

Scottish Pharmacy Review



ISSUE 124 - 2019

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WELCOME

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EDITOR'S LETTER

Welcome to the latest edition of Scottish Pharmacy Review!

Aside from the long stretch of summer holidays – and, frankly, better music scene – if there's one remnant of my youth which I wish I'd tucked safely in my backpack to preserve for my later years, it would be that blissful lack of shame.

Be it tumbling off our bikes; stumbling over our words during a school presentation; or simply saying no, it seemed a lot easier to be unapologetic when we were less accountable for ourselves and others.

A huge perk of my job is that I get to speak first-hand to practitioners and healthcare experts who are on the frontlines of new research, as well as the patients they're driving change for. However, with each issue and condition investigated, we're seeing familiar battle lines drawn.

Patients feel silently consumed by embarrassment and shame, and health leaders are trying to break down stigmatising barriers by encouraging greater public discourse – something which we can all be a part of.

In this edition of SPR, we get a glimpse of the problems which reluctance in opening up can pose – through the shocking number of prostate cancer patients receiving insufficient support for managing erectile dysfunction (page 38), and of the important need to propel

urinary incontinence into mainstream conversation (page 52). We also take a look at the dread of 'inconveniencing' others as one family share their story of a cows' milk allergy diagnosis (page 11).

Get the know-how on all things vitamin D (page 16); immerse yourself in the opportunities available through rural pharmacy in Scotland (page 59); and read the poignant tribute to the much-missed Frances Rooney contributed by some of her friends and colleagues (page 18).

Don't miss our interview with Libby Dowling at Diabetes UK, who shares tips for helping individuals with diabetes self-manage responsibly (page four).

This issue also coincides with the launch of the 2019 Scottish Pharmacy Awards – please do get involved and showcase your team's excellent work to all streams of the sector (beginning on page 21).

Happy reading!



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DIABETES

DIABETES: PLAYING IT SAFE

When it comes to diabetes, the patient's understanding, adherence, and continuous monitoring are key components of effective care. However, with too many people with diabetes still under-estimating the condition's severity, Libby Dowling, Senior Clinical Advisor at Diabetes UK, talks to SPR about how we can encourage individuals to self-manage responsibly.



Libby Dowling

HOW OFTEN SHOULD DIABETES PATIENTS MEASURE THEIR BLOOD GLUCOSE?

It depends on what type of diabetes they have, and what their treatment is. If patients have type 1 diabetes, they're going to be checking their blood sugar levels at least four times a day – but many check more regularly than that, such as anytime they think that their levels might be a bit high or low; or if they're going to exercise etc.

For patients with type 2 diabetes, it's slightly different. If they have the condition and are just managed by diet and physical activity alone, or Metformin, they don't check their blood sugar levels as a general rule. However, if the individual takes insulin or some of the diabetes

tablets that can cause hypoglycaemia, then they should be checking.

WHAT COMPLICATIONS CAN OCCUR IN THE SHORT-TERM IF DIABETES ISN'T CORRECTLY SELF-MANAGED?

However well patients manage their diabetes, they can't get it right all the time – they're essentially taking on the role of their pancreas which is a big ask.

If the patient's blood glucose levels drop too low, they'll suffer from hypoglycaemia, which will make them start to feel dizzy, shaky, and sometimes disorientated. If it's not picked up at that point, then they're in danger of collapsing or having a fit. Low blood sugar needs to be treated very quickly.

More severe symptoms can be too hard for the patient to treat on their own. As a result, most people with diabetes will have a sugary gel which someone else can squirt inside their mouth, and if the patient becomes unconscious through hypoglycaemia, then an injection is also available.

The other thing that can happen in the short-term is that if the patient's blood sugar is too high, they can start to feel thirsty, tired, and drowsy, and they can progress into diabetic ketoacidosis, which can be life-threatening and needs hospital treatment. It's crucial that blood sugar levels are checked regularly so that action can be taken accordingly.

ARE HEALTHCARE PROFESSIONALS PLAYING A BIG ENOUGH ROLE IN PATIENTS' DIABETES EDUCATION?

Anybody who needs to use a blood glucose monitor should receive a basic education package from their healthcare professional which involves the practicalities of using the monitor, information on how often, and the targets which they should be aiming for. The patient should also receive information on what to do should their blood glucose levels get higher or lower.

HOW ARE BLOOD TESTING METERS ALLOCATED?

It's not so common now that diabetes patients can just make a decision regarding their preferred monitor. It's all about cost-effective care, so what often happens is that a particular area will have a number of different blood glucose monitors, and the patient, along with their healthcare team, will decide which device is the most appropriate.

For individuals who don't require a lot of active management for their diabetes, a reasonably basic monitor might be suitable. But those with

type 1 diabetes, who are counting carbohydrates or adjusting their insulin on a dose-by-dose basis, might need something more to allow them to do the required calculations.

HOW OFTEN SHOULD PATIENTS REPLACE THEIR MONITORING DEVICE?

Monitors are pretty robust and will usually last a few years. However, they do need to be properly looked after by the patient.

WHAT LIFESTYLE AND DIETARY TIPS ARE ALSO FUNDAMENTAL TO THE PATIENT'S DIABETES MANAGEMENT?

We advise that they live a generally healthy lifestyle. Type 2 diabetes is often linked to being overweight and not very active. If that's the cause of it, then it's really important that the patient receives support and takes steps towards losing the extra weight.

Everyone with diabetes has an increased risk of cardiovascular disease so keeping healthy is key.

HOW OFTEN SHOULD PATIENTS ATTEND FOR DIABETES CHECK-UPS?

People with diabetes should be seen at least once a year for a check-up – probably more often. It's really crucial that they keep the appointments because the healthcare professional both checks that their diabetes is being managed properly, and whether any long-term complications of diabetes have occurred from a long period of high blood glucose levels. The occurrence of this can damage the blood vessels and nerves and cause heart attacks, strokes, amputations etc. It's important that we check for those conditions, and if anything is picked up early, it can be treated.

People with diabetes will also need to get their eyes checked on a regular basis to make sure that there are no problems there.

ARE THERE ANY LEARNING RESOURCES YOU CAN RECOMMEND?

Diabetes UK have a lot of information on our website on all areas of diabetes management – for healthcare professionals as well as people with diabetes.

For healthcare professionals we provide position statements on certain aspects of diabetes care, a shared practice library, and much more. We also have a learning zone which has tailored information for people living with diabetes – it's as personalised as we can make it.

For more information, visit www.diabetes.org.uk.

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NEWS

ONTO A WINNER

University of Dundee researchers have been presented with a prestigious award by the Medicines for Malaria Venture.

Researchers from the Drug Discovery Unit at the University of Dundee have been awarded the Project of the Year 2018 from the Medicines for Malaria Venture (MMV) for their discovery work on potential new drugs for malaria.

The annual award goes to the scientific partners involved in that year's most exciting project from the MMV portfolio. The MMV is the world's leading product development partnership for discovering and developing new effective and affordable medicines to treat malaria.

Malaria is a serious disease, particularly affecting sub-Saharan Africa, causing approximately 435,000 deaths in 2017 – mainly among children under the age of five – and is caused by a single-celled parasite.

There's a need for new drugs to prevent and treat malaria, due, in particular, to the rise of resistance to existing drugs, as well as the need for simpler dosing regimens that facilitate improved treatment adherence. New medicines able to stop malaria transmission and prevent malaria relapse are also required for the drive to eliminate this terrible disease.

The team at the Drug Discovery Unit, led by Professor Ian Gilbert, Professor Kevin Read, and Dr Beatriz Baragaña, is working on a way to stop the malaria parasite making its own proteins, which is an effective way to kill the parasite. To do this, the team are developing compounds to inhibit an enzyme involved in protein synthesis.

Professor Gilbert explained, 'This is an exciting project, using information about the structure of the enzyme and computational chemistry to design potential new drugs. While there is still a long way to go and many hurdles to overcome, the team has made great progress

over the last year.'

'The Dundee team was awarded MMV Project of the Year 2018 as their work with MMV really represents a step forward from business-as-usual drug discovery,' said Dr Timothy Wells, the MMV's Chief Scientific Officer.

'Having a greater understanding of the structure of the drug target has been like shining a bright light on the work to optimise the drug series – it means we can be really precise as we improve the selectivity and potency of the compounds.'

Some of the background to this work has recently been published in the Proceedings of the National Academy of Sciences.



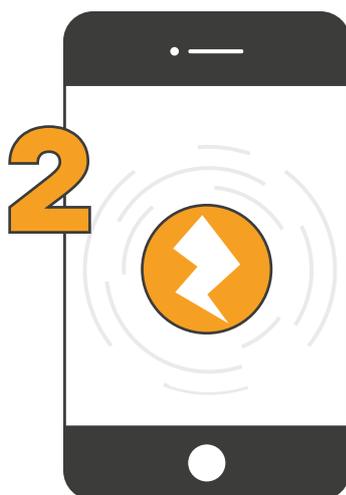
(L to R) Professor Kevin Read, Dr Beatriz Baragaña and Professor Ian Gilbert – all of the Drug Discovery Unit

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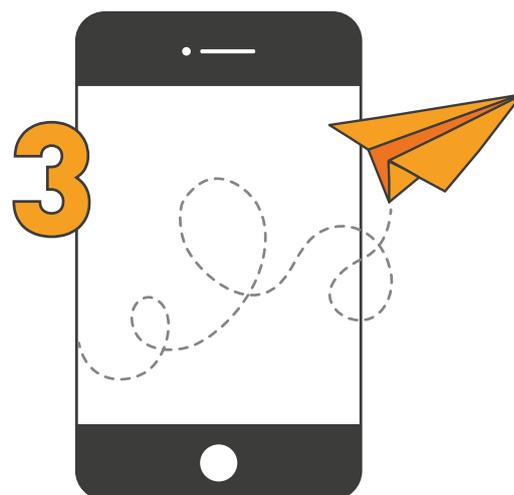
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MANAGING SALIVA CONTROL IN CEREBRAL PALSY

Are you taking the correct steps to provide the highest quality of care for your patients?

Cerebral palsy (CP) is the most common cause of physical disability in children and young people in the developed world, with a prevalence of around two-to-2.5 per 1,000. The term describes a group of permanent, non-progressive abnormalities of the developing foetal or neonatal brain that lead primarily to disorders of movement and posture, causing 'activity limitation' and 'functional impact'.

Sialorrhea refers to drooling of saliva as a result of limitations in a person's ability to control and swallow oral secretions. It occurs in approximately 40 per cent of children and young people with CP, and can have significant medical and psychosocial impact.

NICE guidelines published in 2017 on the management of saliva control advise the following assessment and management steps:

- Assess factors that may affect drooling in children and young people with CP, such as positioning, medication history, reflux and dental issues, before starting drug therapy

- To reduce the severity and frequency of drooling in children and young people with CP, consider the use of anticholinergic medication:
 - Glycopyrronium bromide (oral or by enteral tube) or
 - Transdermal hyoscine hydrobromide or
 - Trihexyphenidyl hydrochloride for children with dyskinetic cerebral palsy, but only with input from specialist services
- When choosing which medicine to use, take into account the preferences of the child or young person and their parents or carers, and the age range and indication covered by the marketing authorisations
- Regularly review the effectiveness, tolerability and side-effects of all drug treatments used for saliva control
- Refer the child or young person to a specialist service if the anticholinergic drug treatments are contraindicated, not tolerated or not effective, to consider other treatments for saliva control

- Consider specialist assessment and use of botulinum toxin A injections to the salivary glands with ultrasound guidance to reduce the severity and frequency of drooling in children and young people with CP if anticholinergic drugs provide insufficient benefit or are not tolerated
- Advise children and young people and their parents or carers that high-dose botulinum toxin A injection to the salivary glands can rarely cause swallowing difficulties, and so they should return to hospital immediately if breathing or swallowing difficulties occur
- Consider referring young people for a surgical opinion, after an assessment confirming clinically safe swallow, if there is:
 - A potential need for life-long drug treatment or
 - Insufficient benefit or non-tolerance of anticholinergic drugs and botulinum toxin A injections

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Contraindications: Hypersensitivity to active substance or excipients; pregnancy and breast-feeding; glaucoma; urinary retention; severe renal impairment/dialysis; history of intestinal obstruction, ulcerative colitis, paralytic ileus, pyloric stenosis, myasthenia gravis; concomitant treatment with potassium chloride solid oral dose or anticholinergic drugs.

Special warnings and precautions for use: Monitor anticholinergic effects. Carer should stop treatment and seek advice in the event of constipation, urinary retention, pneumonia, allergic reaction, pyrexia, very hot weather or changes in behaviour. For continuous or repeated intermittent treatment, consider benefits and risks on case-by-case basis. Not for mild to moderate sialorrhoea. Use with caution in cardiac disorders; gastro-oesophageal reflux disease; pre-existing constipation or diarrhoea; compromised blood brain barrier; in combination with antispasmodics, topiramate, sedating antihistamines, neuroleptics/antipsychotics, skeletal muscle relaxants, tricyclic antidepressants and MAOIs, opioids or corticosteroids. Sialanar® contains 2.3 mg sodium benzoate (E211) in each ml. Patients require daily dental hygiene and regular dental checks. Thicker secretions may increase risk of respiratory infection and pneumonia. Moderate influence on ability to drive/use machines.

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Undesirable effects: Adverse reactions more common with higher doses and prolonged use. In placebo-controlled studies (≥15%) dry mouth, constipation, diarrhoea and vomiting, urinary retention, flushing and nasal congestion. In paediatric literature; very common: irritability, reduced bronchial secretions; common: upper respiratory tract infection, pneumonia, urinary tract infection, agitation, drowsiness, epistaxis, rash, pyrexia. The Summary of Product Characteristics should be consulted for a full list of side effects.

