it is of interest to you, we will cover it.

Many thanks.

John Chater
Editor – PM Healthcare Journal
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- Innovative pharmacy services in the NHS Long Term plan
- Tackling the complex challenges on medicine use across boundaries
- Best value for national spend on medicines
- Provision of better services through a collaborative and integrated approach
- Effective utilisation of the workforce
- Meeting of demand for new pharmacy roles in primary and secondary care
- The prevention of duplication and silo working

Where do you see the most significant opportunities for pharmacy in the new ICS?

For pharmacy, we can see significant opportunities in establishing a more joined-up workforce and practice development which will allow for a more supportive environment for pharmacists and technical staff to thrive and operate in. A joined up workforce will allow greater efficiencies whilst advanced practicing staff could support in creating capacity e.g. utilising pharmacy independent prescribers much more to free up time for medical prescribers.

We can extend this kind of integration to other areas as well, for example in the creation of shared formularies that extend across sectors, the management of high-cost drugs and the sharing of prescribing expertise and medicines value programmes at the system level.

What 'early wins' could there be for the pharmacy profession?

For quick wins we are pushing ahead with medicines value work at system level to realise imminent gains, for example by looking at cost improvement plans collectively for efficient use of medicines such as biosimilar switches and new pathways for value medicines.

We could also set up Pharmacist Medicines Optimisation teams to support Integrated Pharmacy and Medicines Optimisation work at place level, which will benefit local populations whilst still operating at system level. And, of

course, we have the option of engaging with the wider workforce via similar events to the conference I have already mentioned.

Do you see a developing role for Community Pharmacists, for example the Discharge Medicines Scheme?

We have already begun pilot work on referrals from urgent care centres (UTCs) to community pharmacies and so far, the results look promising.

The aim of the Urgent Treatment Centre Community Pharmacy Consultation Service (UTC CPCS) is to support the integration of community pharmacy into the urgent care system and formally refer patients with minor ailments or who require urgent prescriptions to community pharmacy, thus reducing demand placed upon the Urgent Treatment Centres. Additionally, it increases patient awareness of the role of community pharmacy as the 'first port of call' for minor ailments advice as well as being cost effective for the NHS.

The pilot is currently live in Gravesend (Gravesham UTC) and Margate (QEQM UTC) with the hope it will be extended as we progress towards the end of the financial year (March 2023). In total there are seven pharmacies participating in the pilot: four in Margate and three in Gravesend.

There were some technology problems during the initial pilot which caused delay in the roll out in certain areas. This problem has now been resolved, with an official launch at Gravesend and first referral received in July.

Mildred, thank you so much for sharing your ICS experiences in Kent and Medway – I know that this will be of great interest to colleagues across the NHS who are also working within the new system. Can I invite you to come back at a later date to let us know how things are progressing?

You are welcome and yes, I'd be delighted come back and update you on pharmacy developments.

ICSs and the future of the local NHS

By John Chater, Editor – PM Healthcare Journal

Summary

Integrated care systems (ICSs) are the most important organisations to come out of NHS reforms in the last ten years. They are the means by which the Department of Health and Social Care (DHSC) intends to completely restructure the local NHS and are now the main 'care and control' organisations in the system.

ICSs replaced clinical commissioning groups (CCGs) on 1 July 2022 and to understand what is happening in hospitals, GP surgeries, pharmacies and other care providers we need to understand the new environment in which healthcare is being delivered.

Background

Those of us working with or within the NHS sooner or later come to terms with what sometimes seems to be an endless cycle of reforms. The system always seems to be in flux – a reflection of the fact that designing and running a highly complex and demanding healthcare service is difficult and also, in part at least, political.

Whichever set of reforms we are in the middle of, certain priorities remain the same:

- Improving patient care
- Delivering efficiencies (saving money)
- Getting healthcare professionals to work more closely together (called integrated or joined-up care)

Combined, these are the Holy Grail of NHS reforms, and the era of the ICS is the latest (and probably by no means the last) attempt to achieve them.

"ICSs are the successors to an earlier organisation type called sustainability and transformation partnerships (STPs), which were introduced in 2016. STPs were an early attempt to bring together NHS organisations and local authorities in a set area, to deliver integrated improvements.

STPs, then, did the groundwork upon which ICSs are built."

ICSs – Where are we now?

ICSs are now statutory bodies, which means that an act of parliament was necessary to legally create them and give them their full powers on 1 July 2022.

The commissioner/provider split – the system whereby one part of the NHS 'buys' services that are provided by another part of the NHS – has come to an end. Now, there will be 'one pot of money' provided to the ICS to pay for almost all of the agreed services in the ICS area (also called a territory or footprint).

This is a huge change and throws on its head the old system. CCGs, the most important NHS commissioners for a decade, have disappeared, replaced entirely by the new entities.

How are ICSs structured?

42 ICSs cover between them the whole of England.

As far as ICS boundaries are concerned, they are a bit of a hotchpotch, combining local authority, CCG boundaries and sitting roughly on the same boundaries as their predecessor organisations, sustainability and transformation partnerships (STPs).

Each ICS holds within its boundaries all of the organisations that provide NHS healthcare, as well as local authority interests in health, voluntary organisations and some private sector providers as well. This is their *raison d'être*, a major attempt to bring together all of the different healthcare providers under the general objective of creating an integrated healthcare system.

The three levels of ICSs

The NHS Long Term Plan set out three important levels of operation for ICSs, which have been adopted as models. They range from the 'local' all the way up to the wider system setting, as described below:

Neighbourhood

The neighbourhood level accommodates populations of between 30,000 to 50,000 people.

Localism is the name of the game, and we see a range of professions including GPs, care homes, pharmacists, community and mental health teams and the voluntary sector working together to coordinate services.

This is where groups of GPs and others in primary care can work together effectively, identifying local and specific complex needs and aligning services accordingly. At this level we see the all-important primary care networks (PCNs) that enable much shared working and planning at the service level closest to patients.

"Decisions taken closer to the communities they affect are likely to lead to better outcomes."
NHS England – Neighbourhood

Place

The place level accommodates populations of between 250,000 to 500,000 people.

We now go up to town or district level, where possible sharing a boundary with a local authority. It is at this level that the majority of changes to clinical services will happen, as well as incentives to improve public health. We find health and care providers working to connect clusters of primary care networks to broader services, including those provided by local councils, community hospitals or voluntary organisations.

Here, healthcare professionals undertake clinical care redesign (e.g. standardising care pathways across a whole area) and conducting effective population health management (the better use of data to include determinants such as housing, environmental quality and access to good employment).

"Collaboration between partners in a place... can overcome competing objectives and separate funding flows to help address health inequalities, improve outcomes, and deliver joined-up, efficient services for people."

NHS England – Place

System

The system level accommodates populations of between 1 million to 3 million people.

It's here that strategic leadership is provided, across the whole population of the ICS, with all health and care partners coming together to set strategic direction and develop economies of scale.

System leaders will take 'collective responsibility for financial and operational performance, typically through a system-wide board which includes all NHS partners'. The integrated care board (ICB) will be held account by NHS England (via NHS England's regional teams).

A single plan at the system level will include operational and transformation priorities (building on the plans put together at the place level).

Specific responsibilities at the system level:

- Delivering high quality services and access
- Reducing unwarranted clinical variation
- Addressing health inequalities
- NHS workforce planning
- Best use of capital, estates and digital infrastructure
- Spreading good practice
- Clinical, managerial and support functions

"Collaboration between providers (ambulance, hospital and mental health) across larger geographic footprints is likely to be more effective than competition in sustaining high quality care, tackling unequal access to services, and enhancing productivity."
NHS England – System

It should be borne in mind that the above set up is more guidance than an inflexible rule, and that much will depend on local factors such as demography, need and other conditions specific to each ICS.

At the system level - developing provider collaboration

Whereas neighbourhood and place are meant to provide for most health conditions, there will always be circumstances that require coordination over a wider area. For example, complex or acute needs necessitating specialist treatment that can only be planned and organised effectively over the whole ICS.

This scaling up of provider collaboration is meant to achieve a greater concentration of skills and resources in bigger sites, thereby improving quality and promoting efficiency.

To allow for this, some services such as hospital, specialist mental health and ambulance need to be

organised through provider collaboration that operates at a whole-ICS footprint – or even more widely where required.

Leading the ICS

ICSs are led by a board (the integrated care board – ICB). The composition of the board is expected to be 'sufficiently streamlined' to support effective decision-making at the local level.

Leadership is described in guidance as 'broadly permissive', meaning flexible. The only mandated members of the ICB are a chair and CEO and, as a minimum, also representation from:

- NHS Trusts and Foundation Trusts
- General practice
- The local authority

ICB leaders have responsibility for planning health and care services within their system. This includes the coordination of partnerships between the NHS, local authorities, and a range of stakeholders to improve services and the health of people within their area.

Each ICS also has an Integrated Care Partnership (ICP), which is a statutory committee bringing together all system partners to produce a health and care strategy.

Devolving responsibility from NHS England to ICSs

Responsibility for primary medical, dental, ophthalmic and community pharmacy services transfers from NHS England to ICSs.

Transfer of responsibilities also includes the appropriate specialised and public health services that NHS England currently commissions. NHS England, though, will still specify national standards or requirements for ICSs in relation to direct commissioning functions.

Holding everyone to account

As might be expected, accountability will be a big part of a new and relatively untested system.

The job of holding ICSs to account for their performance and also helping with ongoing



development falls to NHS England's seven regional teams (themselves beholden to NHS England). ICSs will agree objectives with their respective team and be accountable for performance against them.

The idea behind ICS regulation is not to create any unnecessary or onerous conditions that will stifle the independence of ICSs to create a system that works for its own, unique, population.

“This is a laudable objective – a system of standardised national approaches to improvement and performance, but enough discretion to allow ICSs to do their own thing (within limits) if they are performing well.”

As systems mature, the regional role is expected to become that of a 'critical friend'. Further autonomy is expected, for example, NHS England's regions not engaging with individual organisations without the knowledge of the ICS and things being resolved locally wherever possible.

However, over and above everything, we will still have NHS England itself, setting policy, the overall healthcare strategy, the provider landscape and the strategy for commissioning. Nothing here is going to change that...

How ICSs plan services

Each ICS will publish a five-year system plan before April of each year. This plan must include the strategy produced by the integrated care partnership (ICP), and the joint strategic needs assessments and joint health and wellbeing strategies produced by the relevant health and wellbeing board in the ICS local authority. (In other words, a lot of planning documents to summarise in the main system plan.)

It is expected that ICS refreshed five-year system plans will be submitted in March 2023. This will give each ICB and its local authority partners time to agree a strategy for the ICP that has broad support and to develop a plan to support its implementation.

Through 2022/23, ICBs will work to ensure that the five-year system plans deliver specific objectives to:

- Improve outcomes in population health and healthcare
- Tackle inequalities in outcomes, experience and access
- Enhance productivity and value for money
- Support broader social and economic development

They should also reflect national priorities for the NHS and include new commissioning responsibilities (e.g. those formerly directly commissioned by NHS England, such as primary care and some specialised services).

How ICSs are funded

The idea is to organise the finances of the NHS at the ICS level, with as much decision-making as possible devolved to the ICS board.

To do this a 'single pot' approach to finance has been developed, bringing together current CCG commissioning budgets, primary care budgets, most specialised commissioning spend, budgets for certain other directly commissioned services, central support funding and transformation funding.

Despite this local autonomy, the ICB will still need to spend the money in line with nationally agreed strategies for such services as mental health and tackling health inequalities priorities.

The expectation is that ICS leaders will delegate significant budgets to the 'place' level, for example ensuring adequate resources for general practice and other primary care services. New powers will also make it easier to form joint budgets with the local authority, including for public health functions.

How providers will be funded

Providers, through their role in ICS leadership and representation on the ICB, will take an active role in shaping services. They will also be central to new initiatives to improve care, for example in 'lead provider models' at place level.



The expectation is that providers, especially those who spend most of the money (in secondary care) should be fully engaged with determining how services are funded and delivered and also how different bodies involved in providing joined-up care work together.

As set out in the NHS Long Term Plan, the NHS will mostly move away from episodic or activity-based payment. Instead, it will use the 'blended payment model' for secondary care services.

'Blended' payments are meant to ensure that provider collaboratives will have greater certainty about the resources available to them. The proposition is not unreasonable as purely activity-based remuneration has often been achieved at the expense of such ideas as collaborative working or system-wide efficiency.

As usual with any change to a financial system, there is also the promise of reduced administrative and transactional costs when set against the current approach to commissioning and paying for care. This is expected to release resources for new services at the ICS level.

Capital payments

At the ICS level, responsibility for allocating capital payments will sit alongside the responsibility for allocating money for day-to-day services.