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UK-SIA-2019-017



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ADHD

ADHD: A QUEST FOR MORE

While many with ADHD lead happy, healthy, and successful lives, there is mounting evidence that undiagnosed and untreated, the impact on physical and mental health can be devastating. An enhanced understanding of this and the likelihood of a greater role for primary care in treatment will inevitably impact on pharmacists who will increasingly be called upon for advice and guidance by patients. Dr Tony Lloyd, CEO of the ADHD Foundation, tells us more.



Dr Tony Lloyd

A wider acceptance and understanding of ADHD has resulted in increasing numbers of children and adults seeking a diagnosis and a doubling of prescriptions for ADHD medications in the past decade.

The global prevalence of ADHD is 5.26 per cent, yet in the UK it remains underdiagnosed at 2.9 per cent, and under-medicated at 0.9 per cent. Diagnostic rates for Scotland, Wales and Northern Ireland are even lower at between one-and-two per cent.

Contrary to what many believe, ADHD is not a behavioural disorder. It's an enduring myth that ADHD is a diagnosis given to children who are hyperactive or behave inappropriately. ADHD – like autism, dyspraxia, dyslexia, dysgraphia and dyscalculia – is a neurodevelopmental disorder, with researchers stating that there is a developmental delay throughout childhood of up to three years.

Like autism, we now know that the brains of those with ADHD are structurally and functionally different, and like autism, it is a lifespan condition. While many parts of the neurological delay are overcome once the brain reaches full maturity in early 20s, ADHD can still significantly impair quality of life. The World Federation for ADHD, based in Munich, has now published a free online guide for clinicians, and it's also valuable for pharmacists in understanding the condition and the pharmacological interventions available. (1)

Access to healthcare, however, has remained a controversial issue, with waiting times of between one-and-five years to see a specialist in both child and adult services. A report published by a coalition of charities in 2017 was sent to every MP and every NHS commissioner in the UK highlighting the disparity of care in various parts of the UK. The report, 'A Lifetime Lost, or a Lifetime Saved?' sought to inform government and NHS commissioners of the impact of ADHD and raised the issue of whether stigma was influencing the lack of commissioned services when the scientific evidence was unequivocal. (2)

Undiagnosed and unmanaged ADHD correlates with a range of poor health outcomes, such as high blood pressure, stroke, obesity, anxiety, depression, bipolar disorder and addiction. Research due to be published this year cited significantly increased prevalence of self-harm and attempted suicide in the ADHD population. (3)

The impairment to cognitive functioning and learning increases the risk of academic underachievement and school failure which can lead to a lifetime of deprivation and dependency, which was highlighted

in the DEMOS report published in 2018 highlighting the social and economic impact of ADHD. (4)

ADHD is genetic in origin, with approximately 20 per cent of cases acquired through brain injury, epilepsy or severe sleep deprivation in early infancy. More recent research suggests that preterm births increase the risk of a range of neurodevelopmental disorders by up to 17 per cent which may account for some of the increase in those diagnosed in childhood over the past two decades. (5)

The improvements in identifying, diagnosing and treating ADHD in children, however, has not met with increased capacity in adult services and the report published by the ADHD Foundation, 'Will the Doctor See me Now?' in July 2019, cites Freedom of Information data that proves that lack of data on prevalence and comorbidity and a lack of forward planning has resulted in many children ceasing access to healthcare at a critical juncture of their lives when transitioning from education to employment in adulthood.

With increasing demands on healthcare budgets, NHS England is exploring a national strategy for the care of those with ADHD that will sit alongside the National Autism Strategy, outlined in the 10-Year Long-Term Plan. Several ideas are currently being explored, such as a greater role for the diagnosis and treatment of ADHD in primary care, with specialist nurse prescribers playing a greater role to ease the pressure on GPs. More complex cases with comorbidity – a frequent occurrence for adults seeking a late diagnosis – will likely remain in secondary care and specialist psychiatry until they are proven to be responding well to treatment and stabilised, at which point they will transition to primary care. A public health campaign is also being called for by patient groups and charities to reduce the stigma that may prevent some people from accessing healthcare and potentially being misdiagnosed with anxiety, depression, and bipolar disorder. It will be 2020 before any plans are made public, however, patient groups in Scotland, Wales and Northern Ireland are concerned that no such discussions are taking place in the devolved assemblies about how patient care for ADHD will be addressed and whether they will follow NHS England's lead.

A major source of controversy is that many health boards and clinicians in both primary and secondary care are not adhering to NHS guidelines on treatment for ADHD. Guidelines state clearly that treatment should be multi-modal, including programmes for parents on understanding and supporting their child's ADHD, psycho-social and psycho-educative guidance on self-care and self-management for adults and when needed, psychological therapies such as CBT. NHS guidelines of ADHD medications can be found on www.pathways.nice.org.uk/pathways/attention-deficit-hyperactivity-disorder/medication-for-adhd.

ACHIEVING BETTER CARE

In most parts of the UK, medication is the first and often only line of treatment. With an effect size of 0.8, methylphenidate is one of the most effective compounds available, with numerous research studies demonstrating that early diagnosis and treatment significantly improves long-term mental and physical health. The coalition of ADHD patient charities has produced an accessible report for patients on NHS guidelines, a copy of which should be readily available in every pharmacy. (6)

The necessary changes to achieve better care requires a systemic approach to ensuring that the interplay between genetic heritability and environmental factors are optimised. Short-term and siloed budgets have made it difficult to build a case for ADHD services as the benefits are considerably more impactful across the entirety of statutory services for health, education and social care. A systemic approach begins with educating parents and indeed expectant parents, so that they understand the risk factors associated with familial neurodevelopmental conditions, preterm births and how parenting and early life trauma, such as adverse childhood experiences, can exacerbate the genetic potential and severity of ADHD presentation.

ADHD IN EDUCATION

Training for school teachers is considered by many to be inadequate to ensure accurate identification and early intervention. The Department for Education states that currently 14.6 per cent of the school age population have some form of learning impairment, and as many as two-in-five of those with a learning impairment are not identified until after age 16.

At the ADHD Foundation, over 50 per cent of referrals for children received from schools for assessment don't prove positive for ADHD, resulting in unnecessary costs and increasing waiting times. The imperative for a referral from schools is usually because the child's behaviour is considered inappropriate for a classroom setting.

Yet many teachers remain unaware that acute anxiety is the main cause of inappropriate behaviour and that pervasive 'learner anxiety' can be countered with effective teaching strategies to accommodate neurodiverse learners, such as those with ADHD, autism, dyspraxia, dyscalculia and dyspraxia. Symptom overlap and the estimated 40 per cent-plus comorbidity across the neurodevelopmental spectrum of course makes this difficult for teachers. The ADHD Foundation trains over 12,000 teachers and over 3,000 healthcare professionals every year and has produced a booklet specifically for school nurses and GP practice nurses so that they can better advise parents and schools on how to accurately identify and support children and their families which may also be of use to pharmacists when asked for advice and guidance by patients. (7)

The emerging trend in education, and especially in industry, of a '21st Century neurodiverse paradigm' also influences the current debate on healthcare and indeed those who believe that labelling children is pathologising, what are in fact natural variations and diversity of human brains. This is particularly so of ADHD which historically has been criticised and discredited as an invention of the pharmaceutical industry.

Fortunately, the conversation and science has moved on considerably. ADHD is prevalent in one-in-20 of the population; autism affects one-in-100; and dyslexia is estimated to affect between one-in-five, and one-in-10 individuals. From an evolutionary perspective, if as many as one-fifth of humans are neurodiverse, should we be challenging the medical model that classifies them as errors of genetics or 'disordered'? What remains clear is that public perceptions and our educational paradigm of intelligence, ability and employability are being scrutinised, debated and challenged. Major growth industries, such as robotics, technology and creative industries, are actively recruiting neurodiverse employees because they are 'creative, innovative thinkers'.

This change led by Microsoft, Apple and Google has now crossed over to finance and commerce. Within medicine and education, however, not much has changed in how we classify the one-in-five who are neurodiverse and whether this is simply a question of language and medical terminology or indeed a fundamental shift to a more strength-based approach.

The coalition of UK charities, together with leading academics and clinicians, initiated and led by the ADHD Foundation, psychiatrist Dr Phil Asherson of King's College London, and United Kingdom adult ADHD Network and clinical psychologist, Dr Susan Young, will publish a peer reviewed consensus statement in 2019 calling on the government to act in response to the overwhelming evidence on ADHD.

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- Branded Xaggitin® XL is a prolonged-release form of methylphenidate
- Prescribing branded Xaggitin® XL tablets in place of Concerta® XL* saves the NHS up to 50%^{†2,3}
- Branded Xaggitin® XL is available in 4 strengths: 18 mg, 27 mg, 36 mg and 54 mg¹

*Concerta® is a registered trademark of Janssen-Cilag Ltd.

† Based on the category C reimbursement price for generic prolonged-release methylphenidate tablets, 3 and based on 18, 27 and 36 mg doses.

References: 1. Xaggitin® XL prolonged-release methylphenidate tablets Summary of Product Characteristics. Available from <https://www.medicines.org.uk/emc/search?q=xaggitin> (last accessed July 2019). 2. Drug Tariff July 2019 (England and Wales). 3. Concerta XL prolonged-release methylphenidate tablets Summary of Product Characteristics. Available from <https://www.medicines.org.uk/emc/search?q=concerta> (last accessed July 2019).

Item code: UK-XAG-2 Date of Preparation: July 2019



Prescribing Information for Xaggitin XL® (methylphenidate hydrochloride) prolonged-release tablets

Please refer to the Summary of Product Characteristics (SPC) before prescribing.

Presentation: Available in a range of doses. Prolonged-release tablets containing 18mg, 27mg, 36mg or 54mg of methylphenidate hydrochloride, equivalent to 15.6 mg, 23.3 mg, 31.1 mg or 46.7 mg of methylphenidate, respectively. **Indication:** Attention Deficit/Hyperactivity Disorder (ADHD). Indicated as part of a comprehensive treatment programme for ADHD in children aged 6 years of age and over when remedial measures alone prove insufficient. Treatment must be under the supervision of a specialist in childhood behavioural disorders. Diagnosis should be made according to DSM-IV criteria or the guidelines in ICD-10 and should be based on a complete history and evaluation of the patient. Diagnosis cannot be made solely on the presence of one or more symptom. Xaggitin XL treatment is not indicated in all children with ADHD and the decision to use the medicinal product must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age. **Dosage and Administration:** **Refer to SPC for details and recommendations:** For oral use. Take once daily in the morning. The tablet must be swallowed whole with liquids and must not be chewed, broken, divided, or crushed. It may be administered with or without food. **Pre-treatment screening:** Conduct a baseline evaluation of a patient's cardiovascular status including blood pressure and heart rate prior to prescribing. A comprehensive history should document concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death and accurate recording of pre-treatment height and weight on a growth chart. **Ongoing monitoring:** growth, psychiatric and cardiovascular status should be continuously monitored. Patients should be monitored for the risk of diversion, misuse and abuse of methylphenidate. **Dose titration:** Careful dose titration is necessary at the start of treatment. Dose titration should be started at the lowest possible dose and may be adjusted in 18 mg increments at approximately weekly intervals. The maximum daily dosage is 54 mg. **Patients New to Methylphenidate:** Lower doses of short-acting methylphenidate formulations may be considered sufficient to treat patients new to methylphenidate. Careful dose titration by the physician in charge is required. The recommended starting dose is 18 mg once daily. **Patients Currently Using Methylphenidate:** Dosing recommendations are based on current dose regimen and clinical judgement. Please refer to the SPC for dose conversion. **Long-term (more than 12 months) use in children and adolescents:** Methylphenidate treatment is usually discontinued during or after puberty. If prescribed for extended periods (over 12 months), the long-term usefulness of treatment with methylphenidate should be periodically re-evaluated with trial periods off medication to assess the patient's functioning without pharmacotherapy. It is recommended that methylphenidate is de-challenged at least once yearly to assess the child's condition. **Dose reduction and discontinuation:** Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a one-month period. If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued. **Adults:** In adolescents, whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. Initiation of treatment with Xaggitin XL in adults is not appropriate. **Elderly or children under 6 years:** Xaggitin XL should not be used due to lack of data. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients, glaucoma, pheochromocytoma, during treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days of discontinuing those medicinal products, hyperthyroidism or thyrotoxicosis, diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder, diagnosis or history of

severe and episodic (Type I) Bipolar (affective) Disorder that is not well-controlled, pre-existing cardiovascular disorders including severe hypertension, heart failure, arterial occlusive disease, angina, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (disorders caused by the dysfunction of ion channels), pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including vasculitis or stroke. **Precautions and Warnings:** **Refer to SPC for details and recommendations:** **Long-term use (more than 12 months) in children and adolescents:** Careful ongoing monitoring for cardiovascular status, growth, appetite, development of de novo or worsening of pre-existing psychiatric disorders. Psychiatric disorders to monitor for include (but are not limited to) motor or vocal tics, aggressive or hostile behaviour, agitation, anxiety, depression, psychosis, mania, delusions, irritability, lack of spontaneity, withdrawal and excessive perseveration. The use of methylphenidate for over 12 months in children and adolescents with ADHD should be periodically re-evaluated. Recommended that methylphenidate is de-challenged at least once yearly to assess the child's condition. **Use in adults, elderly or children under 6 years of age:** see above. **Cardiovascular status:** Careful history and physical exam should be carried out to assess for the presence of cardiac disease, and patients should receive further specialist cardiac evaluation if initial findings suggest such history or disease. Cardiovascular status should be carefully monitored. Blood pressure and pulse should be recorded at predefined intervals. **Sudden death and pre-existing structural cardiac abnormalities or other serious cardiac disorders:** Sudden death has been reported in association with the use of stimulants of the central nervous system at usual doses in children. **Misuse and cardiovascular events:** Misuse of stimulants of the central nervous system may be associated with sudden death and other serious cardiovascular adverse events. **Cerebrovascular disorders:** Contraindicated in those with certain cerebrovascular conditions (see above). Patients with additional risk factors should be assessed at every visit. Cerebral vasculitis is a very rare idiosyncratic reaction and this diagnosis should be considered in any patient who develops new neurological symptoms consistent with cerebral ischaemia. **Psychiatric disorders:** In the case of emergent psychiatric symptoms or exacerbation of pre-existing psychiatric disorders, methylphenidate should not be given unless the benefits outweigh the risks to the patient. **Consult SPC for additional information for specific psychiatric disorders.** **Growth:** Moderately reduced weight gain and growth retardation have been reported with the long-term use in children. Treatment interruption may be necessary. **Seizures:** Use with caution in patients with epilepsy. If seizure frequency increases or new-onset seizures occur, methylphenidate should be discontinued. **Abuse, misuse and diversion:** Use with caution in patients with known drug or alcohol dependency because of a potential for abuse. **Priapism:** Patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention. **Withdrawal:** Careful supervision is required during withdrawal. Long-term follow up may be required. **Fatigue:** Should not be used for the prevention or treatment of normal fatigue states. **Choice of methylphenidate formulation:** This would be the decision of the treating specialist. **Drug screening:** Methylphenidate may induce a false positive laboratory test for amphetamines, particularly with immunoassay screen test. **Renal or hepatic insufficiency:** No data available. **Haematological effects:** Discontinuation of treatment should be considered in the event of leukopenia, thrombocytopenia, anaemia or other alterations, including those indicative of serious renal or hepatic disorders. **Excipients:** Contains lactose, therefore patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions: Pharmacokinetic interaction:** Caution is recommended at combining methylphenidate with other medicinal products, especially those with a narrow therapeutic window. Methylphenidate is not metabolised by cytochrome P450 to a clinically relevant extent. Inducers or inhibitors of cytochrome P450 are not expected to have any relevant

impact on methylphenidate pharmacokinetics. However, reports indicate that methylphenidate may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (e.g. phenobarbital, phenytoin, primidone), and some antidepressants (tricyclics and selective serotonin reuptake inhibitors). When starting or stopping treatment with methylphenidate, it may be necessary to adjust the dosage of these medicines already being taken and establish plasma concentrations (or for coumarin, coagulation times). **Pharmacodynamic interactions:** **Anti-hypertensive medicines:** may decrease the effectiveness of anti-hypertensives. **Use with medicines that elevate blood pressure:** Caution. **Use with alcohol:** Patients should abstain from alcohol during treatment. **Use with halogenated anaesthetics:** Risk of sudden blood pressure increase during surgery. If surgery is planned, methylphenidate treatment should not be used on the day of surgery. **Use with centrally acting alpha-2 agonists (e.g. clonidine):** Long-term safety of concomitant administration has not been systematically evaluated. **Use with dopaminergic (agonists and antagonists including antipsychotics) medicines:** Caution. **Use during pregnancy and lactation:** **Pregnancy and Breast-feeding:** Not recommended unless benefits outweigh risks. Neonatal cardiorespiratory toxicity has been reported in spontaneous case reports. **Fertility:** No relevant effects observed. **Effects on ability to drive and use machines:** Can cause dizziness, drowsiness and visual disturbances including difficulties with accommodation, diplopia and blurred vision. It may have a moderate influence on the ability to drive and use machines. If affected, patients should avoid potentially hazardous activities. **Undesirable effects:** **Very common (≥ 1/10):** insomnia, nervousness and headache. **Common (≥ 1/100 to < 1/10):** nasopharyngitis, upper respiratory tract infection, sinusitis, anorexia, decreased appetite, moderately reduced weight and height gain during prolonged use in children, affect lability, aggression, agitation, anxiety, depression, irritability, abnormal behaviour, mood swings, tics, initial insomnia, depressed mood, decreased libido, tension, bruxism, panic attack, dizziness, dyskinesia, psychomotor hyperactivity, somnolence, paraesthesia, tension headache, accommodation disorder, vertigo, arrhythmia, tachycardia, palpitations, hypertension, cough, oropharyngeal pain, upper abdominal pain, diarrhoea, nausea, abdominal discomfort, vomiting, dry mouth, dyspepsia, alopecia, pruritus, rash, urticaria, arthralgia, muscle tightness, muscle spasms, erectile dysfunction, pyrexia, growth retardation during prolonged use in children, fatigue, irritability, feeling jittery, asthenia, thirst, changes in blood pressure and heart rate (usually an increase), weight decreased and alanine aminotransferase increased. **Consult SPC for other side effects.** **Overdose:** There is no specific antidote to methylphenidate overdose. Treatment consists of appropriate supportive measures. See SPC for treatment guidance. **Marketing authorisation number and Basic NHS Price:** All strengths are sold in packs of 30 prolonged-release tablets. Xaggitin 18 mg PL 01883/0359 - £15.58; Xaggitin 27 mg PL 01883/0360 - £18.40; Xaggitin 36 mg PL 01883/0361 - £21.22 and Xaggitin 54 mg PL 01883/0362 - £36.80. **Marketing authorisation Holder:** Macarthys Laboratories Ltd, T/A Martindale Pharma, Bampton Road, Harold Hill, Romford, Essex, RM3 8UG, United Kingdom. **Legal category:** POM. **Further information:** Martindale Pharma, Bampton Road, Romford, RM3 8UG. Tel: 01277 266 600. **Date of Preparation:** May 2019.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Martindale Pharma, an Ethypharm Group Company. Tel: 01277 266 600. e-mail: drugsafety.uk@ethypharm.com

COWS' MILK ALLERGY: FAMILY MATTERS

When determined early in life, a cows' milk allergy doesn't just represent a pivotal point for the patient – it thrusts the whole family into the grips of change too. Delve into the full impact of the diagnosis through the perspectives of both the child and the parent.



Lucy and her mother, Andrea

MY WAY OF LIFE

23-year-old Lucy studied BSc Nutrition at Cardiff Metropolitan University, and currently works at Dunbia Crosshands as a Technical Development Technologist. Since being diagnosed with a cows' milk allergy as a child, Lucy's diligence – coupled with medical and familial support – have helped keep the risks of flare-ups at bay. Here, she discusses her journey.

HOW OLD WERE YOU WHEN YOU WERE FIRST DIAGNOSED WITH A COWS' MILK ALLERGY (CMA)?

I was officially diagnosed with a CMA at six months old, and was given a soya-based formula milk as an alternative to dairy-based formula milk. In addition to my allergy, I also have asthma which is controlled with inhalers, and previously suffered with eczema and hay fever as a child.

CAN YOU DESCRIBE THE FLARE-UPS AND HOW THEY AFFECTED / AFFECT YOU?

As an infant the main symptoms / reactions I had included projectile vomiting, inability to keep food down, skin rash and eczema.

My allergic reactions are rare as I am extra vigilant with any food I consume. If an allergic reaction does occur, the severity of the reaction depends on the amount of dairy consumed and how quickly I take my antihistamines and inhalers to counteract the reaction.

I immediately know if I have consumed even trace amounts of dairy as my tongue and the inside of my mouth will begin to tingle / itch within one-to-two minutes and my throat will start to feel tighter, causing me to wheeze.

In total I have suffered two anaphylactic reactions which both required emergency treatment at A&E and a five-day course of antihistamines and steroids to fully counteract the anaphylactic reaction. Both anaphylactic reactions were a direct result of accidental exposure / consuming dairy at a restaurant while eating out with friends and family. When compared to my milder reactions which flare-up straight away, both anaphylactic reactions were delayed by around 15-to-20 minutes after consuming the meal.

WHAT TIPS AND TREATMENT WERE YOU RECOMMENDED TO HELP MANAGE YOUR CMA?

As I was diagnosed over 23 years ago, the best piece of advice given to my parents was for me to completely avoid all foods containing dairy, and to substitute foods with soya-based alternatives. Back in the 1990s, medical professionals advised against any exposure to dairy, whereas today there is more evidence and research to suggest that 'food challenges' and introducing small amounts of the offending allergen may help children grow out of the allergy and reduce sensitivity.

DO YOU THINK THERE IS ADEQUATE AWARENESS OF CMA IN THE PUBLIC DOMAIN?

I believe the overall awareness of CMA has increased significantly over the last decade, with more evidence-based research and a better understanding of CMA in the medical world. I think the increased awareness has helped get faster diagnoses and has explored different ways of managing CMA, including alternative foods and allergy testing.

People are generally more educated about CMA, but often mix up CMA with lactose intolerance and don't understand the severity of CMA which I find frustrating when discussing my allergy with someone new.

Recent media coverage of high-profile cases of people suffering severe allergic reactions has dominated news outlets, and has highlighted the challenges faced by those with food allergies, including CMA.

Although some cases have tragically resulted in fatalities caused by anaphylaxis, I think it has been a real eye-opener for the general public and all food business operators regarding allergies and food safety. The dedicated work by organisations such as the Anaphylaxis Campaign has definitely improved people's perceptions of CMA and other severe food allergies in recent years and they continue to raise awareness.

COWS' MILK ALLERGY

DO YOU HAVE ANY ADVICE AS TO HOW HEALTHCARE PROFESSIONALS CAN BUILD ON THIS?

I believe that schools would benefit from receiving allergy awareness presentations / training at both primary and secondary level, as more children are being diagnosed with food allergies. I think that both children and parents will feel more at ease knowing that schools are doing more to promote awareness and educate all pupils about the dangers of food allergies and how to react in an anaphylaxis emergency.

Furthermore, I think that more allergy leaflets and posters highlighting symptoms, how to use adrenaline injections, and alternative foods, should be visible in GP surgeries, hospitals and other public spaces to educate the general public.

WHAT HAVE BEEN YOUR GREATEST CHALLENGES?

As a child growing up with a serious food allergy it was often restricting at social events where food was involved – this included friends' birthdays and family parties where food choices were limited. As a result, I would always bring my own alternative foods and my parents always ensured that I was never left out. I had the same issue when going on school trips abroad where my parents would ensure that all teachers were aware of my allergy and provided suitable foods.

Putting your trust in restaurant staff and their allergen procedures can be daunting and stressful at times. When eating out with family or friends I will regularly check restaurants in advance by visiting websites to check suitability and menu options for people with food allergies.

Menus are often restricting as dairy is common in a variety of dishes, although I have noticed improvements since the Food Information Regulations were enforced in 2014.

Psychologically, it can be very frustrating and extremely embarrassing if I have a reaction while eating out, especially when out with friends. I hate people making a fuss and sometimes would rather leave the food establishment to avoid talking to the staff in front of other diners etc.

HOW HAVE YOU ENSURED THAT YOUR DIET ISN'T RESTRICTED BY CMA?

My parents have always found dairy-free alternatives and adjusted our family meals accordingly to avoid any cross-contamination. As I have grown up with my allergy I am fully aware of the choices and alternatives available on the market for people with CMA.

Alongside the big retailers, many restaurant

chains and smaller food establishments are now going the extra mile to adapt menus and recipes to cater for allergic consumers when eating outside the home. This new attitude towards food allergies and creating free-from products / menus is welcomed by individuals like myself and families of people with food allergies as it promotes more awareness and improves quality of life. I now feel more confident when eating outside the home, knowing that businesses do want to create safer allergen-free food choices.

THROUGH THE MOTHER'S EYES

Lucy's mother, Andrea, shares her determination to help her daughter experience a childhood that wasn't dominated by her CMA diagnosis.

WHAT SYMPTOMS PROMPTED YOU TO SEEK MEDICAL ASSISTANCE FOR LUCY?

I had a caesarean under full anaesthetic which meant that when I came around the doctors had given my husband a bottle of Aptamil formula milk to feed Lucy with. This was the first type of milk that she was given and she vomited straight away. I breast-fed her later on, but she would continue to projectile vomit all the time and was a very colicky baby.

After a few months of breast-feeding I tried to wean her on to a different formula milk with baby rice provided in the bounty packs that we were given, however it was very challenging. She would constantly scream and spit out the baby rice straight away, which was when we noticed a type of nettle rash under her chin. We didn't realise at the time that it was an allergic reaction to cows' milk protein as this had not previously been flagged up by the doctors or hospital.

I went to see a pharmacist straight away who advised that we see the doctor immediately. After seeing the doctor, they prescribed a soya-based formula milk to try her on which seemed okay. We were then referred to the allergy clinic where Lucy was diagnosed with CMA at six months old. They performed skin prick tests for various allergens and concluded that she was allergic to cows' milk, and possibly egg. We took her to the allergy clinic twice a year for checks ups but she was then discharged aged six and we never went back after that.

HOW DID LUCY'S CMA IMPACT THE DAY-TO-DAY LIFE OF THE FAMILY, AND THE NUTRITIONAL CHOICES WHICH YOU HAD TO MAKE?

When it came to birthdays we would always improvise by making our own birthday cakes so that they were always dairy-free and she was never left out. We would always prepare food to take out with us when out for the day because dairy-free food was not always available at cafés etc. When Lucy would stay at her grandparents' / friends' / relatives' houses we would leave appropriate foods (biscuits, crisps, snacks etc.) so that she always had something to eat.

WERE THERE ANY OTHER RESOURCES OR TIPS WHICH WERE ADVANTAGEOUS TO YOUR MANAGEMENT OF LUCY'S CMA?

The best booklet I had on dairy-free foods came with the formula milk – it included a breakdown of milk components which I used as a basis to look for suitable ingredients which was a huge help.