Combining the two at the ICS level is expected to ensure that strategies for capital investment:

- Align with different NHS providers and local authorities
- Lead to more rational decisions on capital spending over the whole ICS area
- Prioritise capital investments that are beneficial in the long term

Changes to commissioning

To bring commissioning out of the commissioner/provider era it will change in three main ways:

1. The creation of a single, system-wide approach to commissioning, including:
 - Assessing population health needs and modelling demographics



- Improving health and tackling inequalities
 - Funding these priorities to provide good value as well as health outcomes
2. Service transformation, via provider organisations and others, achieved through partnerships and collaboration at place level
 3. Better analysis of local conditions to understand how to use resources to improve outcomes, rather than managing contract performance between organisations

Commissioning at scale, or not

Many commissioning functions are now unified within ICS boundaries, which is the preferred model. However, we also have place-based partnerships backed by devolved funding and other initiatives that will require flexibility in local areas to work effectively.

“The decision will need to be made as to whether individual services are best delivered at the system level or at place – a balance between localism and the efficiencies of working at scale.”

How commissioners choose to work will therefore depend upon a range of factors, often depending upon the size of the ICS, how effectively the place-level is working and also the role of the local authority. As we might imagine, there will be considerable variety in commissioning arrangement as ICSs get up to speed (which is, of course, the point).

Support services

And not forgetting, behind ICSs we have commissioning support units (CSUs), providing support services (a kind of back-office function). It is expected that CSUs will continue their work with ICSs.

Specialised commissioning

Specialised services have been commissioned centrally by NHS England since 2013. Now, ICSs will take over the majority of this work. (These are services for rare conditions that may be complex, infrequent and expensive to treat).

ICSs are expected to be able to provide some system-level nuance to specialised commissioning, redesigning system level services and improving the development and provision of specialised services with linked care pathways. This is quite a departure from the previous rationale, where it was thought that only at the national level could specialised commissioning work effectively.

Four principles have been established to support the devolution of specialised services, summarised below:

1. All specialised services will continue to be subject to NHS England-led national service specifications and evidence-based policies
2. Commissioning and decision-making for specialised services will be led at the appropriate population level – ICS, multi-ICS or national – depending upon the service provided
3. Clinical networks and provider collaborations will drive quality improvement, service change and transformation across specialised services
4. Funding of specialised services will shift from provider-based allocations to population-based budgets, supporting the connection of services back to ‘place’

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Prescribing information. Please refer to the appropriate Summary of Product Characteristics (SmPC) before prescribing. **Fixkoh Airmaster 50 microgram/100 microgram/ dose inhalation powder, pre-dispersed.** Single inhalation provides a delivered dose of 47 micrograms of salmeterol (as salmeterol xinafoate) and 92 micrograms of fluticasone propionate. Corresponds to a pre-metered dose of 50 micrograms of salmeterol and 100 micrograms of fluticasone propionate. **Fixkoh Airmaster 50 microgram/250 microgram/ dose inhalation powder, pre-dispersed.** Single inhalation provides a delivered dose of 45 micrograms of salmeterol (as salmeterol xinafoate) and 229 micrograms of fluticasone propionate. Corresponds to a pre-metered dose of 50 micrograms of salmeterol and 250 micrograms of fluticasone propionate. **Fixkoh Airmaster 50 microgram/500 microgram/ dose inhalation powder, pre-dispersed.** Single inhalation provides a delivered dose of 43 micrograms of salmeterol (as salmeterol xinafoate) and 432 micrograms of fluticasone propionate. Corresponds to a pre-metered dose of 50 micrograms of salmeterol and 500 micrograms of fluticasone propionate. **Indication:** Fixkoh Airmaster is indicated in adults and adolescents 12 years of age and older. **Asthma:** in the regular treatment of asthma where use of a combination product (long-acting β2 agonist and inhaled corticosteroid) is appropriate. In patients not adequately controlled with inhaled corticosteroids and ‘as needed’ inhaled short acting β2 agonist, or patients already adequately controlled on both inhaled corticosteroid and long-acting β2 agonist. Note: Fixkoh Airmaster 50 microgram/100 micrograms is not appropriate in adults and children with severe asthma. **Chronic Obstructive Pulmonary Disease (COPD)** For the symptomatic treatment of patients with COPD, with a FEV1 < 80% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. **Dosage and administration:** Fixkoh Airmaster must be used daily for optimal benefit, even when asymptomatic. Patients should be regularly reassessed by a doctor, so that the strength of Fixkoh Airmaster they are receiving remains optimal and is only changed on medical advice. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. Where the control of symptoms is maintained with the lowest strength of the combination given twice daily then the next step could include a test of inhaled corticosteroid alone. Patients requiring a long-acting β2 agonist could be titrated to Fixkoh Airmaster given once daily if, in the opinion of the prescriber, it would be adequate to maintain disease control. In the event of once daily dosing when the patient has a history of nocturnal symptoms the dose should be given at night, a history of mainly daytime symptoms the dose should be given in the morning. Patients should be given the strength of Fixkoh Airmaster containing the appropriate fluticasone propionate dosage for the severity of their disease. If an individual patient should require dosages outside the recommended regimen, appropriate doses of β2 agonist and/or corticosteroid should be prescribed. **Recommended Doses: Asthma** Adults and adolescents 12 years and older: - One inhalation of 50 micrograms salmeterol and 100 micrograms fluticasone propionate twice daily, or - One inhalation of 50 micrograms salmeterol and 250 micrograms fluticasone propionate twice daily, or - One inhalation of 50 micrograms salmeterol and 500 micrograms fluticasone propionate twice daily. A short term trial of Fixkoh Airmaster may be considered as initial maintenance therapy with moderate persistent asthma (defined as patients with daily symptoms, daily rescue use and moderate to severe airflow limitation) for whom rapid control of asthma is essential. In these cases, the recommended initial dose is one inhalation of 50 micrograms salmeterol and 100 micrograms fluticasone propionate twice daily. Once control of asthma is attained treatment should be reviewed and consideration given to use of an inhaled corticosteroid alone. Regular review of patients as treatment is stepped down is important. Fixkoh Airmaster is not intended for the initial management of mild asthma. Fixkoh Airmaster 50 microgram/100 micrograms is not appropriate in adults and children with severe asthma. **Pediatric population** Fixkoh Airmaster is not recommended for use in children aged under 12 years of age. **COPD Adults:** One inhalation of 50 micrograms salmeterol and 500 micrograms fluticasone propionate twice daily. **Special patient groups:** There is no need to adjust the dose in elderly patients or in those with renal impairment. **Method of administration:** Inhalation use. Patients must also be advised to rinse their mouth afterwards with water and spit it out and/or brush their teeth after inhaling. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Warnings and Precautions:** Deterioration of disease. Fixkoh Airmaster should not be used to treat acute asthma symptoms for which a fast and short-acting bronchodilator is required. Patients should be advised to have their inhaler to be used for relief in an acute asthma attack available at all times. Patients should not be initiated on Fixkoh Airmaster during an exacerbation, or if they have significantly worsening or acutely deteriorating asthma. Serious asthma-related adverse events and exacerbations may occur during treatment. Patients should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen. Increased requirements for use of reliever medication, or decreased response to reliever medication indicate deterioration of control and patients should be reviewed by a physician. Sudden and progressive deterioration in control of asthma is potentially life-threatening and the patient should undergo urgent medical assessment. Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of Fixkoh Airmaster. Regular review of patients as treatment is stepped down is important. For patients with COPD experiencing exacerbations, treatment with systemic corticosteroids is indicated, therefore patients should be instructed to seek medical attention if symptoms deteriorate. **Cessation of therapy:** Treatment should not be stopped abruptly in patients with asthma due to risk of exacerbation. Therapy should be down titrated under supervision. For patients with COPD cessation of therapy may also be associated with symptomatic decompensation and should be supervised by a physician. **Caution with special diseases:** Fixkoh Airmaster should be administered with caution in patients with active or quiescent pulmonary tuberculosis and fungal, viral or other infections of the airway. Cardiovascular effects: Rarely, Fixkoh Airmaster may cause cardiac arrhythmias e.g. supraventricular tachycardia, extrasystoles and atrial fibrillation, and a mild transient reduction in serum potassium at high therapeutic doses. Fixkoh Airmaster should be used with caution in patients with severe cardiovascular disorders or heart rhythm abnormalities and in patients with diabetes mellitus, thyrotoxicosis, uncorrected hypokalaemia or patients predisposed to low levels of serum potassium. **Hypertension:** Rare reports of increases in blood glucose levels. This should be considered when prescribing to patients with a history of diabetes mellitus. **Paradoxical bronchospasm:** Paradoxical bronchospasm may occur with an immediate increase in wheezing and shortness of breath after dosing. Paradoxical bronchospasm responds to a rapid acting bronchodilator and should be treated straightaway. Fixkoh Airmaster should be discontinued immediately. **Beta 2 adrenoceptor agonists:** Side effects of β2 agonist treatment, such as tremor, palpitations and headache, have been reported, but tend to be transient and reduce with regular therapy. **Excipients:** Contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Systemic corticosteroid effects:** Possible systemic effects include Cushing’s syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). **It is important, therefore, that the patient is reviewed regularly and the dose of inhaled corticosteroid is reduced to the lowest dose at which effective control of asthma is maintained.** **Adrenal function:** Prolonged treatment of patients with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crisis. Very rare cases of adrenal suppression and acute adrenal crisis have also been described with doses of fluticasone propionate between 500 and less than 1,000 micrograms. Situations, which could potentially trigger acute adrenal crisis include trauma, surgery, infection or any rapid reduction in dosage. Presenting symptoms are typically vague and may include anorexia, abdominal pain, weight loss, tiredness, headache, nausea, vomiting, hypotension, decreased level of consciousness, hypoglycaemia, and seizures. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. The benefits of inhaled fluticasone propionate therapy should minimise the need for oral steroids, but patients transferring from oral steroids may remain at risk of impaired adrenal reserve for a considerable time. These patients should be treated with special care and adrenocortical function regularly monitored. Patients who have required high dose emergency corticosteroid therapy may also be at risk. This possibility of residual impairment should always be borne in mind in emergency and elective situations likely to produce stress, and appropriate corticosteroid treatment must be considered. The extent of the adrenal impairment may require specialist advice before elective procedures. **Pneumonia in patients with COPD:** An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features overlap with the symptoms of COPD exacerbations. Risk factors for pneumonia in patients with COPD include current smoking, older age, low BMI and severe COPD. **Visual disturbance:** If a patient presents with symptoms such as blurred vision or other visual disturbances, refer to an ophthalmologist for evaluation. **Pediatric population:** Fixkoh Airmaster is not recommended for use in children under 12 years of age. Adolescents < 15 years taking high doses of fluticasone propionate (typically > 1,000 micrograms/day) may be at particular risk. Systemic effects may occur, particularly at high doses prescribed for long periods. Possible systemic effects include Cushing’s syndrome, Cushingoid features, adrenal suppression, acute adrenal crisis and growth retardation in adolescents and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression. Consideration should be given to referring the adolescent to a paediatric respiratory specialist. It is recommended that the height of adolescents receiving prolonged treatment with inhaled corticosteroid is regularly monitored. **The dose of inhaled corticosteroid should be reduced to the lowest dose at which effective control of asthma is maintained.** **Pregnancy and lactation:** Pregnancy Data on pregnant women indicate no malformative or foetal/neonatal toxicity related to salmeterol and fluticasone propionate. Animal studies have shown reproductive toxicity after administration of β2 adrenoceptor agonists and glucocorticosteroids. Administration of Fixkoh Airmaster to pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. The lowest effective dose of fluticasone propionate needed to maintain adequate asthma control should be used in the treatment of pregnant women. Breastfeeding It is unknown whether salmeterol and fluticasone propionate/metabolites are excreted in human milk. Studies have shown that salmeterol and fluticasone propionate, and their metabolites, are excreted into the milk of lactating rats. A decision must be made whether to discontinue breastfeeding or to discontinue Fixkoh Airmaster therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. **Undesirable effects:** For full list of side effects, consult SmPC. Very common and common events include: headache, nasopharyngitis, candidiasis of mouth and throat, pneumonia, bronchitis, hypokalaemia, headache, throat irritation, hoarseness/dysphonia, sinusitis, contusions, cramps, traumatic fractures, arthralgia, myalgia. Serious adverse events: bronchospasm, anaphylaxis, anaphylactic shock, Cushing’s syndrome, growth retardation in children and adolescents, decreased bone mineral density, hypoglycaemia, atriality, behavioural changes including hyperactivity (mainly in children), depression, aggression (mainly in children), tremor, cataract, glaucoma, blurred vision, palpitations, tachycardia, cardiac arrhythmias, atrial fibrillation, angina. **Overdose:** There are no data available from clinical trials on overdose with Fixkoh Airmaster. Overdose with both active substances are: Salmeterol Dizziness, increases in systolic blood pressure, tremor, headache and tachycardia. If Fixkoh Airmaster therapy has to be withdrawn due to overdose of the β2 agonist component of the medicinal product, provision of appropriate replacement steroid therapy should be considered. Additionally, hypokalaemia can occur and therefore serum potassium levels should be monitored. Potassium replacement should be considered. **Fluticasone propionate:** Acute: Inhalation of fluticasone propionate doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not need emergency action as adrenal function is recovered in a few days. **Chronic overdose of inhaled fluticasone propionate:** Adrenal reserve should be monitored and treatment with a systemic corticosteroid may be necessary. When stabilised, treatment should be continued with an inhaled corticosteroid. **Legal Category:** POM **Pack size:** 1 x 60 dose Fixkoh Airmaster or 2 x 60 dose Fixkoh Airmaster or 3 x 60 dose Fixkoh Airmaster. **Prices:** 50/100mcg £14.47; Fixkoh Airmaster 50/250mcg £19.29; Fixkoh Airmaster 50/500mcg £16.12. **MA Number:** PLO0240/0547, PLO0240/0548, PLO0240/0549. **MA Holder:** Thornton & Ross Ltd. (trading as STABA) Linthwaite, Huddersfield, HD7 5SH, UK. **Date of preparation:** December 2021 **Unique ID No.:** HIX-004a.

Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to 01484 848164

References: * Thornton & Ross Ltd. Fixkoh Airmaster™ 51% cost saving based on approved NHS price: Fixkoh Airmaster™ 50/500 mcg; £16.12 vs. Seretide® 500 Accuhaler™ Drug Tariff Price £32.14 (available at <https://bit.ly/nice>). **1.** Fixkoh Airmaster™ % cost saving based on approved NHS price: Fixkoh Airmaster™ 50/100 mcg; £14.47 vs. Seretide® 500 Accuhaler™ Drug Tariff Price £32.14 (available at <https://bit.ly/nice>). **2.** Fixkoh Airmaster™ % cost saving based on approved NHS price: Fixkoh Airmaster™ 50/250 mcg; £19.29 vs. Seretide® 500 Accuhaler™ Drug Tariff Price £32.14 (available at <https://bit.ly/nice>). **3.** Fixkoh Airmaster™ 50/500 mcg; £16.12 vs. Seretide® 500 Accuhaler™ Drug Tariff Price £32.14 (available at <https://bit.ly/nice>). **4.** Fixkoh Airmaster™ 50/100 mcg; £14.47 vs. Seretide® 500 Accuhaler™ Drug Tariff Price £32.14 (available at <https://bit.ly/nice>). **5.** Swedish Medical Products Agency. 2019. Public Assessment Report: Scientific discussion. Sipova Airmaster, Seretide® and Accuhaler® are registered trademarks of the GlaxoSmithKline group of companies. Job Code: FXX-51. DoP: July 2022.



Increasing uptake of the Discharge Medicines Service across a West Midlands ICS

Authors

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Abstract

The Discharge Medicines Service enables NHS Trusts to refer patients to their nominated Community Pharmacy after discharge for medication guidance and support, helps reduce medicine-related errors, improves communication between teams and with patients, whilst reducing readmission rates. However, service implementation and referrals rates remain low across some systems. NHS Arden & GEM CSU's Medicines Optimisation team worked in collaboration with Black Country and West Birmingham Integrated Care System to uncover the barriers to service implementation and deliver a tailored package of support which has positively impacted staff engagement and referrals.

Introduction

Patient discharge from hospital is associated with an increased risk of avoidable medication related harm.¹ The Discharge Medicines Service (DMS) was introduced as an essential service to the Community Pharmacy Contractual Framework in February 2021² and has been introduced as an indicator within the Commissioning for Quality and Innovation (CQUIN) guidance for 2022/23.³ It enables NHS Trusts to refer patients to their community pharmacy at discharge for medication guidance and support. DMS builds on the work undertaken by Academic Health Science Networks around the Transfers of Care Around Medicines (TCAM), where it is well documented that effective communication during the discharge process has a significant impact on reducing medication related patient harm.⁴

“DMS is one of the first services that pioneers full cross-sector collaboration between hospitals, community pharmacy and GP practices. The involvement of community pharmacy and associated communication and networking required is a positive step in the transition to Integrated Care Systems (ICSs).”

The principle aims of the service include:

- Improving patient outcomes
- Preventing avoidable medicines-related harm at discharge from hospital
- Reducing the risk of hospital readmission
- Improving patients' understanding of their medicines
- Supporting collaborative working, shared decision making and ensuring better communication between teams

Accelerating DMS implementation across an ICS

Black Country and West Birmingham ICS had undertaken work to implement the TCAM programme and subsequent DMS. Nevertheless, service referrals rates remained below target at some Trusts, with zero activity in others. The

Accelerating DMS implementation across an ICS

- Supports the Medicines Safety Improvement Programme and avoidable medicines harm at the interface⁵
- A study showed that 60% of patients have three or more changes made to their medicines during a hospital stay⁶
- Between 50-90% of elderly patients receive a change in medication when in hospital^{6,7}
- 20% of patients experience adverse events within three weeks of discharge, 60% of which could have been ameliorated or avoided^{8,9}
- Preliminary published data demonstrated that support from a Community Pharmacy when a patient had been discharged results in lower rates of readmission and shorter hospital stays for those who were readmitted¹⁰
- NICE guidelines make clear recommendations that medicines related communication systems and reconciliation processes should be in place within a week of discharge¹¹
- The Royal Pharmaceutical Society makes recommendations around communication during a patient's transfer of care, including accurate, timely, clear and legible record keeping, preferably by electronic means¹²

Medicines Optimisation team at NHS Arden & GEM CSU (Arden & GEM) was tasked with working alongside key stakeholders to accelerate the uptake of DMS across the system. We utilised the concept of Genchi Genbutsu to understand potential issues or barriers through being at the location of the process.¹³ We believed this approach would enable us to tailor our solutions for implementation and accurately direct resources.

When implementing any new service or change to practice, we follow a structured approach which is underpinned by effective stakeholder engagement and robust project management.

Leadership endorsement

We were able to gain endorsement from senior stakeholders through their established Pharmacy Leadership Group (PLG), where members consisted of representatives from each pharmacy sector and across each of the four Places across the Black Country and West Birmingham ICS (a Place is typically defined by its Local Authority boundary, and consists of multiple organisations such as acute Trusts, community providers, GP practices, Community Pharmacies and the Local Authority). The PLG is well established across the Black Country and West Birmingham ICS, and the existing collaboration between the pharmacy leaders from different sectors of the pharmacy workforce was a key enabler to the mobilisation of this project.

1. Stakeholder engagement

Understanding stakeholders is vital to any project. Due to the cross-sector approach within DMS, it was important to identify key stakeholders, and their roles, from across the system (see Box 1).

Senior Stakeholders	Acute Trust Stakeholders	Other
<ul style="list-style-type: none"> • Chief Pharmacists • Clinical Commissioning Group (CCG) Head of Medicines Management • Local Pharmaceutical Committee (LPC) Chairs 	<ul style="list-style-type: none"> • Principal Pharmacists • Clinical Service Leads • Clinical Teams • Implementation Leads • IT Support • Data Analysts 	<ul style="list-style-type: none"> • Community Pharmacists • GPs • Primary Care Network (PCN) Pharmacy Teams • Patient representative groups

Box 1 – Potential System Stakeholders



Our initial discussion with the group enabled the agreement of the overall project objectives:

- Increase referrals from baseline rates
- Promote the service across the ICS
- Achieve sustained referrals

This discussion also enabled us to understand the current position and requirements, how project resources needed to be mobilised, and inform the group of the benefits of undertaking an initial onsite scoping exercise.

System engagement

Arden & GEM established and chaired a bi-weekly DMS task group comprising of system stakeholders representing each of the four Places and across different sectors of pharmacy. The group had a clear governance structure, an established route for escalation (via the PLG), documented roles and responsibilities for each member, and an agreed positive focus on collaboration and sharing good practice.

By raising awareness and seeking representation across the system, an increased appetite and commitment from the members became evident: It is expected that this approach will lead to system-wide ownership and a subsequent sustainable service.

The following forums were utilised to access stakeholders:

a. Engagement events

Aimed at those likely to be involved in the DMS process (Hospital and Community Pharmacy teams, CCG/PCN pharmacists and GPs), the focus of these events was to introduce DMS, its benefits and enable delegates to discuss interactive case studies that highlighted the clinical decision-making involved when referring patients.

Events allowed an opportunity to learn how patients are supported across the interface. There is an aspiration that this approach will foster cross-sector links and relationships which can benefit future service implementation programmes.

b. Support for community pharmacy contractors

Community pharmacies and their staff are a fundamental partner for DMS, and we recognised this key stakeholder needed to be involved from an early stage in the project. The LPC have been pivotal in helping the Arden & GEM project team to understand the opportunities and barriers faced within Community Pharmacies and to promote the service to local contractors. We facilitated Trust attendance at local LPC meetings to raise awareness, provide updates on referral activity and help to cultivate positive working relationships across the interface.

It was important to review activity data and understand reasons for unprocessed referrals within the Community Pharmacy workflow. This was achieved through local conversations, identifying potential solutions and raising general awareness of any issues being experienced.

c. Engaging GP practices

For DMS to work effectively and gain maximum benefit, General Practice is a key player to ensuring positive action was taken on any recommendations coming via Community Pharmacy: Feedback loop.

To raise awareness and promote use of DMS across General Practice, we established links with the system medicines optimisation committee and Primary Care commissioning teams and produced content for primary care bulletins.

Where significant barriers may exist between Community Pharmacy and GP practices, organisations may need to consider providing support to foster relationships and identify local barriers to implementation.

Remote team	Peripatetic team
<ul style="list-style-type: none"> • Governance arrangements • Developing bespoke action plans • Project research • Business case development support to allow Trusts to access NHS England and NHS Improvement funding for DMS support roles • Development of training tools • Liaising with EMIS Health • Development of webinars • Managing stakeholder queries • Managing internal and external meetings. 	<ul style="list-style-type: none"> • Understanding systems and processes through discussions and onsite visualisation of systems • Identifying barriers and opportunities for efficiencies • Delivering onsite training • Providing hands on support for processing referrals • Provide onsite troubleshooting and query answering service.

Box 2 – Key roles of project delivery team

2. Approach to project delivery

Adopting a project management approach was pivotal to delivering a project across a large system with varying needs. Arden & GEM established a project team with experience of working across multiple stakeholders and who understood the systems in place.

Team structure

We utilised a combination of remote and peripatetic team members, with the remote team focusing on back-office functions, while the peripatetic team provided onsite visibility and were able to 'walk the floor' of the relevant Trust departments to gain a true understanding of the situation (see Box 2). The delivery of ward-based, one-to-one training and troubleshooting enabled Hospital teams to continue with their core duties. This helped to drive engagement while allowing the team to deliver training and provide more practical and responsive support to Hospital staff.

Baseline assessment findings

The project team arranged to undertake site visits, which included completing an assessment tool in conjunction with the relevant Trust staff, to gather a baseline understanding of the current state of DMS provision. The assessment tool acted as a prioritisation framework through its ability to score and RAG rate each descriptor, which allowed the Arden & GEM team to tailor

support to meet the individual needs of Trusts.

The results were organised into common themes hindering the success of the service and action plans were developed and agreed with the Trust:

- **Variations in processes:** For example, the process for referrals was based upon the previous TCAM model, however since then, Trusts had implemented differing digital systems which meant that previous ways of working were no longer appropriate. In some circumstances the original procedures were no longer practical and new ways of working were required
- **Training:** Training requirements for clinical team members were identified by Trust clinical team leaders and these varied depending on the degree of change to processes, and the level of existing experience with referrals within the team
- **Business intelligence and performance monitoring:** To understand their individual DMS CQUIN indicator target, Trusts needed to identify their target proportion of discharges referred to DMS, in relation to their total number of in-patient discharges. It was also important for them to understand the proportion of referrals made that were completed, rejected or unactioned by Community Pharmacy



- **Communications and engagement:** It was necessary to raise the profile of DMS and remind teams involved of the value the service brings and encourage them to consider this element of patient care as a priority, whilst recognising the demands on the existing workforce capacity

Tailored support focused on the common themes identified in the service baseline assessment and included:

Standardising processes: Arden & GEM updated Standard Operating Protocols and information leaflets, identifying efficient processes that reflected the needs of the Trust, while ensuring national and local best practice was captured.