I found various leaflets that I would scan through for any new bits of information. I also used to keep a list of good dairy-free products that she liked and passed the list on to relatives and friends so they knew what to buy for her when she visited.

HAVE YOU NOTICED A TRANSITION IN THE CMA-APPROPRIATE PRODUCTS AVAILABLE; FROM THEN TO NOW?

Yes, because there was hardly anything available before. In the last 12 months especially, there has been lots of focus on allergy awareness and promoting safer food.

Clearly a lot of research has gone into developing new dairy-free product ranges and restaurants are adapting their menus which is great news for us and families like us.

Coffee shops and smaller cafés seem to be doing a lot more innovation work to create cakes and sandwiches suitable for allergy sufferers which will make life a lot easier for families with allergic children when going out on day trips for example. Having somewhere local to pop in to for a coffee and cake is something that we could never do before.

TO NOTE

The use of a soya-based formula is not currently common practice for the treatment of CMA as hydrolysed formulas are now more readily available.

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visit: eln.nutricia.co.uk/NICE or contact our healthcare professional helpline on **0800 996 1234**

* National Institute for Health and Care Excellence

References: 1. NICE. Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people. 2015. Available at: www.nice.org.uk/guidance/NG1 [Accessed: February 2019]. 2. Wenzl TG *et al.* Pediatrics 2003;111:e355-9. 3. Nutricia Research, Data on File. 4. Vandenplas Y *et al.* Eur J Pediatr 1994;153:419-23. 5. Borrelli O *et al.* Ital J Gastroenterol Hepatol 1997;29:237-42.

IMPORTANT NOTICE: Breastfeeding is best for babies. Aptamil Anti-Reflux is a food for special medical purposes, for the dietary management of frequent reflux and regurgitation. It should only be used under medical supervision, after full consideration of the feeding options available including breastfeeding. Suitable for use as the sole source of nutrition for infants from birth, and as part of a balanced diet from 6-12 months.

MIGRAINE

GETTING A HEAD START

Frequently misconstrued by society – and reduced to ‘just a headache’ – patients wrangling with the pain of a migraine may not be sufficiently informed about how they should react when faced with its severity. Ria Bhola, Migraine Nurse at The Migraine Trust, delves into the complexity of the condition – from the signposts and escalation, to why we should have an optimistic outlook for future migraine management.

Migraine is a common neurological disorder that is extremely disabling and often misunderstood. It is a primary headache disorder, meaning that its cause is not due to an underlying illness, trauma, or disease; migraine is therefore the disorder itself. A further classification is made based on frequency, where sufferers experiencing migraines for 15 days or more per month are categorised as ‘chronic’, and for less than 15 days as ‘episodic’.

For many people, the main feature is a painful headache that will typically be accompanied by other symptoms.

Migraine symptoms may vary between sufferers and different attacks in the same individual. According to the International Classification of Headache Disorders, the most common types of migraine fall broadly into two categories: migraine without aura, and migraine with aura.

Migraine without aura will usually occur with pain on one side of the head, commonly throbbing in nature, which restricts normal activity and is associated with increased sensitivity to light, sound, and smells, and also nausea and / or vomiting.

Migraine attacks will last between four-and-72 hours untreated or inadequately treated, and sufferers would usually prefer to be still and undisturbed during the attack.

People who have migraine with aura will have these typical migraine features plus some reversible neurological symptoms, occurring before or during the attack, which may be: visual (e.g. zig-zag lines, flashing lights, loss of vision); sensory (e.g. numbness, tingling); or motor (e.g. weakness down one side of the body). These neurological symptoms will commonly fade within an hour with no lasting effect. Figure 1 shows the typical phases of a migraine attack.

MIGRAINE PREVALENCE AND IMPACT

In the latest Global Burden on Disease (2017) study, migraine was shown to be the third most common disease in the world, with an estimated global prevalence affecting around 15 per cent of the population: around one-in-seven people. In the UK population, this equates to over six million people – making migraine more prevalent than diabetes, epilepsy, and asthma combined.

It is up to three-times more common in women than men. This difference is believed to be hormonally driven. Often starting at puberty, migraine attacks can impose substantial personal suffering, impaired quality of life, and high financial cost.

Its impact on society includes its effects on individuals, the direct costs of medical treatment, and the indirect costs of lost productivity at work and in family life.

Repeated headache attacks – and often the constant fear of the next one – can affect daily activities and impact family life, social life, education, and employment.

MIGRAINE TRIGGERS AND LIFESTYLE FACTORS

A number of factors may trigger migraines, but not all can be avoided, and these may not always be consistent.

Sometimes it may be a combination of triggers occurring together that will precipitate an attack. However, where possible, sufferers are advised to minimise triggers.

Some common triggers are alcohol, stress, changes in sleep pattern, skipping meals, dehydration, food additives (e.g. monosodium glutamate), weather change, and hormonal fluctuations in women.

Sometimes triggers can be wrongly identified. For example, at the beginning of an attack, one may experience a craving for sweet things. If a sweet or chocolate is then eaten to satisfy this craving and a migraine later occurs, chocolate may be incorrectly identified as a trigger. However, the migraine attack had started before the chocolate was eaten.

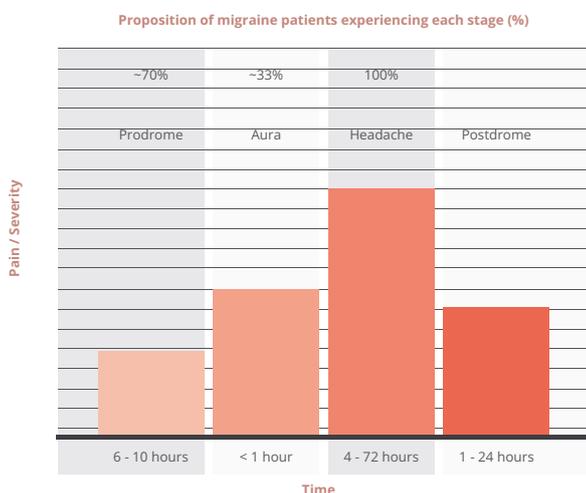


Figure 1

MIGRAINE

ACUTE VS PREVENTIVE TREATMENT

Migraine treatment strategy depends on the frequency and severity of the headaches, the degree of disability they cause, and consideration of other comorbid medical conditions.

Acute or abortive treatments are pain-relieving medications. They will usually include simple analgesics (e.g. ibuprofen), migraine specific Triptans (e.g. sumatriptan), and opioids (best avoided e.g. co-codamol).

However, frequent attacks often lead to the excessive use of painkillers. Excessive use of acute medications, for three months or more, can become problematic for migraineurs, leading to medication overuse headache (MOH), and further disability. (National Institute for Health and Care Excellence (NICE), 2012) MOH also results in a reduction in response to preventive migraine treatments, making the headaches more disabling and difficult to treat. NICE (2012) advises GPs and other healthcare professionals to consider MOH as a possible cause for worsening symptoms among patients who have been taking such drugs for three months or more.

Preventive medications, on the other hand, are types of treatments taken regularly, often on a daily basis, to reduce the overall severity or frequency of migraines.

Preventives are typically built up gradually to optimal dosing, over weeks to months, to improve tolerability and minimise side-effects.

NEUROMODULATION

Non-invasive single pulse transcranial magnetic stimulation (sTMS) has acute and preventive treatment application for migraine. (NICE, 2014) This device uses technology that delivers magnetic pulses to the back of the head to reduce migraine symptoms.

THE ANTI-CGRP TREATMENTS

To date, four monoclonal antibody compounds have been developed that either inactivate the CGRP molecule by binding to it, or block its receptor, to prevent migraine.

Four Monoclonal Antibodies (or mAbs)

CGRP Compounds	Erenumab	Fremanezumab	Galcanezumab	Eptinezumab
How it is Administered	Subcutaneous injection once per month	Subcutaneous injection once per month	Subcutaneous injection once per month	Intravenous injection once in three months

These compounds have completed or are completing Phase 3 clinical studies. They aim to clearly assess how effective the drug is, and can be compared with placebo (in the CGRP studies) or current best available or established treatments. Adverse event rates in these studies were similar to placebo and commonly occurred at injection sites.

OPTIMISTIC OUTLOOK

Despite this burden of illness, migraine is often not diagnosed or treated effectively. This highlights the inadequate levels of treatments and access to treatments, leading to inadequate service provision to effectively manage the condition. The debilitating nature of migraine is often misjudged and underestimated.

The new CGRP treatment advance represents a positive translation of the biological understanding of the disorder back to the bedside. It is bringing hope and an optimistic outlook to the management of a highly disabling disorder. While CGRP-targeting antibodies have numerous advantages over currently available treatments, post-marketing surveillance will be essential to monitor any side-effects and determine safety in both long-term use and special populations.

For more information on all things migraine-related, you can sign up to The Migraine Trust e-bulletin at www.migrainetrust.org, or follow them on Twitter – @MigraineTrust – and Facebook – themigrainetrust.

REFERENCES

- National Institute for Health and Care Excellence. Headaches in over 12s: diagnosis and management. Clinical guideline [CG150]. 2012 (updated 2015)
- National Institute for Health and Care Excellence. Transcranial magnetic stimulation for treating and preventing migraine. Interventional procedures guidance [IPG477]. 2014

VITAMIN D

IN THE LIGHT OF DAY

Approximately one-in-five adults and one-in-six children have inadequate vitamin D levels – but how much do you know about the different ways in which this deficiency can impede your patient's life? SPR delves into the nutrient's hidden depths.

Bolstering spirits, boosting activity, and brimming with opportunity, summer's arrival in the UK sparks mass anticipation. However, many individuals fail to recognise the benefits which the brighter days lend to our wellbeing as well as our social life – particularly through the role of vitamin D and the nutrient's crucial maintenance of calcium levels in the body; safeguarding the health of bones, teeth and muscles.

Produced by the body in response to sunlight, in the UK we attain most of our vitamin D from sunlight exposure from around late March / early April to the end of September. In the UK, sunlight doesn't contain enough UVB radiation in winter (October to early March) for our skin to be able to make vitamin D. During these months – and often outside of them – we are heavily dependent on receiving vitamin D from food sources (including fortified foods) and supplements.

VITAMIN D AND BONE HEALTH

Homing in on the role of vitamin D in the prevention of weakening bones, the National Osteoporosis Guideline Group (NOGG) 2017: Clinical Guideline for the Prevention and Treatment of Osteoporosis outlines, 'In postmenopausal women and older men receiving bone protective therapy for osteoporosis, calcium supplementation should be given if the dietary intake is below 700 mg/day, and vitamin D supplementation considered in those at risk of, or with evidence of, vitamin D insufficiency.'

However, it must be remembered that where rapid correction of vitamin D deficiency is required, such as in patients with symptomatic disease or those about to commence treatment with a potent antiresorptive agent, the recommended treatment regimen is based on fixed loading doses followed by regular maintenance therapy. The Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management subsequently advises that calcium / vitamin D combinations should 'not be used as sources of vitamin D' for fixed loading regimens due to the 'resulting high dosing of calcium.'

VITAMIN D AND THE IMMUNE SYSTEM

Fresh insights have been directing our attention to the significance of vitamin D through its association with our immune system, and how its deficiency may influence susceptibility to autoimmune diseases.

Shedding light, a University of Edinburgh team focussed their research on how vitamin D affects a mechanism in the body's immune system –

dendritic cells' ability to activate T cells. In healthy people, T cells play a crucial role in helping to fight infections; in people with autoimmune diseases, however, they can start to attack the body's own tissues.

By studying cells from mice and people, the researchers discovered that vitamin D caused dendritic cells to produce more of a molecule called CD31 on their surface and that this hindered the activation of T cells. They subsequently observed how CD31 prevented the two cell types from making a stable contact – an essential part of the activation process – and the resulting immune reaction was far reduced.

VITAMIN D AND MENTAL HEALTH

Although prominently linked to bone health – and, at recent, various non-bone health outcomes, such as inflammation and diabetes – the potential relationship between vitamin D and mental health has been shrouded in uncertainty. Addressing this gap in knowledge a study by researchers from The Irish Longitudinal Study on Ageing at Trinity College Dublin got underway – demonstrating for the first time in Ireland that a deficiency in vitamin D was associated with a substantial increased risk of depression over a four-year follow-up period.

This finding remained robust after controlling for a wide range of relevant factors, including depressive symptoms, chronic disease burden, physical activity and cardiovascular disease. Furthermore, excluding participants taking anti-depressant medication and vitamin D supplementation from the analyses did not alter the outcome.

But what is the science behind the correlation between insufficient vitamin D and depression? The authors have suggested that the findings could be due to the possible direct effect of vitamin D on the brain in that given the structural and functional brain changes seen in late life depression, vitamin D may have a protective effect in attenuating these changes.

VITAMIN D AND CHILDREN

The risk of fractures in those with inadequate vitamin D has long been an area of interest for clinicians – with a report last year weighing in and showcasing the important link between low vitamin D levels and the severity of fractures in children caused by low-energy, less traumatic events, such as falling off a bike or falling while running.

The data indeed revealed that children who are vitamin D deficient have a greater risk of having more severe forearm fractures requiring surgical treatment and suggested how we can intervene to help.

'This study provides an important takeaway for parents and paediatricians,' explained Dr Pooya Hosseinzadeh, MD, Assistant Professor, Department of Orthopaedic Surgery at Washington University School of Medicine in St Louis.

'If a child does have a forearm fracture, we would encourage the physician to check the patient's vitamin D levels. The good news is that in most cases, children can reduce deficiency with a vitamin D supplement and increasing outdoor activity.'

When it comes to bone health
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In cases of hypercalcaemia or impaired renal function, reduce the dose or discontinue treatment. Use caution in cases of sarcoidosis, immobilised patients with osteoporosis. In patients with a history of renal stones, hypercalcaemia should be excluded. Use close medical supervision if prescribing additional calcium or vitamin D via other medicines. Concomitant use of tetracyclines or quinolones is not recommended. Do not take in case of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency. This medicinal product contains aspartame (E951), a source of phenylalanine which may be harmful for people with phenylketonuria. **Interactions:** Thiazide diuretics, cardiac glycosides, systemic corticosteroids, phenytoin, barbituates, ion exchange resins, laxatives. Do not take calcium within 2 hours of eating foods high in oxalic acid and phytic acid. Administer tetracycline <2 hours before or 4 to 6 hours after Accrete D₃. Administer bisphosphonate or sodium fluoride at least 3 hours before Accrete D₃. Do not use levothyroxine within 4 hours before or after Accrete D₃. Administer quinolone antibiotics <2 hours before or 6 hours after Accrete D₃. **Pregnancy and Lactation:** During pregnancy, daily dose should not exceed 1500 mg calcium and 600 IU vitamin D. Halve tablet if necessary to reduce dose. Suitable for use during breastfeeding. Calcium and vitamin D pass into breast milk. This should be considered when giving additional vitamin D to the child.

Undesirable effects: Allergic reactions may be possible. Uncommonly hypercalcaemia or hypercalcaemia. Rarely gastro-intestinal disorders, rash, pruritus, urticaria. **Legal Category:** **Accrete D₃ One-a-Day: P; Accrete D₃ Film-Coated: P.** **Pack size:** **Accrete D₃ One-a-Day:** £2.95 for 30 tablets; **Accrete D₃ Film-Coated:** £2.95 for 60 tablets. **MA Number:** Accrete D₃ One-a-Day: PL04416/1318; Accrete D₃ Film-Coated: PL 40861/0001. **Distributor (Accrete One-a-Day)/MA Holder (Accrete D₃ Film-Coated):** Internis Pharmaceuticals Ltd., Linthwaite Laboratories, Linthwaite, Huddersfield, HD7 5QH, UK. **Date of preparation:** August 2018. **Unique ID:** ACC-0101

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 Medical Information on 01484 848164.

References: 1. Drug Tariff, June 2019.
2. IMS Sales data (Accessed April 2019)
3. Accrete-D₃ One a Day Chewable tablets SmPC www.medicines.org.uk/emc/product/8506/
4. Adcal D₃ chewable tablets SmPC www.medicines.org.uk/emc/medicine/5336

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STADA GROUP

Date of preparation: August 2019 Job code: ACC-118

IN TRIBUTE: FRANCES ROONEY

It is with great sadness that we learned of the unexpected passing of Frances Rooney after a short illness. As a noted leader within the pharmacy profession in Scotland, she was admired for her professional and personal integrity, as well as her tenacity and resilience. In this edition of SPR, a number of Frances' friends and colleagues share an insight into her significant legacy.

Talking to a range of people about Frances, it is clear that she was at ease with establishing relationships. She showed an interest in people in all areas of her work, regardless of their role or position: it was the person who mattered most to her. She motivated people and had confidence that they would achieve. She was talented at nurturing individuals to develop and reach their potential, even when the individuals had doubts themselves.

As Director of Pharmacy at NHS Tayside, Frances led the pharmacy service from June 2013. However, she began her career as a community pharmacy manager in Eastbourne, before moving to Harrogate and taking the role of area manager for a national pharmacy chain. Frances joined Tayside in 1999 as a practice pharmacist and became Head of Pharmacy Services in Perth within a short time. Taking on the role of Head of Medicines Governance in 2010, and appointed Deputy Director of Pharmacy in 2012, her talents were quickly recognised, bringing a wealth of experience from her time served working across the pharmacy profession.

Under Frances' leadership, pharmacy in Tayside was noted across Scotland for its innovation and forward-looking approach. Tayside was the first place in Scotland where pre-registration trainees could work in all three sectors of practice; an approach to be adopted across Scotland.

Andrew Radley, Consultant in Public Health Pharmacy at NHS Tayside, said, 'On a personal level, Frances will be sorely missed as a much-valued friend and colleague. She was well-known for her sense of humour and quirky ways, which made the experience of working with her all the more enjoyable and rewarding. She has provided a very important legacy for pharmacy in Tayside through her interest in, and nurturing of, all members of her team.'

'She created a belief that you can achieve even when the challenges seem immense and, most importantly, she helped to create a workplace which was an enjoyable place for all. Our thoughts and sympathies are with her husband, her three beloved children and all of her friends and pharmacy colleagues for this loss,' he added.

Around the table of the NHS Scotland Directors of Pharmacy Group, Frances' abilities were held in high regard, and in 2018 she was made Chair of the North of Scotland Directors of Pharmacy Group; one of three regional groups that feeds into the overall directorate.

Angela Timoney, Director of Pharmacy at NHS Lothian, knew Frances from their time as undergraduates at Heriot Watt University, Edinburgh.

She said, 'Frances was a dear friend and close colleague. Her significant skills and attributes were always clear. We worked together for many years in Tayside and her straight-talking and sense of humour made every day a pleasure. She was a skilled manager and a compassionate leader, and I am pleased to remember the hard work and fun from that time.'

Christine Gilmour, Chair of the NHS Scotland Directors of Pharmacy Group, added, 'As a fellow Director of Pharmacy she was an asset around the table, keen to innovate and to advance practice in all sectors. She will be remembered by the directors as a kind, thoughtful and straight-talking colleague who got things done, and her loss will leave a big gap. Her untimely death was a huge shock and our thoughts are with her husband and children.'

IN TRIBUTE

Frances' contribution to the national agenda was considerable and, in 2017, she was asked by the Chief Pharmaceutical Officer at the Scottish government to chair the implementation group for the national Achieving Excellence in Pharmaceutical Care Strategy Group.

Harry McQuillan, Chief Executive Officer of Community Pharmacy Scotland, commented, 'I had yet to meet a better chair of a large group. Frances excelled at gaining input from all and keeping a meeting focused and on-track. It was no surprise the number of initiatives she was asked to lead or be involved in, including the appointment of Scotland's first cohort of clinical leadership fellows. I know the pharmacy owner network in Tayside enjoyed working with Frances and they are very grateful for the legacy she leaves.'

Alex MacKinnon, Director for Scotland at the Royal Pharmaceutical Society (RPS), remarked that, 'Frances was also a great advocate for her professional body, personally contributing to many of the work streams of the RPS.'

He added, 'She will be very sadly missed across the RPS, but particularly by her colleagues in the Scottish directorate. Her enthusiasm and passion for the pharmacy profession will be remembered by us all. I had the privilege of knowing and working with Frances for many years and what I admired and respected most was, whatever the situation, she would welcome and treat you in the same engaging, respectful way.'

Rose Marie Parr, Chief Pharmaceutical Officer for Scotland, and Alison Strath, Principal Pharmaceutical Officer at the Scottish government, said, 'We would like to add to the comments of many others who have expressed their appreciation of the life and work of Frances Rooney.'

'Frances was always a very thoughtful and innovative leader in pharmacy and especially in the advancement of pharmaceutical care. She was a real pleasure to work with and chaired meetings with both flair and aplomb. She was also passionate about education and research, and was instrumental in providing leadership to establish the north of Scotland joint board between the NHS and the School of Pharmacy at Robert Gordon University. Frances, as an ambassador for the pharmacy profession, was a dynamic force: determined, intelligent, kind, quick-witted and always with a great sense of humour. Those of us who were privileged to know Frances can testify to her sense of fun – the life and soul of any occasion – which ensured that her company was always sought out and always remembered. She will be sadly missed.'

Christine Gilmour, Chair of the NHS Scotland Directors of Pharmacy group; Alex MacKinnon, RPS Director for Scotland; Harry McQuillan, Chief Executive Officer of Community Pharmacy Scotland; Rose Marie Parr, Chief Pharmaceutical Officer for Scotland; Andrew Radley, Consultant in Public Health Pharmacy at NHS Tayside; Alison Strath, Principal Pharmaceutical Officer for Scotland; and Angela Timoney, Director of Pharmacy at NHS Lothian.



Frances Rooney

NEWS

NEW LIVER TEST 'COULD SAVE THOUSANDS OF LIVES'

A revelatory way of detecting liver disease decades before it can become fatal has been developed by a team of scientists at the University of Dundee and NHS Tayside.

A new method for the early identification of liver disease has been devised hot on the heels of clinicians warning of a 'ticking time bomb' of alcohol-related and obesity-related liver diseases.

Liver disease – which is notoriously asymptomatic – has become the second most common cause of death in under 65-year-olds in the UK. Unlike other common causes of death which have begun to decline in recent years, the age-standardised mortality rates for liver disease have risen by nearly 600 per cent since the 1970s.

Professor John Dillon, Consultant Gastroenterologist and Hepatologist, and Consultant in Biochemical Medicine, Dr Ellie Dow, worked with colleagues from the University of Dundee and NHS Tayside to develop the intelligent liver function tests (iLFTs) using the automated Blood Sciences laboratory infrastructure at Ninewells Hospital.

Applying advances in laboratory technology, the team created the new iLFTs which see more tests automatically carried out on a patient's blood sample if there is a suspected liver disorder or abnormal results with no clear explanation. Initial results from the trial showed a 44 per cent increase in diagnosis of liver disease, giving patients earlier access to treatment.

Professor Dillon said, 'In looking at a large set of patient data from Tayside we noticed abnormal liver function tests popping up that were not fully investigated. All too often we were seeing patients dying of liver failure who had abnormal liver function tests recorded years before when something could have been done. This stopped us in our tracks. We asked ourselves if these had been detected earlier, what difference could it have made?'

'By applying variables to the existing IT systems in the lab, we

were able to develop a system that detects the early warning signs of liver disease and which can then give GPs the tools they need to make a solid diagnosis and begin treatment plans. More importantly, our modification allows us to immediately differentiate between alcoholic or non-alcoholic fatty liver disease and the more rare diseases such as autoimmune liver diseases, Hepatitis C or metabolic diseases, meaning those who need immediate assistance receive it faster.'

Since being launched in NHS Tayside in June last year, more than 2,500 patients have been tested, with 30 per cent of these showing abnormal results.

iLFTs have now been made standard practice across NHS Tayside and the Scottish government's Modern Outpatient Programme is considering the opportunities this might present, with work underway to determine whether there is potential to roll this out more widely across Scotland.



Professor John Dillon

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SCOTTISH PHARMACY AWARDS 2019

A SHOW OF SUCCESS

Steer your team's work into the spotlight, and allow it the recognition it deserves, by getting involved in the Scottish Pharmacy Awards. Entry for the 2019 ceremony is now open!

Boundless in enthusiasm, undeterred in the face of difficulty, and persistent in the implementation of the very best patient care – these are only a few of the qualities which shape the members of our pharmacy sector.

While we can't fully summarise the excellence of your team's services, we can grant you a public platform before your peers, courtesy of the Scottish Pharmacy Awards.

Plan ahead and plot 6th November in your calendar, as the 2019 ceremony is set to spark the arrival of esteemed guests – spanning all areas of the industry – to the Crowne Plaza Hotel, Glasgow, for an evening brimming with celebration, dining, and networking.

If you would like to put your work front and centre, and be in with a chance of securing one of the sought-after accolades, the time is now.

Simply read on as we overview each of the categories open for entry, and the fuss-free instructions as to how you can apply.

The 10 awards up for grabs are:

- Community Pharmacist of the Year (Independent)
- Hospital Pharmacy Team of the Year
- Innovations in Clinical Development in Cardiology Pharmacy
- Innovations in Prescribing, Quality and Efficiency in Scotland
- Innovative Use of Technology in Community Pharmacy
- Management of Substance Misuse in the Community
- Student Leadership
- Respiratory Project of the Year
- Community Pharmacy Practice of the Year
- Delivery of Pharmaceutical Care

COMMUNITY PHARMACIST OF THE YEAR (INDEPENDENT)

Sponsored by
Cambrian Alliance
Group



The title of Scottish Pharmacist of the Year (Independent) will be awarded to an independent pharmacist from the community setting who has made significant, influential and sustained contributions to pharmacy practice in Scotland.

This category is open to independent or independent multiple pharmacists only. Directors of Pharmacy, and their teams, will be contacted and invited to nominate an independent community pharmacist, from their board, whom they feel is worthy of this prestigious title. Ideally, nominations are sought for pharmacists who have been involved in innovative, collaborative work with the extended healthcare team. They will have made a continued effort to improve patient care and will have made a strong contribution to the compliance of safe and appropriate use of medications.

They will be a leader and role-model for others within the pharmacy industry and will, through their various initiatives, have endeavoured to enhance the key role played by pharmacists in the healthcare arena.

Once we have received all nominations, Scottish Pharmacy Review will contact those nominated to invite them to submit an information form for the judges to consider.

JUDGING PANEL

The judging panel, made-up of respected members of the pharmacy industry, will select three finalists, based on the entries submitted. They may then liaise with the three finalists before selecting the overall winner.

JUDGES

This year's judging panel includes:

David Thomson

Lead Pharmacist, Community Pharmacy Development & Governance, NHS Greater Glasgow & Clyde, and Treasurer, Royal Pharmaceutical Society

David Coulson

Interim Director of Pharmacy, NHS Tayside

Diane Robertson

Chair of the Primary Care Lead Pharmacists in Scotland

DEADLINE FOR NOMINATIONS

Once nominated, the candidates will be emailed an information form to complete. Early nomination affords the candidate a longer time to complete the information form. The closing date for nomination is Tuesday 27th August.

DEADLINE FOR ENTRY

The closing date for nominees' completed entries is **Monday 9th September 2019**. Entries **MUST** be accompanied by a digital photograph; at least **500KB** for printing quality. Testimonies from colleagues, local community groups and allied healthcare sectors are welcome.