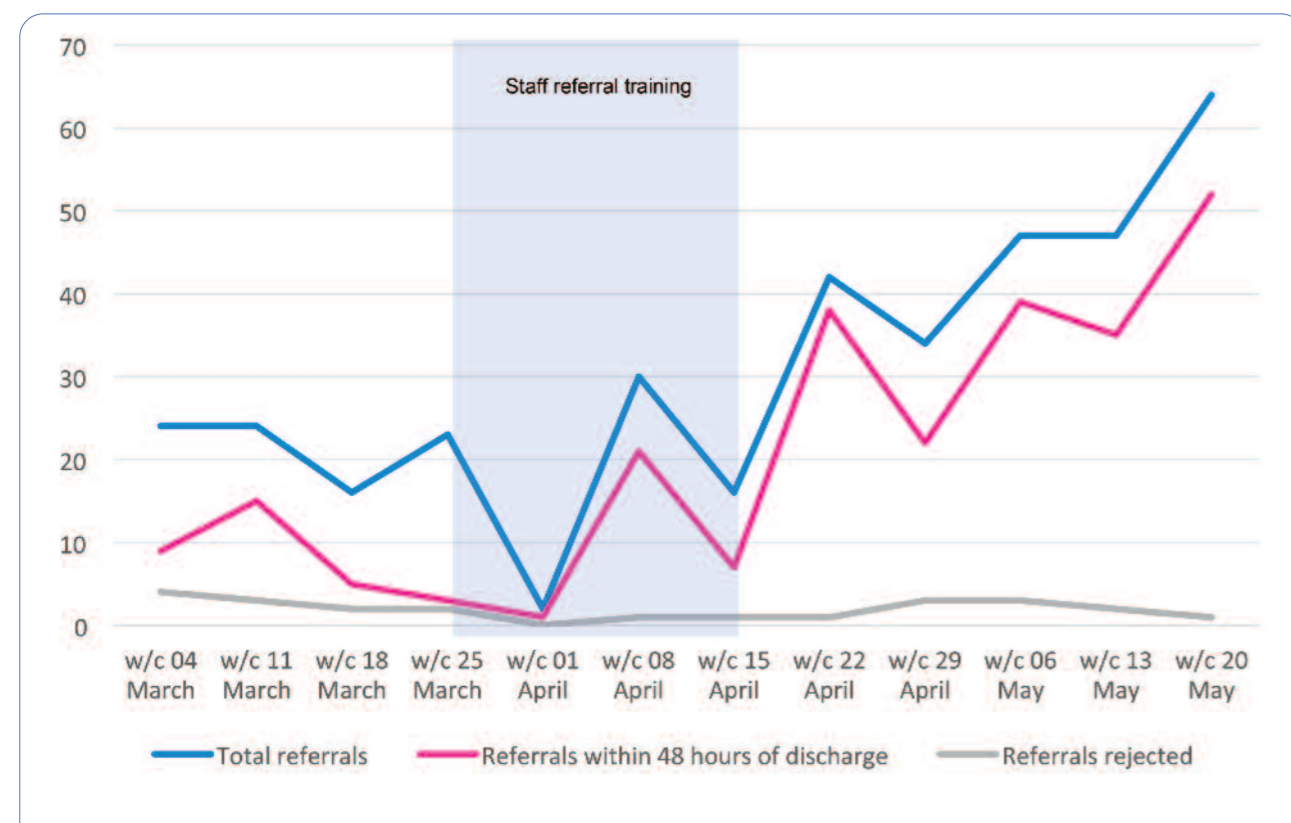
Training and coaching: Training was undertaken on DMS, ensuring DMS support teams were aware of its benefits and the process required to make a referral. Group training was delivered to clinical ward-based teams and further 1-2-1 coaching support was also provided where required.

3. Tailored support model

Our initial scoping exercise enabled us to identify the baseline position at each Trust, and it was decided to pilot the new support model on the site with the most embedded infrastructure for DMS referrals, namely Dudley Group NHS Foundation Trust.

Month	January	February	March	April	May*
Total DMS Referrals	83	67	116	100	181

Table 1: Monthly DMS referral activity for Dudley Group NHS Foundation Trust Jan- May* 2022



Graph 1: Dudley Group NHS Foundation Trust – Weekly DMS Referrals, March-May* 2022

*incomplete month, data only available until 26/05/2022

Data and reporting: guidance was given on how to access referral data and monthly progress highlight reports were provided to the PLG.

Communications and engagement: as described above, the system-wide approach to stakeholder engagement enabled regular communication and networking to maintain project momentum and foster greater awareness of DMS.

learning from the approach taken with Dudley Group NHS Foundation Trust

- Work collaboratively with Community Pharmacy to identify reasons for avoidable rejections and minimise delays in processing outstanding referrals

Project learnings

There is great enthusiasm across pharmacy teams from both Hospital and Community Pharmacy sectors for improving patient experience and minimising medicines related avoidable harm at the interface. Recognising the challenges faced across the NHS, with demand for support being at its highest, providing practical support for implementing new services is essential. In particular, recognising the increasing workload and burden on Hospital Pharmacy and Community Pharmacy teams, and Community Pharmacy numbers are reduced.

“A good understanding of processes and challenges facing secondary care has been invaluable to enable discussions to identify issues and solutions. Mobilising effective support based on individual needs is critical to enable engagement, establish credibility and ensure ‘buy in’ at both a local and system level.”

Outcomes

The decision to test the proposed support model in the Dudley Group NHS Foundation Trust, and tailor this to the findings of the baseline service assessment, proved successful.

Staff within the Trust were fully engaged with the project, attendance levels at the training were high, with an increase in confidence in making referrals that resulted in an instant increase in the number of referrals being made by the Trust. The significant improvement in the number of referrals being made within 48 hours of discharge can be seen in Table 1 and Graph 1.

For April 2022, 77% of referrals were made within 48 hours of discharge, an increase of more than double upon the previous month.

The team closely monitored referral data, identifying the number of rejections and the associated reasons for rejection or being left unprocessed. The positive engagement from the Trust and ability to galvanise the adoption of this project has led to increased referrals, with lower rates of rejections. Feedback (Box 3) from another Trust where we have delivered training has been positive, and further demonstrates Trust engagement.

The next steps for the project are to:

- Roll out and replicate this model across the remaining Trusts within Black Country and West Birmingham ICS, building upon and

“The training has been well received...I believe it has given those unfamiliar the confidence to go ahead and has also been a valuable reminder to those who had forgotten a lot of what we did before. The one-to-one training has also helped those less tech savvy and less tech confident” –

Senior Pharmacy Technician

Box 3: Feedback from a DMS training attendee at an NHS Trust





Inevitably systems will face challenges and barriers, the most common of which we identified during the initial phase, and include:

- **Data:** The data available via the NHS Business Services Authority is retrospective and lacked the detail to provide an understanding of the current situation. Access to data was challenging for both the Hospital Trusts and LPC stakeholders, which made it difficult to monitor the service and drive change
- **Pharmacy Workforce:** Limited capacity may restrict the ability to implement the DMS project. Workforce pressures may also limit the number of referrals made within the Trusts, those actioned within Community Pharmacy, and subsequently GP Practices if required
- **Incompatible Infrastructure:** There is a lack of interoperability between acute Trust systems and those for DMS leading to manually inputting patient details into the referral

Summary

The growing body of evidence indicates DMS significantly improves patient care and should be more widely adopted. However, work undertaken across Black Country and West Birmingham ICS has identified that implementing large scale change at the interface requires a structured approach.

Systems should ensure both stakeholder engagement and implementation processes are

factored when exploring the needs of each sector, and then tailor the delivery model accordingly. Our experience across the ICS shows a key element to achieving sustainable implementation is broad, and continued communication and engagement with system stakeholders is required, as well as anticipating and removing common barriers for all parties.

Acknowledgments

The authors would like to thank Hemant Patel, Director of Medicines and Clinical Policy, NHS Black Country and West Birmingham ICS, and Ruckie Kahlon, Associate Director of Medicines Optimisation and Chief Pharmacist, Dudley Group NHS Foundation Trust, along with their respective teams and wider stakeholders within the Black Country and West Birmingham ICS, for their support during the project, and permission to use their data.

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Pharmaceutical Procurement - Collaboration Supporting Patient Safety and Efficiency

Authors

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Abstract

Introduction

Medicines Optimisation evolved from medicines management through a greater focus on the patient and his/her experience rather than processes and systems. The four principles for Medicines Optimisation guide healthcare professionals, through a patient-centred approach, to improved patient outcomes. Pharmaceutical procurement is a complex process clearly embedded within the principles of Medicines Optimisation.

Case study

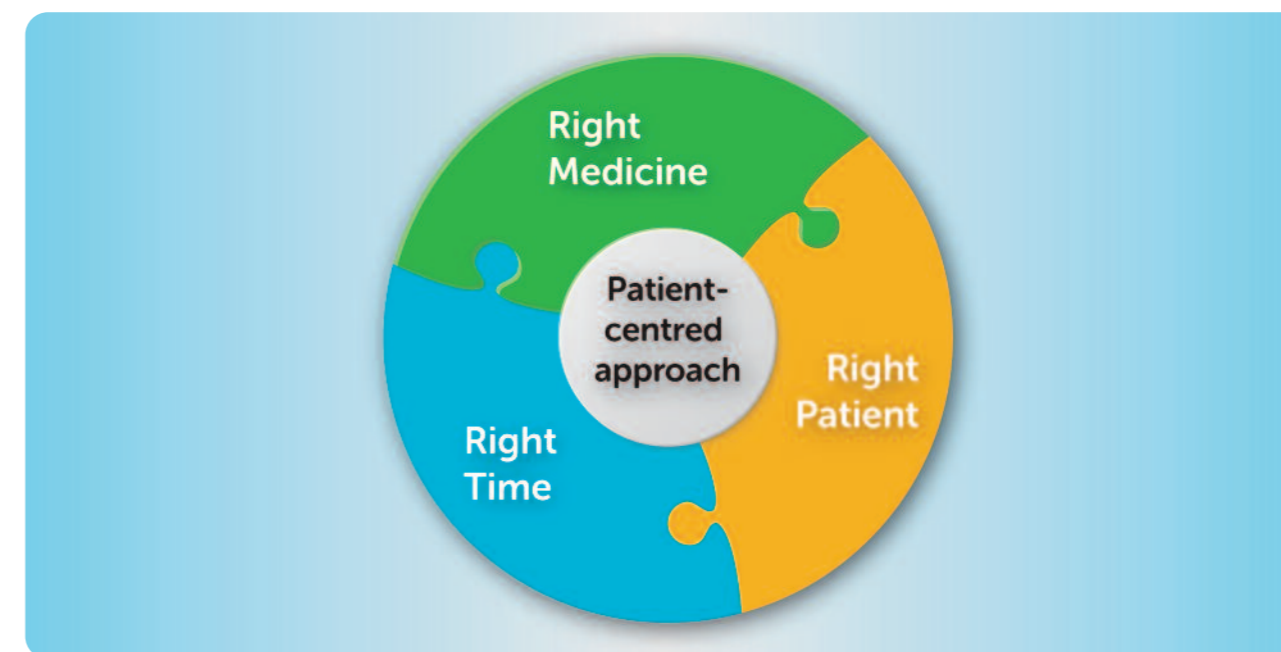
A routine tender process by the Regional Pharmaceutical Procurement Service (RPhPS) and the Business Services Organisation Procurements and Logistics Service (BSOPaLS) in Northern Ireland included the product micafungin. The Health and Social Care Trust's Medication Safety Team, acting as a Contract Adjudication Group (CAG), deemed the only product available following tender compliance and quality assessments, to be high risk, as it did not state on the packaging that the product must be diluted before use, and therefore it would be necessary to put risk mitigations in place before it could be used. A collaborative approach to introducing such mitigations involving the RPhPS, the CAG, and the Plenum pharmaceutical quality system, resulted in the creation and introduction of a secondary warning label for the micafungin, which mitigated against the perceived risk.

Discussion

There is evidence available that multidisciplinary collaboration within healthcare improves patient care and patient outcomes, by improving communication, reducing adverse events, decreasing length of stay, and improving patient satisfaction. However, there is little evidence of the impact of multi-disciplinary collaboration involving healthcare teams such as procurement teams who do not have patient contact but who are, nonetheless, involved in ensuring the principles of medicines optimisation. This paper demonstrates that multi-disciplinary team working across healthcare settings, between different sectors within the same profession – manufacturing, clinical, medication safety and procurement – has an important role in Medicines Optimisation.

Conclusion

Effective communication and collaboration between procurement teams, clinicians, and service providers can improve patient safety and access to the most cost-effective choice of medications.



Introduction

Medicines Optimisation, ensuring that the right patient gets the right medicine at the right time, evolved from medicines management through a greater focus on the patient and his/her experience rather than on processes and systems.¹ Through a patient-centred approach healthcare professionals are guided to improved patient outcomes by the four principles for Medicines Optimisation.