(NB. Please ensure either all patients' personal information is sought for publication or their details are omitted from view).

THE AWARDS PRESENTATION

Those nominated will be announced in Scottish Pharmacy Review and invited, with a guest, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

SPONSOR QUOTE

The Cambrian Alliance Group is delighted to be involved once again in sponsoring the Community Pharmacist of the Year (Independent) Award. At a time when pharmacy and independent contractors are facing such a difficult time, it is more important than ever to recognise their success and recognise the significant contribution to healthcare and patient outcomes that they make.



HOSPITAL PHARMACY TEAM OF THE YEAR

Sponsored by
Ethypharm



The Hospital Pharmacy Team of the Year Award has been developed to recognise hospital pharmacy teams from all backgrounds who are at the forefront of their profession, whether developing best practice models or implementing improvements in patient care. This is your opportunity to nominate peers and colleagues who have demonstrated outstanding dedication and commitment to the pharmacy profession or to submit your own team's work for consideration.

WHO CAN ENTER?

Applications are invited from hospital pharmacy teams who can submit work / projects which demonstrate one or more of the following:

- Development of the accessibility of the service provided
- Establishment of high levels of safety in order to minimise risk
- A health improvement among selected patients
- Achievement of outcomes / initiatives, leading to a positive impact for the public
- Where savings have been achieved, leading to increased cost-effectiveness by providing best value

The points above are suggestions only. Any pharmacy teams working in the hospital environment who demonstrate a unique commitment to clinical innovation and / or technical development are eligible for nomination / self-nomination for this award.

JUDGING PANEL

The judging panel, made-up of respected members of the pharmacy industry, will select three finalists, based on the written entries submitted. They may then liaise with the three finalists before selecting a winner.

Evelyn McPhail

Retired Director of Pharmacy, NHS Fife

Sandra Melville

Lead Pharmacist, Oncology & Acute Care, Lorn & Islands Hospital

Alison Wilson

Director of Pharmacy, NHS Borders

Andrea Smith

Lead Pharmacist, NHS Fife

HOW TO NOMINATE

If you wish to nominate a hospital pharmacy team, or require an application form, please contact **Bridget McCabe**. Telephone: 02890 999 441 or email: bridget.mccabe@nimedical.info.

DEADLINE FOR NOMINATION

Once nominated, the candidates will be emailed an application form to complete. Early nomination affords the candidate a longer time to complete this form. The closing date for nomination is Monday 2nd September.

DEADLINE FOR ENTRY

The closing date for completed application forms is **Wednesday 11th September**. Entries **MUST** be accompanied by a digital photograph; at least **500KB** for printing quality. Judges welcome testimonies from relevant sources.

THE AWARDS PRESENTATION

The selected finalists will be announced in Scottish Pharmacy Review and invited, with a guest, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

INNOVATIONS IN CLINICAL DEVELOPMENT IN CARDIOLOGY PHARMACY

Sponsored by
Daiichi-Sankyo



Daiichi-Sankyo

Clinical pharmacists work as part of the general practice team to resolve day-to-day medicine issues and consult with and treat patients directly. This includes providing extra help to manage long-term conditions, advice for those on multiple medications, and better access to health checks. The role is pivotal to improving the quality of care and ensuring patient safety.

WHO CAN ENTER?

This award category has been designed to encourage clinical GP pharmacists who have developed innovative methods of patient care (in relation to cardiology patients) and can give evidence of having set up the provision of one or more of the following in this medical field:

- Provision of critical input on medication use and dosing
- Working with patients to solve problems with their medications and improve adherence
- Consulting with secondary and / or primary care team members about medication-related issues
- Assisting with on boarding of new patients by reviewing medications and aligning treatment options
- Reviewing and providing assistance with patients on multiple medications (polypharmacy) to help to simplify medication regimens
- Provision of alternative visit care, such as teaming with PCP in group visits and addressing medication questions that are posed by patients via email or telephone enquiries

JUDGING PANEL

The judging panel, made-up of respected members of pharmacy and GP practice, will select finalists, based on the written entries submitted. They may then liaise with the finalists before selecting a winner if a decision has not been reached.

Iain Speirits

West Glasgow ACH Cardiology Pharmacist, NHSGG&C

Pernille Sorensen

Teaching Fellow, University of Strathclyde and Honorary Cardiology Specialist Pharmacist, NHSGGC

Joanne Adam

Locality Principal Clinical Pharmacist (Angus)

HOW TO ENTER

If you require an application form or would like any further information, please contact **Bridget McCabe**. Email: bridget.mccabe@nimedical.info or telephone: 02890 999 441. Entries **MUST** be accompanied by a digital photograph; at least 500KB for printing quality. Judges welcome testimonies from relevant sources.

(NB. Please ensure either all patients' personal information is sought for publication or their details are omitted from view.)

DEADLINE FOR ENTRY

The closing date for entries is **Wednesday 11th September 2019**.

THE AWARDS PRESENTATION

The selected finalists will be announced in Scottish Pharmacy Review and invited, with a guest, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

INNOVATIONS IN PRESCRIBING, QUALITY AND EFFICIENCY IN SCOTLAND

Sponsored by
Napp
Pharmaceuticals
Limited



WHO CAN ENTER?

Nominations are invited for medicines management pharmacists / teams who have developed an innovative programme in primary care medicines' management.

Nominations are invited for projects which show evidence of:

- Innovations and / or a successful implementation programme for a new therapy or pathway in pharmaceutical care
- Examples of improvements in prescribing, quality and efficiency
- How their projects or initiatives have improved inter-professional working

Once we have received all nominations, Scottish Pharmacy Review will contact those nominated to invite them to submit an application form for the judges to consider.

JUDGING PANEL

The judging panel, made-up of respected members of the pharmacy industry, will select finalists, based on the written entries submitted. They may then liaise with the finalists before selecting a winner.

JUDGES

This year's judging panel includes:

Fiona Thomson

Lead Pharmacist, Argyll & Bute HSCP, NHS Highland

Jill Nowell

Head of the Prescribing Support Unit, Pharmacy, NHS Tayside

Audrey Thompson

Lead Pharmacist, Prescribing Services, NHS GGC

Gillian Cook

Advanced Primary Care Pharmacist, Forth Valley

HOW TO ENTER

If you require an application / nomination form, or would like any further information, please contact **Bridget McCabe**. Email: bridget.mccabe@nimedical.info or telephone: 02890 999 441.

DEADLINE FOR NOMINATION

Once nominated, the candidates will be emailed an information form to complete. Early nomination affords the candidate a longer time to complete the information form. The closing date for nomination is Monday 2nd September.

DEADLINE FOR ENTRY

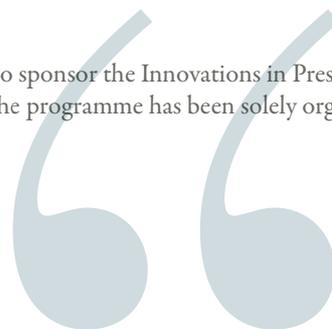
The closing date for entries is **Wednesday 11th September 2019**. Entries **MUST** be accompanied by a digital photograph; at least **500KB** for printing quality. Judges welcome testimonies from relevant sources.

THE AWARDS PRESENTATION

The selected finalists will be announced in Scottish Pharmacy Review and invited, with a guest, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

SPONSOR QUOTE

Napp Pharmaceuticals Limited is delighted to sponsor the Innovations in Prescribing, Quality and Efficiency Award in Scotland. The programme has been solely organised by Medical Communications Limited.



INNOVATIVE USE OF TECHNOLOGY IN COMMUNITY PHARMACY

Sponsored by
Cegedim Rx



Technology is at the heart of pharmacy and Cegedim Rx is delighted to sponsor a platform which acknowledges the excellent projects in this category. Nominations are invited from pharmacists / pharmacy teams who developed an innovative programme or project and can show evidence of one or more of the following:

- Improvement in quality of service through the use of technology
- How their projects or initiatives have improved inter-professional working
- Innovations and / or a successful implementation programme for a new therapy or pathway in patient care
- Capacity increase, demand reduction, or cost savings through the introduction of innovative technology

JUDGING PANEL

The judging panel, made-up of respected members of the pharmacy industry, will select a maximum of five finalists, based on the written entries submitted. They may then liaise with the finalists before selecting a winner.

JUDGES

This year's judging panel includes:

George Romanes

Managing Director, Romanes Pharmacy Group

Sam Reid

Managing Director, Buchanhaven Pharmacy

Philip Galt

Managing Director, Superintendent Pharmacist, Lyndsay & Gilmour Group

Steve Bradley

Group Managing Director, Cegedim UK

HOW TO ENTER

If you require an application form, or would like any further information, please contact **Bridget McCabe**. Email: bridget.mccabe@nimedical.info or telephone: 02890 999 441. Entries **MUST** be accompanied by a digital photograph; at least 500KB for printing quality. Judges welcome testimonies from relevant sources.

(NB. Please ensure either all patients' personal information is sought for publication or their details are omitted from view.)

DEADLINE FOR ENTRY

The closing date for entries is **Wednesday 11th September 2019**.

THE AWARDS PRESENTATION

The selected finalists will be announced in Scottish Pharmacy Review and invited, with a guest, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

MANAGEMENT OF SUBSTANCE MISUSE IN THE COMMUNITY

Sponsored by
Ethypharm



Substance misuse is unfortunately a growing problem in Scotland and quite often it is the pharmacist who is at the forefront of this patient service. This category is aimed at pharmacists or pharmacies which have developed and successfully adapted to improve the management of their substance misuse services to the patient.

WHO CAN ENTER?

(These points are suggestions only.)

A pharmacy which can:

- Describe how they have supported the management of patients with substance misuse problems
- Identify the ways they have improved communication and enhanced patient care
- Give evidence of how they have engaged with their GP in the provision of services for substance misusers
- Describe future developments of the pharmaceutical care of these patients

JUDGING PROCESS

The judging panel, made-up of respected members of the pharmacy industry, will select a minimum of three finalists, based on the written entries submitted. They may then liaise with the finalists before selecting a winner.

This year's judging panel includes:

Duncan Hill

Specialist Pharmacist in Substance Misuse, NHS Lanarkshire

Carole Hunter

NHS Greater Glasgow & Clyde

Colin Miller

Lead Pharmacist for Substance Misuse Services, NHS Lothian

HOW TO ENTER

If you require an application form, or would like any further information, please contact **Bridget McCabe**. Email: bridget.mccabe@nimedical.info or telephone: 02890 999 441. Entries **MUST** be accompanied by a digital photograph; at least 500KB for printing quality. Judges welcome testimonies from relevant sources.

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STUDENT LEADERSHIP

Sponsored by
The Pharmacists'
Defence
Association



Strong leaders are driven by their vision of what their organisations could become. The role of a leader is to make people feel strong, informed, unified and capable. Leaders need to have a combination of relentless effort, steadfastness, competence and attention-to-detail. Understanding the unique qualities of a team in order to deliver a great service is vital.

Leaders must find their own voice and use their values to engage others in their common aspirations. Words and deeds need to be consistent. Behaviour evokes respect.

Do you respect the leadership qualities in one of your peers enough to nominate them for this accolade, or indeed do you feel you have the qualities within you to merit this award? A leader is not afraid to step forward!

JUDGING PANEL

The judging panel, made-up of respected members of the pharmacy academia and industry, will select a maximum of five finalists based on the entries submitted. They may then liaise with the finalists before selecting the overall winner.

JUDGES

This year's judging panel includes:

Professor Donald Cairns

Head of School, Pharmacy and Life Sciences, Robert Gordon University

Professor Robin Plevin

Head of Institute, Strathclyde Institute of Pharmacy and Biomedical Sciences

Professor Bill Scott OBE

Former Chief Pharmaceutical Officer for the Scottish government

Alima Batchelor

Head of Policy, The Pharmacists' Defence Association

DEADLINE FOR NOMINATIONS

Nominations / self-nominations are invited from students and lecturers. The closing date for nominations is 2pm on Monday 2nd September. Nominees will then be emailed an application form to complete. Early nomination / self-nomination affords the candidate more time to complete all information on the form.

DEADLINE FOR COMPLETED ENTRIES

The closing date for entries is 2pm on Wednesday 11th September 2019. Entries MUST be accompanied by a digital photograph; at least 500KB for printing quality. Testimonies from colleagues, local community groups and allied healthcare sectors are welcome.

THE AWARDS PRESENTATION

The selected finalists will be announced in Scottish Pharmacy Review and invited, with a guest, compliments of The Pharmacists' Defence Association, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

SPONSOR QUOTE

If the pharmacy profession is to thrive, then it will need strong leadership. Some leaders are born to lead, others are trained. Irrespective of their origins, all leaders have to be nurtured if they are to rise to the top and make a difference. The quest to inspire and encourage leadership in pharmacy must start at undergraduate level.

These days all pharmacy students are hugely absorbed in their extensive, and often very challenging, studies. Despite that, some manage to involve themselves in additional activities that demonstrate that not only do they have a passion for their profession, but that they are becoming leaders in their own right.

As pharmacists, we all have a responsibility to encourage these passionate individuals who will likely be the leaders of our profession in the future. The Pharmacists' Defence Association is proud to be associated with this important award category.

Mark Koziol M.R.Pharm.S.

Chairman, The Pharmacists' Defence Association



RESPIRATORY PROJECT OF THE YEAR

Sponsored by
Teva Respiratory



Whether they work in community pharmacies or GP surgeries, pharmacists are in a pivotal position to contribute to the overall management of respiratory diseases such as asthma and COPD. Every year, pharmacists fill prescriptions for respiratory medications which remain the principal treatment for the diseases.

Being qualified to advise patients on all aspects of their medication, and offer comprehensive reviews of patients' medicines, ensures that the patient is correctly using the medication prescribed.

Pharmacists have many other opportunities to assist in the management of respiratory diseases and this award is in recognition of the excellent work carried out by pharmacists throughout Scotland.

WHO CAN ENTER?

Are you working to improve the care of your asthma and COPD patients within your GP practice clinic or your community pharmacy, or with a partner organisation? Projects or working models are welcome where the applicants can give evidence of improved outcomes for their patients in helping them to live with, and improve, their wellbeing and management of their disease.

We would like submissions from pharmacists who are helping to improve the quality of life for those patients who are living with a respiratory disease.

This award aims to highlight the outstanding, innovative projects pharmacists have developed which have led to significant improvement in the care or clinical outcomes of patients with respiratory conditions.

Community and GP practice pharmacists who can provide evidence of one or more of the following may apply:

(These points are suggestions only.)

- The opportunity for patients to have a review of the use of their respiratory medicines, relating to the effectiveness and safety of those medicines
- Having trained pharmacy staff to be more involved in patient care regarding patients with asthma or COPD
- The development of effective inter-professional teamwork and communication with other healthcare professionals
- Improvement in patients' understanding of their medication and thereby encouraging the patient to manage their condition more effectively

JUDGING PROCESS

The judging panel, made-up of respected members of the pharmacy industry, will select a minimum of three finalists, based on the written entries submitted. They may then liaise with the finalists before selecting a winner.

This year's judging panel includes:

Jane Hall

Principal Pharmacist Pharmacotherapy, NHS Ayrshire & Arran

Stephen McBurney

Associate Director of Pharmacy Primary Care, NHS Lothian

Roisin Kavanagh

Director of Pharmacy, NHS Ayrshire & Arran (Interim)

HOW TO ENTER

If you require an application form or would like any further information, please contact **Bridget McCabe**. Email: bridget.mccabe@nimedical.info or telephone: 02890 999 441. Entries **MUST** be accompanied by a digital photograph; at least 500KB for printing quality. Judges welcome testimonies from relevant sources.

(NB. Please ensure either all patients' personal information is sought for publication or their details are omitted from view.)

DEADLINE FOR ENTRY

The closing date for entries is **Wednesday 11th September 2019**.

THE AWARDS PRESENTATION

The selected finalists will be announced in Scottish Pharmacy Review and invited, with a guest, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

SPONSOR QUOTE

Teva Respiratory is committed to being a long-term key partner to NHS organisations where we work together to improve healthcare outcomes for patients with asthma and COPD. Sharing best practice for the benefit of your patients and others in Scotland is the focus of this award and one we are delighted to sponsor.

COMMUNITY PHARMACY PRACTICE OF THE YEAR

The Community Pharmacy Practice of the Year Award is targeted at pharmacies who have demonstrated high standards of healthcare delivery. The pharmacy may display excellence in a particular professional aspect which ensures outstanding service to the consumer.

WHO CAN ENTER?

Any independent or multiple pharmacy practice which has developed its practice or undertaken a project / initiative in the last 12 months which has raised levels of patient care and consumer pharmacy standards is eligible to enter.

A pharmacy which has:

- Offered specialist services, for example, diabetes screening or cholesterol testing and / or introduced or redesigned a private treatment room specifically for diagnostic services
- Supported self-care initiatives
- Introduced out-of-hours access
- Liaised with GPs, nurses, hospitals and nursing homes to provide additional services and support to patients / customers
- Increased the size of its dispensary, making it more open and organised with special fittings, such as innovative dispensary features

(The above points are suggestions only.)

JUDGING PANEL

The judging panel, made-up of respected members of the pharmacy industry, will select a maximum of five finalists, based on the written entries submitted. They may then liaise with the finalists before selecting a winner if a decision has not been reached.

JUDGES

This year's judging panel includes:

Dr John McAnaw

Head of Pharmacy, NHS 24

Gordon Winter

MD Pharmacist, Dalston Pharmacy

Graeme Bryson

Director of Pharmacy, Dumfries and Galloway

HOW TO ENTER

If you require an application form or would like any further information, please contact **Bridget McCabe**. Email: bridget.mccabe@nimedical.info or telephone: 02890 999 441. Entries **MUST** be accompanied by a digital photograph; at least 500KB for printing quality. Judges welcome testimonies from relevant sources.

(NB. Please ensure either all patients' personal information is sought for publication or their details are omitted from view.)

DEADLINE FOR ENTRY

The closing date for entries is **Thursday 12th September 2019**.

THE AWARDS PRESENTATION

The selected finalists will be announced in Scottish Pharmacy Review and invited, with a guest, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

DELIVERY OF PHARMACEUTICAL CARE

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The Delivery of Pharmaceutical Care Award has been introduced to acknowledge pharmacy staff working within independent or multiple pharmacy sectors or practice pharmacists in a GP setting in order to improve the wellbeing of their patients.

The aim is to offer NHS pharmacists and registered pharmacy technicians continuing education which is relevant, up-to-date and high in quality to help enhance knowledge and skills for delivering pharmaceutical care services.

WHO CAN ENTER?

Any community pharmacy team / GP practice pharmacist who has taken steps to further improve the pharmaceutical care of their patients within the past 12 months is eligible to enter.

Examples would include a pharmacist / pharmacy practice team who has been involved in innovative ways of working to:

- Improve patients' understanding of their medication and medical condition
- Undertake a review of the use of medicines and, in particular, aspects relating to the effectiveness of and safety of medicines
- Empower pharmacy staff to be more involved in patient care regarding areas such as cardiovascular disease, diabetes or respiratory conditions.
- Redesign pharmacy work flow to enable the pharmacy team to spend more time with their patients
- Develop effective inter-professional teamwork and communication with other healthcare professionals or social services

JUDGING PANEL

The judging panel, made-up of respected members of the pharmacy industry, will select finalists based on the written entries submitted. They may then liaise with the finalists before selecting a winner.

Bernadette Brown

Pharmacy Practitioner and Managing Director, Cadham Pharmacy

Professor Scott Bryson

Visiting Professor in Pharmacy Practice, Strathclyde University

Noel Wicks

Managing Director, Right Medicine Pharmacy

HOW TO ENTER

If you require an application form, or would like any further information, please contact **Bridget McCabe**. Email: bridget.mccabe@nimedical.info or telephone: 02890 999 441. Entries **MUST** be accompanied by a digital photograph; at least 500KB for printing quality. Judges welcome testimonies from relevant sources.

(NB. Please ensure either all patients' personal information is sought for publication or their details are omitted from view.)

DEADLINE FOR ENTRY

The closing date for entries is **Wednesday 11th September 2019**.

THE AWARDS PRESENTATION

The selected finalists will be announced in Scottish Pharmacy Review and invited, with a guest, to attend the black-tie awards ceremony at the Crowne Plaza Hotel, Glasgow, on Wednesday 6th November 2019. The winner will be announced at the awards ceremony and will receive a unique crystal trophy to mark the occasion.

A WORLD OF OPPORTUNITY

As a result of an exciting trip embarked on by one Scottish pharmacist, the sector's sphere of influence has experienced a new global reach. Owner of Cadham Pharmacy Health Centre & Travel Clinic in Glenrothes, Bernadette Brown, reflects on her visit to New Zealand to meet with the board and members of the Canterbury Community Pharmacy Group for liaising and learning.

I was honoured and proud to have been invited by the Canterbury Community Pharmacy Group to New Zealand in July 2019. I met Aarti at the FIP in Glasgow after I presented on behalf of the Royal Pharmaceutical Society on what is possible to deliver from community pharmacy in Scotland with use of innovation, technology and clinical services. They were interested in how I transformed a retail pharmacy into a health centre community hub with face-to-face triage assessments with our pharmacist practitioners.

They were also interested in how we support long-term care, in particular, with saving lives in asthma, as this disease is highly prevalent in their country and on average one person dies per day there. It is particularly a problem with their high-needs populations, and after meeting with policymakers, it is also an area of interest which community pharmacists can support by reducing hospital admissions, and so hospital avoidance became a clear priority in my thinking.

A common comment from Kiwi pharmacists I met was that they were interested in offering new services but couldn't see how to free up pharmacist time from dispensing. I observed that in actual fact their young pharmacists do not only do the final check, they also dispense. In one pharmacy there were five pharmacists on duty at the same time.

I was so very honoured and proud to have met up in person – along with his pharmacy advisors and Ian McMichael, the President of the Pharmaceutical Society of New Zealand, and Richard Townley, Chief Executive Officer of the Pharmaceutical Society of New Zealand – with the Minister of Health, New Zealand, the honourable Dr David Clark.

He spoke with me, with his advisors, and the Pharmaceutical Society of New Zealand for 30 minutes and was interested in listening to my stories where the outcomes were improved

quality of life in asthma and hospital avoidance, as well as greater access to the public to a highly qualified workforce for minor illness. I explained how my team and I have skilled up to provide an enhanced common clinical conditions clinic which is not only improving access, but we have evidenced the ways in which this clinical care is supporting saving appointments in GP practices and accident and emergency and out-of-hours services. I shared how Choose Pharmacy First is a big campaign which allows the pharmacists to skill up and assess and treat their own patients.

I met with the Pharmaceutical Society of New Zealand senior team – also in Wellington – and we discussed the education of pharmacists, and how I have been particularly lucky in Scotland with our universities and education bodies, as well as the government getting behind us and providing excellent training resources. I discussed Common Clinical Conditions as being the one course that transformed my thinking as to what could be possible to deliver from community pharmacy.

I am so very proud that my pilot in Fife – which took over two years and a nine-month evaluation phase – is now a priority of NHS Fife and any community pharmacy can now apply for funding with the correct level of education, skills and experience to deliver a funded common clinical conditions clinic. There are now three pharmacies offering this and more doing their training so that they can apply for funding.

I have a service level agreement that was adapted from a Welsh one thanks to the amazing generosity of my Welsh colleague and I can now assess and treat any person registered in my town at the seven local GP practices as a drop-in centre with a wider scope of practice including ear, nose and throat infections; chest infections; cellulitis; paronychia; acute exacerbations of asthma; COPD; eczema; and psoriasis.

The pharmacists were keen to hear about our innovations on how we have achieved releasing pharmacists away from the final check and into a more person-centred role. The key for the consultations is that we as pharmacists like science and numbers and our team at Cadham have realised that the public respond to these when they are explained in the context of their diagnosed conditions and how those medicines can relate to that and improve their quality of life.

I spent time sharing my case studies in asthma and how we have seen people who have been sick for years, and how with that simple support and motivational interviewing, in the space of just three months their lives have been turned around.

I have had contact from one of the pharmacists I met and she and I are working together to support her starting up her own clinic to support saving lives in asthma in her town.

I'm so happy that I was given this opportunity of a lifetime to meet with these wonderful people who all have a desire and want to do more. I do hope that in some small way I have been able to inspire on what is possible and then support with advice and the tools on how to deliver more clinical funded services in New Zealand, making the most of their exceptionally-talented workforce.



Bernadette (second left) at the Ministry of Health in Wellington in New Zealand

A FLARE WARNING

Lined with confused patients and concerned parents, the road of atopic eczema in infants is a seemingly complex one to navigate. Dr Paula Beattie MB BCh BaO, BSc, MD, Consultant Dermatologist and British Skin Foundation spokesperson, Royal Hospital for Children, Glasgow, advises on how you can help to demystify their treatment plan.



Dr Paula Beattie

Atopic eczema is a multifactorial skin disease with both genetic and environmental factors influencing the structure and function of the skin barrier. An abnormal barrier allows water loss, leading to dryness, and leaves the skin vulnerable to irritants and allergens, as well as viruses and bacteria.

Natural moisturising factor, a compound in the skin that has the ability to absorb water from its surroundings, can be reduced in amount as a result of a genetic mutation and surfactants in wash products reduce that further.

Skin dryness often precedes clinically-obvious inflammation and is likely to represent subclinical inflammation. It's one of the first signs of eczema and can be detected as early as day two of life in children who go on to develop eczema. (1) Scratching damages the barrier, leading to the release of cytokines which drive inflammation and itch.

Eczema affects 16-to-30 per cent of children in the UK (2), persisting into adulthood in around 40 per cent – particularly in those with early and widespread disease. Children with eczema are also more likely to develop other atopic disease, namely food allergy, asthma and allergic rhinitis. The mechanism of development of food allergy in infants with eczema is again an impaired skin barrier, so that food allergens are presented to the immune system via the skin for the first time, leading to sensitisation rather than the

ECZEMA

tolerance which occurs when presented via the gut. Skin barrier dysfunction at birth predicts food allergy at two years. (3)

EMOLLIENTS IN ACTION

Use of emollient improves skin hydration by replacing lipids and trapping water in the skin when used after bathing. Hence bathing can be encouraged so long as soap is avoided. Emollients also improve the function of the skin barrier and have been shown to help prevent irritant occupational eczema. Dryness is often associated with itching, and improved emollient use has been shown to reduce scratching and sleep disturbance, eczema severity, and flares of eczema; thereby reducing the need for topical corticosteroid (TCS). (4, 5) Emollients should be used on all skin – not just areas of active eczema – and should be applied twice daily or more, continuing use between flares.

They should be prescribed in large quantities (250g-to-500g weekly) with additional pumps / tubs for childminder / nursery to encourage frequent use. Depending on skin dryness and acceptability, a cream and / or an ointment should be provided so that parents can decide which suits best. In general, ointments are better for dry skin and should be encouraged at night. Thick emollients are more effective as a barrier to chlorine in pool water and food in babies and infants being weaned. When prescribing or dispensing an emollient, advice should be given to apply it in a downward fashion along the direction of the hair.