Principle 1 supports an understanding of the patient's experience through open dialogue. Principle 2 supports the use of the evidence-base to make clinical and cost-effective medicine choices, while Principle 3 supports the safe use of medicines in all aspects of medicine usage. Principle 4 states that Medicines Optimisation should be part of routine practice for all those involved in healthcare.

Pharmaceutical procurement is a complex process clearly embedded within the principles of Medicines Optimisation. The World Health Organisation (WHO)² describe four strategic objectives for effective pharmaceutical procurement: procuring the right quantity of the most cost-effective medicines, the selection of reliable suppliers of high-quality product, products delivered in a timely manner, and being able to achieve the most economical product. The Medicines Optimisation Quality Framework for Northern Ireland³ provides strategic direction to improve the use of medicines for patient health

and wellbeing benefit, and within the framework one of the key recommendations is:

“Within the HSC, a regional organisational infrastructure for medicines optimisation should be maintained that incorporates the Medicines Governance Team, Pharmacy and Medicines Management Team, Regional Pharmaceutical Procurement Service, Medicines Information service, Medicines Optimisation Innovation Centre.”

In addition, the Department of Health made a 5-year commitment to support the transformation of medication safety within Northern Ireland in response to WHO's third Global Patient Safety Challenge 'Medication Without Harm'^{4,5} with a key aim being to 'Build good practice in medication safety into the supply of all medicines'

Pharmaceutical procurement encompasses financial, risk and product identification strategies, bound by legislation and governance controls. The purpose of the EU Public Contracts Directive 2014/18/EC is to harmonise public procurement rules and facilitate



fairness, equitability and transparency in public procurement processes in which a value threshold is exceeded. The EU Directive was subsequently transposed into UK law as the Public Contracts Regulations 2015 (PCR 2015).

Contracts for the purchase of medicinal products in secondary care in Northern Ireland are awarded with adherence to the Northern Ireland Public Procurement Policy (NIPPP), and complying with the PCR 2015. The NIPPP principles are that all public contracts must be awarded to the most economically beneficial offer with fair and open competition, although other award criteria, such as safety, quality and suitability can be applied for pharmaceutical products.

Within Northern Ireland, the Regional Pharmaceutical Contracting Executive Group (RPCEG) is composed of Heads of Pharmacy from the NI Health and Social Care (HSC) Trusts, the Business Services Organisation Procurements and Logistics Service (BSOPaLS), Department of Health (DoH) and Regional Pharmaceutical Procurement Service (RPhPS) members. The responsibility of RPCEG is to determine the strategic management of pharmaceutical procurement and to ensure that there are contracts in place to meet the pharmaceutical products needs of Health and Social Care in Northern Ireland. BSOPaLS is the Centre of Procurement Expertise (CoPE) for the HSC in Northern Ireland and provides services including professional procurement and logistic services. Invitations to tender are submitted via the eTenders NI portal involving a Dynamic Purchasing system (DPS). The RPhPS provides professional and technical support, advice and leadership for HSC procurement.

The Standing Group for Contract Evaluation (SGCE) is composed of the procurement leads from each Trust, the RPhPS and representatives from BSOPaLS, and has responsibility for the evaluation of prices, quantities and products to make a final recommendation to RPCEG as to whether or not a contract should be awarded. The SGCE, along with end-user involvement in the form of multi-professional Contract Adjudication Groups (CAG) where it is appropriate to get clinical specialist input, complete a Pharmaceutical Quality Analysis (PQA) for all products submitted for tender.

Micafungin case study

The purchase of pharmaceutical products generally begins with a tendering process, which will consider the four WHO strategic objectives previously described and apply the four principles of Medicines Optimisation.^{1,2} In August 2021, there was a tender process completed, and micafungin was one of the products included in this process. Micafungin is supplied as a powder for concentrate for solution for infusion requiring reconstitution and dilution for administration. It is indicated for the treatment of invasive candidiasis, oesophageal candidiasis for patients suitable for intravenous therapy, and prophylaxis of Candida infection for patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia for 10 or more days.⁶ While usage in secondary care in Northern Ireland is relatively low, with 126 of 100 mg product and 56 of the 50 mg product being dispensed during the preceding 12 months period, its relatively high cost means that it exceeds the value threshold. Three bids were received as part of this process, but one was immediately rejected as the bid was non-compliant as per the terms of the tender process (no sample was received).

The two remaining bids were subject to a PQA, as per the second strategic objective of procurement to select high-quality products and Medicines Optimisation Principle 3.^{1,2} Completion of the PQAs resulted in one product deemed first line and the other second line. The company with the first line bid was awarded the contract. However, they subsequently rejected the award as they stated they had now discontinued the product from the UK market.

“The Trust’s Medication Safety Team, acting as a CAG, deemed the second line product to be high risk at the PQA, as it did not state on the packaging that the product must be diluted before use, and therefore it would be necessary to put risk mitigations in place before it could be used.”

On completion of the tender process, there were therefore two options in place:

Option 1: Purchase the product initially rejected as non-compliant for tender as a Direct Award Contract. This is permitted under PCR 2015 Regulation 32, which allows where, following a tender process when no suitable products are identified, that a direct award can be made. However, it was a more costly choice, and therefore this option would not align to strategic objectives of pharmaceutical procurement and Medicines Optimisation.^{1,2}

Option 2: Award to the high-risk product through either Trust-level or Regional-level risk mitigations. This would realise a potential annual cost saving of over £47,000 over Option 1, which would meet the final strategic objective of pharmaceutical procurement, to achieve the lowest-possible cost² and Principle 2 of Medicines Optimisation in relation to a cost-effective choice. However, without appropriate mitigations, Principle 3 of Medicines Optimisation,¹ to make sure medicines use is as safe as possible, would not be met, leaving the system vulnerable to potential medication errors and patient harm if the medication was not further diluted.

The Regional Pharmaceutical Contracts Executive Group determines any action to be taken when there is a difference in approach between the Regional Medicines Governance Team and

Regional procurement teams. The RPCEG asked the RPhPS to seek appropriate risk mitigations for Option 2 that would meet the approval of the Regional Medicines Governance team and enable alignment with Principle 3 of Medicines Optimisation.¹

The RPhPS approached the Trust’s Medication Safety Team to consider suitable risk reduction measures for the product. Risk reduction measures debated included the use of an additional label to act as a warning/alert for the end user, or preparing the medication in an aseptic unit. As there was no capacity to involve aseptic teams, it was agreed that a suitable risk reduction measure would be to attach a warning label, and doing this would bring this tendered product up to the same standards of the currently in-use product.

The Medication Safety Team then developed appropriate wording for an over label for the product that they deemed sufficient risk mitigation to meet patient safety assurances, taking into account other stakeholder’s views. Considerations in label design included the NPSA guidelines on labelling of injectable medications,⁷ the opportunities for colour, and ensuring any product produced would not be similar to other labelled products in use.

Victoria Pharmaceuticals (VP), based on the Royal Victoria Hospital Belfast Health and Social Care Trust site, is the regional ‘Specials’



Figure 1: Micafungin over-label as alert for requirement to dilute before use



manufacturing unit for Northern Ireland. The RPhPS approached VP with a view to producing this secondary warning label for the micafungin to alert to the need for dilution before use, as the risk mitigation strategy with the Trust's Medication Safety Team approval.

VP worked alongside The Royal Victoria Hospital Regional Pharmaceutical Quality Assurance System at Victoria Pharmaceuticals and Regional Pharmaceutical Quality Assurance Service (VP Plenum) to develop this label. This was at a time of Covid-19 pandemic challenges, but VP Plenum were able to create the capacity and prioritise this work stream. While there would be a minimal charge for this service, the potential cost savings were still significant. A label was created (Figure 1) which met the patient safety needs of the Medicines Governance team, enabling safety and cost-effectiveness to be realised with an annual saving of almost £48,000.

Discussion

Morley and Cashell,⁸ analysing the many different definitions of collaboration that exist in the literature, describe collaboration as *"an integration of activities and knowledge that requires a partnership of shared authority and responsibility"*. There is evidence available that multidisciplinary collaboration within healthcare improves patient care and patient outcomes, by improving

communication, reducing adverse events, decreasing length of stay, and improving patient satisfaction.^{9,10,11,12,13} The multi-disciplinary nature of this evidence is, however, largely drawn from teams involved directly with patient care. Evidence is available on how procurement teams within other disciplines (mostly the construction industry) can be developed to maximise success^{13,14} but there is little evidence of the impact of multi-disciplinary collaboration involving healthcare teams, such as procurement teams, who do not have patient contact but who are, none-the-less, involved in ensuring the principles of Medicines Optimisation. This paper demonstrates that multi-disciplinary team working across healthcare settings, between different sectors within the same profession – manufacturing, clinical and procurement – has an important role in delivering Medicines Optimisation.

Conclusion

Effective communication and collaboration between procurement teams, clinicians, medication safety pharmacists and service providers can assure patient safety whilst achieving substantial efficiency savings.

Declaration of interests

There are no declarations of interest.

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A review of adherence to NICE criteria for initiation and continuation of treatment with calcitonin gene-related peptide monoclonal antibodies in migraine

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Abstract

Title

A review of adherence to NICE criteria for initiation and continuation of treatment with calcitonin gene-related peptide monoclonal antibodies in migraine

Author List

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Introduction

Migraine is a highly disabling neurological disorder which manifests clinically as recurrent attacks of headache with a range of accompanying symptoms. The current range of treatments includes acute medications, preventative medications, and non-pharmacological therapies. Calcitonin gene-related peptide monoclonal antibodies (CGRP mAbs) have been approved by NICE for the preventative treatment of migraine according to certain criteria. We aimed to identify whether these medicines have been used in accordance with NICE guidance.

Method

This was a retrospective, single site study in a teaching district general hospital. Adult patients who commenced CGRP mAbs treatment for migraine and who were then potentially eligible to receive such treatment for more than 12 weeks were identified. Medical records in the form of correspondence from Neurology were searched for relevant information.

Results

Over the study period ending September 2021, 33 patients (mean age 44, 30% male) had commenced one of erenumab, fremanezumab or galcanezumab and would have been eligible to continue past the 12-week review period. All 33 patients had a documented record of failing at least three prior preventative treatments, and all patients had met the required headache frequency prior to starting. For most patients the medical correspondence stated a number for headache episodes a week, whilst in a few cases there was more of a general description. Of the 27 patients who continued with treatment beyond 12 weeks, the records contained documented benefit in 21 (78%) cases, unclear documentation in five (18%) cases, and 1 (4%) patient had not actually undergone the 12 week review.

Conclusion

In this very small study, the use of CGRP mAbs for the treatment of migraine was in accordance with NICE guidance in the majority of patients. These results from a very small sample size suggest the need for a repeat study once changes to the process have been made in the Neurology specialty.

Keywords:

migraine, CGRP monoclonal antibodies

Introduction

Migraine is a frequent and highly debilitating disorder that manifests clinically as recurrent attacks of headache with a range of accompanying symptoms.^{1,2} It is the second most prevalent neurologic disorder (after tension-type headache), with a female-to-male ratio of 3:1.³ Migraine is subdivided into migraine with and without aura. It is defined as episodic and chronic. Episodic migraine occurs on less than 15 days per month and can be further subdivided into low frequency (1–9 days per month) and high frequency (10–14 days per month). Chronic migraine occurs on 15 or more days per month with superimposed migraine on eight or more days per month, for more than three months.⁴

Treatments for migraine include acute and preventive medications and a range of non-pharmacological therapies. For many patients, the abortive treatment of the acute attack with simple analgesics (i.e. ibuprofen, aspirin or paracetamol) or triptans may be insufficient to taper the burden of the disease. A frequency of four or more migraine headache days per month is associated with significant disability and patients who report this frequency of migraine attacks are eligible for preventative therapy.⁵ Hence, more than a third of the patients qualify for prophylactic treatment (see Box 1).⁶ The goal of preventative therapy in migraine is to decrease the overall clinical characteristics of migraine including frequency, intensity, and duration of attacks; to improve responsiveness to acute therapy; and to reduce migraine-related disability while avoiding occurrence of medication overuse headache.

The third-line medications are the calcitonin gene-related peptide monoclonal antibodies

(CGRP mAbs) which have been approved for the preventative treatment of migraine in the past few years and have been incorporated into recently developed international and institution-specific guidelines.^{7,8,9,10}

Across England and Wales, guidance from the National Institute for Health and Care Excellence (NICE) assesses the clinical and cost effectiveness of health technologies, including pharmaceuticals. The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals (TA). Furthermore, the NHS Constitution, which sets out rights to which patients, public and staff are entitled, and pledges which the NHS is committed to achieve, states that patients have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if their doctor believes they are clinically appropriate.¹¹

The CGRP mAbs - erenumab, fremanezumab and galcanezumab – are licensed for prophylaxis of migraine in adults who have at least four migraine days per month. NICE guidance describes the various treatment options and identifies the relevant technology appraisals (TAs).^{12,13,14} In all cases NICE requires patients to have experienced four or more migraine days a month, and to have tried at least three previous preventative medications. This requirement for patients not to have responded to at least three prior pharmacological prophylaxis therapies matches how NICE approved the use of botulinum toxin type A for the prevention of headaches in adults with chronic migraine.¹⁵ For these three CGRP mAbs, treatment can be continued if patients with episodic migraine (less than 15 headache days a month) have experienced a $\geq 50\%$ reduction in

First-line medication

Beta blockers (propranolol, metoprolol, atenolol, bisoprolol); Topiramate; Candesartan

Second-line medication

Flunarizine; Amitriptyline; Sodium valproate

Third-line medication

CGRP monoclonal antibodies

Box 1. Preventative treatment



migraine days, or those with chronic migraine (15 headache days a month or more with at least 8 of those having features of migraine) have experienced a $\geq 30\%$ reduction in migraine days after three months.

“These three medicines each have a patient access scheme or commercial arrangement associated with the NICE guidance as a way for pharmaceutical companies to lower the acquisition cost to the NHS to improve its cost-effectiveness, so enabling patients to gain access to high-cost medicine treatments. High-cost medicines are so named as they are expensive prescribed items, representing a disproportionate cost relative to the total NHS cost of the relevant hospital episode in terms of volume and cost.”

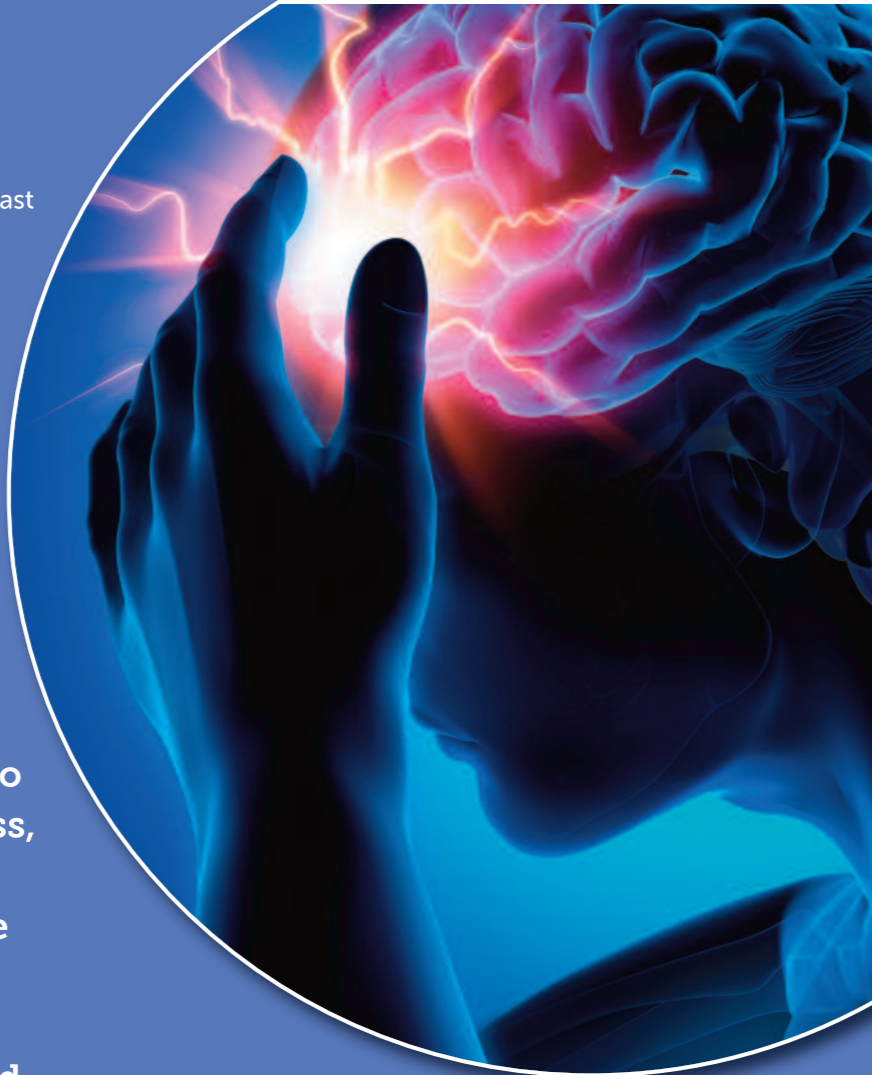
Royal Cornwall Hospitals NHS Trust is a 750-bed acute teaching district general hospital in the south-west of England. The hospital, in conjunction with the local clinical commissioning group (CCG), utilises the Blueteq high-cost drug management system. CCGs are statutory regional NHS bodies that are responsible for the planning and commissioning of healthcare services for their local area. Many CCGs in England use this Blueteq web-based system which allows clinicians to complete an online proforma for patients prescribed a high-cost medicine and receive automatic approval for funding if the patient meets all the relevant criteria which normally reflect the NICE TA guidance. This ensures that clinicians receive the approval to treat immediately. The Blueteq system retains, as an audit trail, the request

history, including patient name, drug, indication, criteria for use, date of request, requesting clinician, and whether the request was granted or not. This enables CCGs to monitor the use of expensive treatments, so that only treatments prescribed in line with NICE guidelines are reimbursed to the hospital.

We aimed to identify whether these medicines have been used according to the criteria based on the three NICE TAs.

Methods

This was a retrospective, single site study in an acute teaching district general hospital. An extract was downloaded from the Blueteq system for adult patients granted approval to commence CGRP mAbs treatment for migraine and who were then potentially eligible to receive such treatment for more than 12 weeks. Relevant data (patient demographics and treatment details) for the period 2020 and September 2021 were imported into Excel by a member of the pharmacy team. Neurology correspondence (as part of the medical record) was examined for relevant information about patients' treatment.



Health Research Authority criteria about research and service evaluation were considered. This was a retrospective assessment involving no changes to the service delivered to patients, and we used the NHS Health Research Authority tool (<http://www.hra-decisiontools.org.uk/research/index.html>) which helped confirm that no ethical approval was required for this project. Patient data were used in accordance with local NHS hospital policy.

Results

As of the end of September 2021, 33 patients (mean age 44, age range 23-67, 30% male) had commenced one of the named medicines and would have been eligible to continue past the 12-week review period. Four patients received erenumab, nine received galcanezumab, and 20 fremanezumab. At commencement of treatment all of the 33 patients had a documented record of failing at least three prior preventative treatments, noting that five of these had previously been receiving botulinum for migraine. For all patients it was documented in Neurology correspondence that they met the required headache frequency prior to starting. This description was a mixture of a stated numerical frequency of migraines or headaches such as in Box 2.

“Six of these 33 patients ceased treatment during the time period covered - four due to lack of benefit, one due to side effects (this patient had previously tried 11 preventative treatments), and one due to the patient becoming pregnant.”

Categorisation into episodic or chronic migraine as used in the NICE guidance was not apparent in the patient records. Of the 27 patients who continued with treatment beyond 12 weeks, the medical records contained documented benefit in 21 (78%) cases, unclear documentation in five (18%) cases, and 1 (4%) patient had not actually undergone the 12-week review. The five cases where benefit was not expressed numerically contained descriptions of benefit such as “Patient states number of acute migraines has diminished, background headache persists”, and “Still daily headaches but less intense. Will consider stopping but not yet”.

Discussion

This small-scale study found that all 33 patients met the NICE starting requirements for preventative treatment, but the required treatment benefits for those 27 who continued past the 12-week review period was not clear in five patients or missing in one patient. This lack of objective numerical benefit for a few patients may be due to the impact of the Covid pandemic. Though it is advised that all patients who are prescribed CGRP mAbs must keep a headache diary, it is understood that as Neurology review of patients moved from face-to-face clinics to a telephone review the opportunity for the clinician to look at and scrutinise a diary diminished. The drug cost impact of continuing inappropriate treatment in these six patients would be about £30,000 per year at NHS price and excluding VAT as these are provided via homecare. The actual cost impact is less than this due to the commercial arrangement in place.

As these are still relatively new drugs there is a lack of long-term data, as well as a recognition that pivotal trials have generally involved a comparison with placebo, and so it is uncertain if they are equally or more effective than the previously approved therapies.¹⁶ NICE guidance recognised that the long-term benefits of these drugs

**“Continuous background headache Migraine
a couple of times a month.”**

“Couple of migraines a week and very few pain free days.”

Box 2 Examples of description of frequency of attacks



compared with best supportive care remained uncertain. The British Association for the Study of Headache advises that how long patients should continue to receive CGRP mAbs will depend on the severity of their condition pre-treatment, but the need for ongoing treatment should be assessed on at least an annual basis.¹⁷

The finding that 70% of the 33 patients in our small study were female is to be expected as migraine is between two and three times more common in women than in men, which is likely to be a result of hormonal factors, genetic differences and potential under-reporting among men.¹⁸

In our small uncontrolled review of use of these drugs we noted four (13%) of the 31 patients who commenced CGRP mAbs therapy treatment had been explicitly recorded as stopping therapy due to perceived lack of benefit over the 12-week observation period. There were another five (18%) patients where benefit from therapy was not clearly documented. Published observation studies with many more patients and using more rigorous outcomes suggest that after three doses of these drugs we would expect to see at least a half of patients recorded as not meeting the outcome as described in the NICE guidance.^{19,20}

As a result of our pharmacy-led review, there is a need to discuss with Neurology about improving the headache frequency recording so that it is more explicit in its documentation. Though all three drugs are associated with a commercial access scheme, there is an opportunity to develop with commissioners a pathway that lists the least expensive as the recommended first choice CGRP mAbs. The pattern of drug usage seen in this study

is a reflection of when they were approved for use by NICE and the organisation of homecare services within the trust. Such a future pathway would also acknowledge that the homecare provision differs between the three drugs with one of them having a nurse training provision for teaching administration to the patient.

We recognise the limitations of a single centre, very small-scale study. We do not report prolonged follow up of patients in relation to any improvement in their headache other than what we observed documented in Neurology letters at commencement and review of treatment. This correspondence did not contain sufficient detail for us to calculate robustly the number of migraine or headaches days per month before treatment and at 12 week follow up. These results therefore cannot be generalised to other hospitals.

Conclusion

In this very small study, the use of CGRP mAbs for the treatment of migraine was in accordance with NICE guidance in the majority of patients. Where deviation from the guideline occurred, this was around apparent inadequate documentation at 12-week follow up in the Neurology letters we reviewed. These results from a very small sample size suggest the need for a repeat study once changes to the process of better documentation of headache frequency have been made in the Neurology specialty.

Declaration of interests

The authors have no interest to declare.

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How to pursue a clinical academic career within the pharmacy profession

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Developing your research potential

The Royal Pharmaceutical Society (RPS) has secured a contract with the National Institute for Health Research (NIHR) to deliver a range of e-learning modules to develop research capability within the pharmacy profession. This is an exciting opportunity for the profession to become more research active¹ and to develop clinical academic careers within pharmacy.

What is a clinical academic?

Clinical academics are clinically active health researchers. They combine research and research leadership with continued practice and professional development. By continuing clinical work in a health and social care setting, clinical academics are able to research new ways to deliver care and improve patient outcomes. The principle aims of a clinical academic's research are to inform and improve the quality, safety and effectiveness of patient care.

Why are clinical academics important?

Evidence suggests that healthcare organisations engaging with research activities offer better patient outcomes and clinical academics contribute to this through their research.² The skills and knowledge developed through clinical academic training enables healthcare professionals to design and deliver research studies, build multidisciplinary research teams, secure research funding and communicate findings through publications. Clinical academics understand the challenges and issues in

healthcare through their clinical practice and can use their research capabilities to make a difference to patient experiences and outcomes. The publication of research findings helps to enable services and interventions to be implemented at scale.

NIHR Funding and Opportunities

The NIHR is the UK's largest provider of funding for research and clinical academic training, with a £1 billion spend from the Department of Health and Social Care on research each year.³ Since 2014, pharmacy professionals including pharmacists and pharmacy technicians have been eligible for fully funded clinical academic training, however the profession remains under-represented in research training and clinical academic careers.³ Statistics from the Medical Research Council (MRC) estimated that less than 0.1% of nurses, midwives and allied health professionals (NMAHP) are clinical academics compared to 4.6% of the medical consultant workforce.⁴ The NIHR highlights the need to raise awareness of the opportunities available to pharmacy professionals to build research capabilities in areas such as multimorbidity and polypharmacy.⁵

NIHR Applications and Awards

Data provided by the NIHR Academy (shown in Chart 1 and 2),⁵ show the number of pre-doctoral and doctoral fellowship applications and awards since 2014. As you can see, the number of pharmacist and pharmacy technician applications and awards are the lowest amongst all professionals. Despite being eligible for NIHR

Number of NIHR Pre-doctoral and Doctoral Fellowship Programme Applications by Professional Background

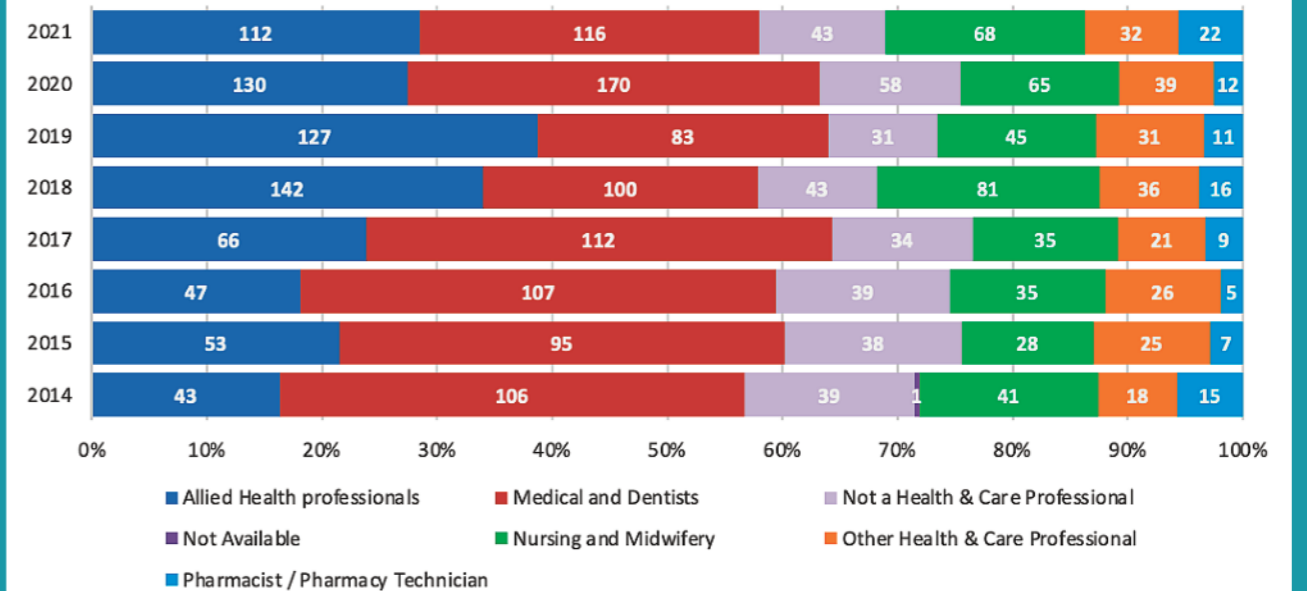


Chart 1. Number of NIHR Pre-doctoral and Doctoral Fellowship Programme Applications by Professional Background

Number of NIHR Pre-doctoral and Doctoral Fellowship Programme Awards by Professional Background

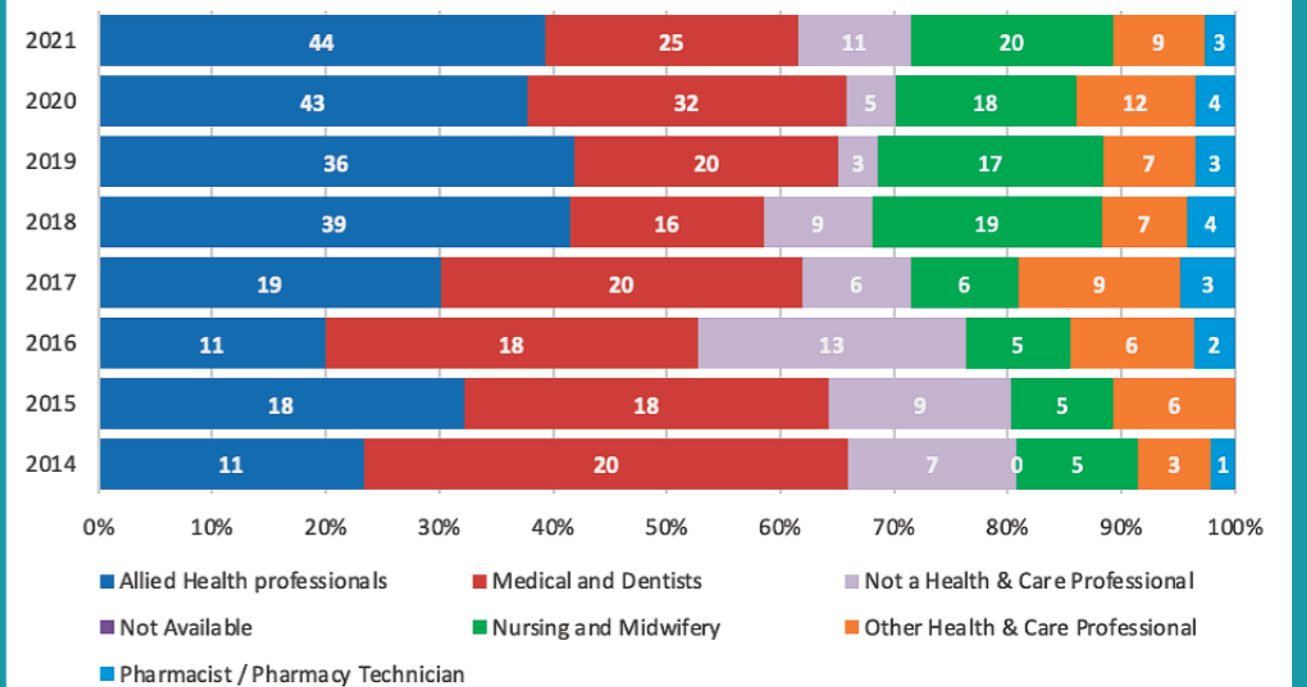


Chart 2. Number of NIHR Pre-doctoral and Doctoral Fellowship Programme Awards by Professional Background



funding for the last 8 years, there has not been a rise in number of applications or fellowships awarded. There is a lack of awareness about clinical academic training and careers for pharmacy staff. Pharmacists in many sectors will complete a postgraduate clinical diploma and independent prescribing however very few will consider a Research Masters, MSc or PhD. The RPS and NIHR e-learning research modules are a step in the right direction to raise awareness of clinical academic careers for pharmacy professionals.

How to become a clinical academic

The Health Education England (HEE) and NIHR Integrated Clinical and Practitioner Academic (ICA) Programme provides research training awards for health and social care professionals (excluding doctors and dentists), who wish to develop clinical academic careers. This programme is designed to support individuals with research, clinical and professional development whilst undertaking a research project. It is tailored to the development needs of the individuals and their area of research interest. The programme is fully funded, covering salary back fill, training, development and research costs, making it highly competitive.

The ICA Programme is made up of four schemes to support individuals at different stages of their clinical academic career.⁶ The ICA programme also offers short duration Bridging Awards that are run through the local HEE teams in the North, Midlands and East, London and South.⁷ These programmes support development of doctoral or post-doctoral award applications. See Table 1 for a summary of the ICA programmes.

For more information about the ICA Programme and application visit:

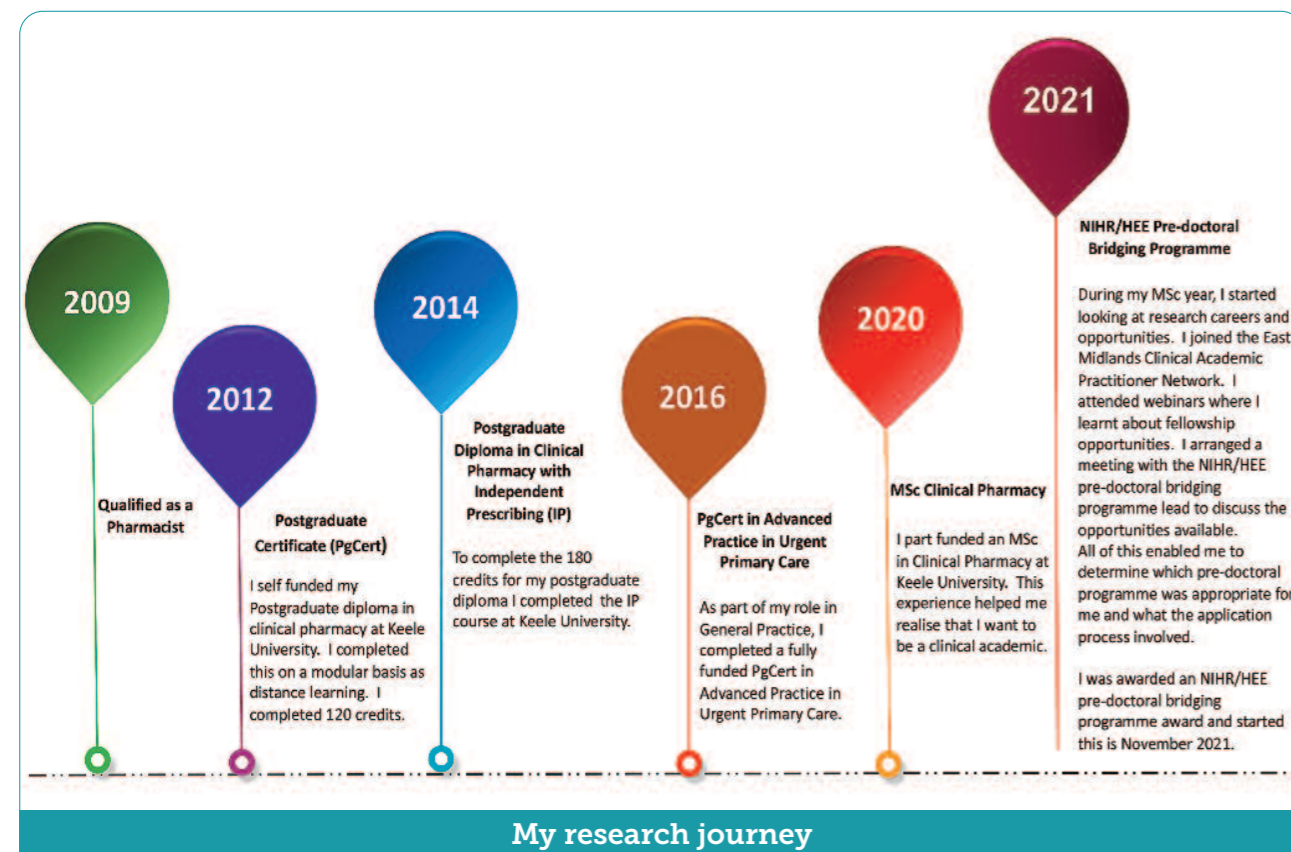
<https://www.nihr.ac.uk/explore-nihr/academy-programmes/hee-nihr-integrated-clinical-and-practitioner-academic-programme.htm>

For information about the bridging programmes, contact the local HEE teams or via:

<https://www.hee.nhs.uk/our-work/clinical-academic-careers/integrated-clinical-academic-ica-programme/bridging-scheme>

My research journey

My research journey is very much at the beginning, but it has taken 12 years of being a qualified pharmacist to realise that I am passionate about research and want to be a clinical academic:



Scheme	Specifics
HEE Internship	<ul style="list-style-type: none"> 6-month programme Introduction to clinical research For individuals who have not completed a Research Masters or MSc Develop practical skills to undertake a research project Supported by an expert supervisor Salary costs are covered for days away from healthcare role
HEE/NIHR ICA Pre-doctoral Clinical and Practitioner Academic Fellowship (PCA)	<ul style="list-style-type: none"> Open to early career researchers who want to pursue a clinical academic career Individual to determine level of funding and support required: <ul style="list-style-type: none"> ⇒ Funding to support the individual develop a doctoral fellowship application and undertake academic training at Masters level ("standard" PCAF) ⇒ Funding to support the individual develop a doctoral fellowship application and undertake a small amount of academic training at Masters level (PCAF Bridge) Completed over 6 to 30 months Salary costs are covered for days away from healthcare role
HEE/NIHR Doctoral Clinical and Practitioner Academic Fellowship (DCAF)	<ul style="list-style-type: none"> Open to individuals who have Masters level research experience or training Individuals undertake a PhD Three-year award (up to six years part time) Approximately 80% of this will be spent working academically and the remaining 20% will be devoted to practice and development Funding covers salary costs, PhD tuition fees, the cost of a research project and tailored clinical and academic training
HEE/NIHR ICA Advanced Clinical and Practitioner Academic Fellowship (ACAF)	<ul style="list-style-type: none"> Open to individuals who have completed or are soon to be awarded a PhD and are supported to develop their academic career Between 2 to 5 years depending on whether it is completed full-time or part-time and between 50% and 100% WTE Between 20 to 40% of the time funded through the ACAF should be spent developing the individual's service or practice role Funding to cover salary costs, the costs of an appropriate research project, and the costs of a tailored academic and professional development programme
HEE/NIHR pre-doctoral bridging programme	Suitable for early career researchers who have completed Masters level research training and require additional support and training to develop a proposal for a doctoral award such as DCAF
HEE/NIHR post-doctoral bridging programme	Suitable for individuals who have completed or are near completion of a PhD and are looking for support to develop a proposal for a post-doctoral award, such as ACAF

Table 1. Summary of the ICA programmes

“Reflecting on my journey, I think the best advice I can give to colleagues is that, if you have completed a postgraduate diploma, then consider undertaking an MSc. This will give you an introduction into research and a prepare you for any future applications for NIHR fellowship programmes.”

Top tips for developing a clinical academic career:

- 1. Talk to people.** Research is a collaborative process, and you will not be able to do it alone. Join your local research networks, seek out research teams in your organisation, contact the NIHR or Pharmacy Research UK to discuss opportunities and develop links with Higher Education Institutes. Speaking to people will help you connect with potential academic or clinical supervisors and mentors so do not be afraid to contact people without any formal introductions. Most people will be happy to offer advice and support, but some may not, so don't be disheartened by any setbacks. This is all part of the process and will help you build the resilience required to succeed in research.
- 2. Be true to yourself.** Completing a MSc or PhD requires motivation, commitment, and focus. It is a long journey, albeit an exciting one. When thinking about your research ideas and proposals, my advice would be to research an area you are interested in and passionate about. Being a pharmacist or pharmacy technician exposes you to a wide range of clinical environments and experiences, use those to inform your research. Be true to your ideas but be willing to accept advice from experienced researchers and experts. Their advice and experience will be invaluable for the success of your research grant or fellowship application as well as for the successful delivery of your research project.
- 3. Don't be afraid to learn new skills.** Academic writing was a distant memory when I started my

MSc but it was a skill that I had to relearn. There were lots of online resources available, the University ran courses on academic writing and I received invaluable feedback on assignments. Research will force you to learn new skills but be reassured that there will always be resources available and people around that can support you. The academic training and development through the NIHR programmes are tailored to your learning and development needs so take the opportunity to identify your knowledge gaps and develop a training plan. The Researcher Development Framework (RDF) is a good tool to help identify your strength and training needs but also to help you prioritise your development.⁸ Access RDF here: <https://www.vitae.ac.uk/researchers-professional-development/about-the-vitae-researcher-development-framework/developing-the-vitae-researcher-development-framework>

- 4. Publish your work.** If you have been involved in an audit, quality improvement project, service evaluation or have completed a dissertation for a Masters level course, you should consider publishing your work. It may seem daunting at first, but all journals will provide a structure and guidance for submissions, and you can always contact the editors for advice if needed. Publishing your work not only allows you to demonstrate a commitment to a clinical academic career, but the peer review process for publications also enables you to receive feedback that you may not have received otherwise. This will help you develop as a researcher and build your confidence in academic writing.

Conclusion

As an early career clinical academic, I value the balance between clinical practice and research as this enables me to use my research skills in day-to-day practice to improve patient care and service delivery. The announcement from the RPS to deliver research related e-learning modules in collaboration with NIHR is the first step to raising the profile of research in pharmacy and building a research active profession. Everyone's research journey is different and the NIHR ICA Programme is just one of many pathways into clinical academia. Pharmacy professionals have a wealth of knowledge and experience that could make significant contributions to research and patient care, and I hope that my journey inspires others to consider a clinical academic career.

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After the pandemic – delivering respiratory services in a post-Covid NHS

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Sanjay Tanna, Senior Clinical Pharmacist, offers a perspective on how respiratory care services in different care settings across the NHS can work together to tackle the significant backlog that exists following the Covid-19 pandemic.

Summary

Asthma UK and the British Lung Foundation have provided evidence (see below) that there is a significant backlog in the diagnosis and management of respiratory disease due to the Covid-19 pandemic. Routine reviews of asthma and COPD patients have not occurred in general practice, meaning existing patients may have seen their condition deteriorate (for example, become more symptomatic and thereby affecting their quality of life).

A few options are suggested to restart services for respiratory patients. These include services from GP practice, services via a Primary Care Network (PCN) based diagnostic hub or services via a secondary care based diagnostic hub. The pros and cons of these options are discussed in this paper.

Pharmacists operating in various settings – GP practice, the PCN, or the hospital – may be able to play a key role in improving access and capacity to help restart respiratory services.

Asthma UK and the British Lung Foundation submitted evidence to the government in September 2021 regarding the backlog of respiratory care:¹

‘The Covid-19 pandemic has had an enormous impact on the care of people with lung disease as the NHS suspended many of its services during lockdown, and an average of over 3,000 respiratory patients per week having missed out on a referral for specialist care, treatment or diagnosis in England.

‘Of people diagnosed with a lung condition in the last year, 25% had to wait 6 months to receive a diagnosis, while a further 20% had to wait over a year. These significant delays are extremely problematic for effective and safe care, but also indicate that there are large volumes of patients in the system in need of diagnosis. The fact that spirometry testing was suspended for a long time, and its restart appears to be extremely slow and without publicly available data, is a great worry.

‘Of patients with a diagnosis, 85% have experienced some sort of delays or disruptions to their care. While the use of remote or virtual appointments has been both useful and necessary, there are concerns about the quality of these and the fact that conducting proper inhaler technique checks virtually is unlikely to be effective. This drop in the standard of care is likely to result in worse outcomes, and additional demand on the NHS.’

COPD and Asthma can be difficult to distinguish clinically and may co-exist. It is possible that some people are diagnosed with Asthma when in fact they have COPD. Under and over diagnosis of COPD remains an issue in practice. This is in part because of poor access to spirometry services. NICE 115 guideline states that where COPD is

suspected, diagnosis is made based on history of signs and symptoms. Quality assured spirometry is then used as a supportive/ confirmatory test. The guideline spirometry should be undertaken:

1. As part of the diagnosis of COPD
2. When diagnosis is reconsidered
3. For monitoring the progression and severity of disease.

COPD guidelines recommend that a diagnosis of COPD should be confirmed with a post-bronchodilator spirometry test. A post-bronchodilator FEV1/FVC ratio < 0.7 confirms the presence of persistent airflow limitation and in combination with a clinical history would be consistent with a diagnosis of COPD. Post-bronchodilator testing is appropriate for all patients with suspected COPD who display a complete reversal of baseline airflow limitation, once treatment with a bronchodilator is initiated, to exclude the possibility of asthma.

“Spirometry testing itself is not an aerosol generating procedure but may induce coughing in 50% of patients. All aspects of the testing procedure, (including staff, equipment, premises) must comply with Infection Prevention Control (IPC) measures to prevent the spread of SARS-CoV-2.”

Spirometry is a non-invasive testing procedure used in the diagnosis of lung and respiratory conditions. It is used in primary, community, and secondary care settings for both adults and children and is necessary for establishing a diagnosis of and can be helpful in ongoing disease management. Spirometry measures specific lung function parameters, i.e., the volume and/or flow of air that can be inhaled and exhaled. It is also used in the diagnosis and management of pulmonary fibrosis and cystic fibrosis.

Airway inflammation is a core indicator of asthma and other lung diseases. The measurement of Fractional Exhaled Nitric Oxide (FeNO) testing is a new test which supports the diagnosis and management of asthma.

Historically spirometry has been provided by many GP practices, whereas FeNO testing has not. National commissioning guidance aims to ensure – ‘a standardised level of competence in the performing and interpreting of spirometry testing and aid accurate diagnosis of COPD (and asthma) in primary care’. The guidance further states that new infection control requirements should be met and that staff performing testing and interpreting results should be appropriately trained and accredited.

Since the Covid-19 pandemic, there has been a suspension of respiratory services in many settings. Post Covid, the problem arises as to how to get services up and running to deal with the backlog of reviewing existing respiratory patients and to help with the diagnosis of new patients.

Several options are available to restart the services.

Option 1 - GP practices resume services.

Option 2 - PCN can offer a Diagnostic Hub - where a suitably trained team of respiratory clinicians can offer a full suite of diagnostic tests to help with diagnosis of respiratory conditions and offer management plans.

Option 3 - Secondary care based Diagnostic Hub where patients can be referred for diagnosis and ongoing management.

Looking at the options in detail:

GP practices

They may have suitably qualified nurses, pharmacists who can provide quality assured spirometry and interpretation along the necessary equipment. The benefits of such services are that they are based closer to the patient, some degree of continuity of care may be possible as clinicians may know their patients, existing staff with the relevant skills, experience are utilised to provide high standards of care. Existing payments via QOF would help to fund resumption of services.

The limiting factor in practice may be that the





rooms used to undertake spirometry may not be able to facilitate the air changes, etc, as mandated by NHS England commissioning guidance for spirometry (2020).² Also, the practice may/may not have access to FeNO testing, so may not be able to provide a full diagnostic service in-house. Some practices may also have capacity issues as experienced clinicians look to retirement.

Practice-based pharmacists may be able to help in some cases. They could provide patient facing clinics to assess inhaler technique checks, facilitate reviews and help to optimise inhaler therapies. They may also be involved in patient education as well as clinician education. Practice-based pharmacists would also be able to stratify high risk patients who may need 'urgent reviews' and carry out audits related to respiratory care.

PCN delivered Hub model

The British Thoracic Society (BTS) suggested a service configuration which would see spirometry provided at PCN level.³

PCNs covering populations of around 30,000-50,000 people have been established within the English NHS and are charged with shaping how local services are delivered in response to local needs. The NHS Long-Term Plan (2019) outlined a commitment to 'detect and diagnose respiratory

problems earlier' and supports the diagnosis of respiratory conditions through PCNs.⁴

PCNs are based on GP registered patient lists and designed to understand and respond to the needs of their local community and to foster better collaboration between GP practices and others in the local health and social care system. PCNs determine how and where community respiratory services will be delivered for their local community.

The primary objectives of the service as proposed could be to:

- Enable the optimal management of respiratory disease through early identification and diagnosis with an emphasis on Asthma and COPD
- Ensure accurate diagnosis and severity assessment
- Provide local access to spirometry
- Develop a care model of respiratory care provision, based on integrated pathways
- Increase the number of people accurately diagnosed at an early stage of the disease
- Ensure accurate and consistent interpretation of results and promote effective communication between relevant health professionals

- Reduce the overall rate of exacerbations
- Help improve the quality of life of people with respiratory disease and those close to them
- Help to decrease the number of people dying prematurely from respiratory disease
- Improve value for money from the investment in treating respiratory disease

The advantages of a PCN Hub would be utilisation of existing workforce (team from GP practices), shared expertise, shared use of equipment and the ability to provide the service from a fixed or mobile site. This would also mean that skills would be retained in primary care with potential economies of scale and volume. Patients would benefit from equitable access to such a service. ARRS roles including physiotherapists, dieticians, social prescribers, mental health practitioners could be used to provide MDT approach for the more complex patients with respiratory disease. PCNs' are also being encouraged to become more collaborative with other providers - community pharmacists may also be involved in providing smoking cessation services, inhaler technique checks, therapy reviews via new medicines services as well as providing flu vaccinations.

The main limitations of such a service would be to recruit a suitable team given the current workforce issues within primary care. There would also be a need to assess capacity depending on prevalence of disease (asthma, COPD, other respiratory conditions). Also, there is no existing funding stream available to set up such a service.

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PCN pharmacists could be involved in carrying out respiratory reviews, inhaler technique checks and inhaler therapy optimisation. There are also workstreams around the 'green agenda' which could be tackled by these pharmacists.

Secondary care-based Hub

In some areas, secondary care teams provide a diagnostic and management service for respiratory patients. Due to the pandemic, such services may have been suspended but may now reopen. The main benefits of such services could be quality assured diagnostics and equitable access. Such services may already be centrally funded. The workforce would be mainly comprised of secondary care personnel.

The concern would be that the services could be overwhelmed due to a large backlog of patients. These services may be place-based (at the hospital) and may prove difficult to access for older, frailer patients. Workforce issues may also limit the capacity of such services.

Pharmacists could therefore provide a key role in restarting respiratory services by providing extra capacity at most clinical settings.

The Primary Care Respiratory Society document 'Fit to Care' would be a great resource to help identify gaps in skills and knowledge for all pharmacists. As their confidence and competence increases, they could also use the resources in the document for bench marking purposes.⁵