THE EMOLLIENT EFFECTS

Emollients can be associated with adverse effects; thick emollients can occlude the hair follicles, resulting in inflammation, and application of any emollient to the skin in the opposite direction of hair growth can also irritate the hair follicles. Contamination of emollients in tubs with bacteria from the hands can occur but should not occur with pump dispensers and if the emollient is removed from the tub with a clean spoon to a clean surface. Creams and lotions contain preservatives and can sting when applied to broken or inflamed skin. Treating the inflammation with TCS will help reduce this.

Emollients such as aqueous cream and emulsifying ointment contain Sodium lauryl sulphate, a surfactant (soap) which can irritate and exacerbate dryness so they should never be used as a leave-on emollient and should probably also be avoided as a soap substitute.

It's important to note that while emollients will improve the skin barrier, skin inflammation, which manifests clinically as redness, should be managed with TCS. TCS should be used according to NICE guidance with the use of a mild potency TCS to the face and a mild TCS, stepping up to a medium

TCS, if not responding to areas of eczema on the body. In children over a year TCS potency can be increased to potent for the body and used in the same way.

Treatment should be for seven-to-14 days initially, and this should be repeated for flares. Treatment on two consecutive days each week to problem areas in those experiencing frequent flares (more than two each month) has been shown to reduce the frequency and duration of flares (www.nice.org.uk/guidance/cg57). TCS should be initiated at the first sign of skin inflammation from birth onwards. Gaining control of inflammation quickly will reduce the risk of skin infection and may improve disease outcomes long-term.

Unfortunately there is a paucity of evidence on whether it is more effective to apply emollients before or after TCS, but it's likely that applying emollients first is more effective and the vast majority of recent publications – including NICE guidance – reflect that and advise a delay of approximately 30 minutes before TCS application. This is to allow absorption of the emollient and minimise dilution of the TCS by emollient.

SUMMARY

In conclusion, when used in sufficient amounts alongside TCS for areas of inflammation, emollients help to reduce the symptoms and signs of atopic eczema, irritation by external environmental triggers, and the frequency of flares.

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2. Odhiambo et al. Global variations in prevalence of eczema symptoms in children from ISAAC Phase Three. *J Allergy Clin Immunol.* 2009 ;124(6):1251-8
3. Kelleher M et al. Skin barrier impairment at birth predicts food allergy at 2 years of age. *J Allergy Clin Immunol.* 2016; 137(4): 1111-1116
4. Mason JM et al. Improved emollient use reduces atopic eczema symptoms and is cost neutral in infants: before-and-after evaluation of a multifaceted educational support programme. *BMC Dermatol.* 2013;16:13:7
5. Wirén K, et al. Treatment with a barrier-strengthening moisturizing cream delays relapse of atopic dermatitis: a prospective and randomized controlled clinical trial. *J Eur Acad Dermatol Venereol.* 2009; 23(11):1267-72



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A WELCOME RELIEF

Cannabidiol is undoubtedly at the centre of increasing medical research right now – but what benefits does it boast for your patients? SPR examines the product's exciting paths of potential, and just why it's reaching new heights of popularity.

UNDER THE SPOTLIGHT

Saving you the hassle of scouring the different streams of CBD-focused information, SPR rounds up the need-to-know details for you to deliver to patients.

WHAT IS CBD?

Cannabidiol – or CBD as it is widely termed – is a type of cannabinoid; a chemical found naturally in the cannabis and hemp plants. At least 113 different cannabinoids have been found in hemp. CBD differs from another commonly-known cannabinoid tetrahydrocannabinol (THC) in that it doesn't induce the 'high' typically associated with cannabis use.

The history of CBD as an identifiable compound can be traced back to the 1940s. Now, we see an explosion of scientific interest into CBD with scientific papers being published, and different products being seen in stores.

HOW DOES CBD WORK?

CBD interacts with the endocannabinoid system (ECS). This is a network of CBD receptors and naturally-occurring chemical messengers, called endocannabinoids, that play a part in the body's overall health and wellness.

The two main CBD receptors were found to be CB1 receptors, located in the brain and central nervous system, and CB2 receptors found throughout the rest of the body. The naturally-occurring endocannabinoids interact with the body's CBD receptors, and it is through this process that the ECS regulates a range of bodily functions.

HOW CAN INDIVIDUALS USE CBD?

If the individual wants to maintain steady levels of CBD throughout the day, then an oral product could be appropriate, however, the amount of CBD in oral products can vary widely.

The bioavailability of the chosen CBD product also needs to be considered (how much effect they will get based on how much gets absorbed into their bloodstream). It's also important to know how much CBD they are using – with capsules making it easier to keep track of this process and accurately calculate the dosage and absorption rate.

EXCEEDING EXPECTATIONS

As CBD is catapulted further into the arena of public awareness and use, SPR takes a look at new indicators of its potential.

FINDINGS FOR PSYCHOSIS

Research underway at King's College London has found that a single dose of CBD can play a part in reducing brain function abnormalities seen in people with psychosis.

As expected, the brain activity in the participants at risk of psychosis was abnormal compared to the healthy participants. However, among those who had CBD, the abnormal brain activity was less severe than for those who received a placebo, pointing towards the possibility that the product can help re-adjust brain activity to normal levels. The influence of CBD on the three brain regions could underlie its therapeutic effects on psychotic symptoms.

Hot on the heels of the promising results reaped, Dr Bhattacharyya and colleagues at The Institute of Psychiatry, Psychology and Neuroscience set about launching the first large-scale, multi-centre trial to investigate whether CBD can be used to treat young people at high risk of developing psychosis. The trial is supported by a £1.85 million grant from an NIHR and MRC partnership.

'There is an urgent need for a safe treatment for young people at risk of psychosis,' commented Dr Bhattacharyya.

'One of the main advantages of CBD is that it is safe and seems to be very well-tolerated, making it in some ways an ideal treatment. If successful, this trial will provide definitive proof of CBD's role as an anti-psychotic treatment and pave the way for use in the clinic.'

ADVANCES IN EPILEPSY

A new large-scale, randomised, controlled trial further showcased the benefits brought on by CBD employment, in which it significantly reduced the number of dangerous seizures in patients with a severe form of epilepsy, called Lennox-Gastaut Syndrome.

In the new study comparing two doses of CBD to a placebo, the researchers reported a 41.9 per cent reduction in 'drop seizures' – a type of seizure that results in severe loss of muscle control and balance.

The phase III trial was led by principal investigator and study first co-author, Orrin Devinsky, MD, a Professor of Neurology, Neurosurgery, and Psychiatry at New York University (NYU) School of Medicine, and Director of NYU Langone's Comprehensive Epilepsy Centre, and was published online in The New England Journal of Medicine.

'While the news gives hope for a new treatment option to the epilepsy community, more research remains imperative to better determine the effects of CBD and other similar cannabis-derived compounds on other forms of the disease and in more dosing regimens,' Dr Devinsky explained.

ASK THE EXPERT

Local Practice Pharmacist, Maeve Devlin, who has witnessed the increasing utilisation of CBD across the different facets of the sector, explained, 'The product market for CBD is growing at a rapid pace and undoubtedly, regulated CBD-containing products have the potential to benefit many patients.'

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MEN'S HEALTH

LET'S TALK ABOUT SEX

Erectile dysfunction is one of the most common side-effects of prostate cancer treatment, yet a large subset of patients still aren't reaching out for help – obstructed by embarrassment and a myriad of other concerns. Sophie Smith, Specialist Nurse at Prostate Cancer UK, tackles the scale of the problem, and how you can provide support.



Sophie Smith

One-in-eight men in the UK will get prostate cancer in their lifetime, and over 47,000 men are diagnosed with prostate cancer every year.

Unfortunately, Prostate Cancer UK's latest research shows that thousands of these men are missing out on the support they need to manage erectile dysfunction – one of the most common side-effects of treatment.

As a specialist nurse at Prostate Cancer UK I regularly speak to men about these issues and can see the impact it has on their lives. If left unchecked, not only can erection problems put a complete stop to a man's sex life, they can also have devastating longer-term implications, including depression and relationship breakdowns. (1)

However, we know that if healthcare practitioners across the country are willing to have honest and open discussions about side-effects and the support available, it can make a huge difference to these men's lives.

WHAT SUPPORT DO THEY NEED?

In line with NICE guidelines (2), all men should be given the opportunity to discuss their sexual problems after prostate cancer treatment, and it's particularly important that men feel informed of their options and in control of their own care.

This may involve men being offered access to an NHS erectile dysfunction clinic, an appropriate choice of medication like tadalafil, vacuum pumps, psychosexual clinics, and counselling services.

This advice also needs to be tailored depending on what treatment they receive and their personal circumstances. For example, we know that men receiving hormone therapy can be particularly impacted by erection problems.

Despite the importance of these discussions, we know that it's not always easy for men or their clinicians to initiate them, which is why the Movember Foundation and Prostate Cancer UK have also funded two online tools to help:

- A self-management resource to help men manage their own sexual wellbeing after prostate cancer (3)
- An e-learning module designed to support healthcare professionals to offer sexual care to men with the disease (4)

WHAT IS THE SCALE OF THE PROBLEM?

The Life After Prostate Cancer Diagnosis study, funded by the Movember Foundation in partnership with Prostate Cancer UK, showed that more than four-in-five men with prostate cancer struggle with poor sexual function following treatment for the disease regardless of the stage of their disease (5), their treatment (6), or their age (7). Even worse, just over half of these men reported that they were not offered help to manage it.

CAN WE AVOID THESE SIDE-EFFECTS?

Each year thousands of men are diagnosed with prostate cancer that is still contained within the prostate and is considered to have a low risk of causing harm. NICE recommends active surveillance for these men, which could allow many more men to avoid or delay the side-effects of invasive treatment.

Prostate Cancer UK and other health bodies are also investing in new precision medicine technologies to target individual men with the best treatment for them, as well as improved diagnostic tools and focal therapies. All of this could help reduce the impact of these side-effects in future.

WHAT NEXT?

Despite the recent advances, the number of men diagnosed with prostate cancer is still increasing year-on-year, and they will continue to need support with erectile dysfunction and the other side-effects of treatment.

However, with the right support and information, men can find out about treatments or counselling that could help them manage, or come to terms with, erection problems.

By continuing to discuss these issues in an open and unembarrassed way, we can make sure that all men get the help they need.

For more information, and to sign up to one of Prostate Cancer UK's free Primary Care Masterclasses, visit www.prostatecanceruk.org/masterclass.

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2. Full NICE guidelines available here: <https://www.nice.org.uk/guidance/NG131>
3. Available online here: <https://prostate.lifeguidewebsites.org/>
4. Available online here: <https://talkingaboutsex-prostatecancer.org/>
5. Three-quarters of men (75%) diagnosed with localised prostate cancer reported poor sexual function, compared to 90.4% of men with locally advanced disease (cancer that has spread to the tissue surrounding the prostate gland), and 96% of men diagnosed with advanced prostate cancer.
6. Breakdown of the percentage of men who experienced poor sexual function, by treatment type:
 - Active surveillance – 51 per cent
 - Watchful waiting – 58 per cent
 - Brachytherapy – 63 per cent
 - Surgery – 84 per cent
 - Surgery and radiotherapy / ADT – 92 per cent
 - Radiotherapy – 79 per cent
 - Radiotherapy + ADT – 88 per cent
 - ADT – 94 per cent
 - Systemic therapy (i.e. chemotherapy, abiraterone or enzalutamide) and ADT – 98 per cent
 - Systemic therapy (i.e. chemotherapy, abiraterone or enzalutamide) + radiotherapy +/- ADT – 95 per cent
7. Breakdown of the percentage of men who experienced poor sexual function, by age:
 - <55 years – 54 per cent
 - 55-to-64 years – 66 per cent
 - 65-to-74 years – 79 per cent
 - 75-to-84 years – 88 per cent
 - 85+ years – 95 per cent



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*Only once per 24 hour period

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Name of product: Vitaros® (urethral alprostadil cream)
Composition: Alprostadil 300 micrograms in 100mg of cream (3mg/g). Indication: Treatment of men ≥18 years of age with erectile dysfunction. **Dosage & Administration:** Vitaros® is applied into the opening at the tip of the penis (meatus) 5 to 30 minutes before attempting intercourse. Bring the contents of the single-dose container to room temperature by rolling the container between the hands and twist the plunger several times to make sure it will glide easily. The tip of the container should be placed as close as possible to the opening at the tip of the penis for the cream to go down the urethra. Do not insert the tip of the AccuDose™ container into the opening of the penis. Any excess cream covering the opening at the tip of the penis should be gently moved into the opening with the tip of a finger. Use as needed to achieve an erection to a maximum frequency of once every 24 hours and no more than 2-3 times per week. Vitaros® Accudose™ container is for single use only. **Contraindications:** Should not be used in patients with orthostatic hypotension, myocardial infarction, syncope, abnormal penile anatomy, urethritis, balanitis, tendency to thrombosis, hyperviscosity syndrome, underlying conditions that may predispose them to priapism, known hypersensitivity to alprostadil or any excipients. Should not be used in patients for whom sexual activity is inadvisable (men with unstable cardiovascular or cerebrovascular conditions). A condom must be worn for sexual intercourse with a woman who has child bearing potential. **Special Warnings & Precautions:** Treatable causes of erectile dysfunction should

be excluded before initiation of Vitaros®. If priapism occurs, the patient should seek medical assistance immediately. Avoid driving or hazardous tasks due to risk of hypotension or syncope after administration, dose may need to be lowered in patients with hepatic and/or renal impairment. Inadvertent intraurethral exposure may result in penile burning, tingling sensation and pain. Vitaros® offers no protection from the transmission of sexually transmitted diseases, partners of Vitaros® users can experience adverse effects such as vaginal irritation. The effects of Vitaros® on the oral or anal mucosa have not been studied. A condom barrier is recommended for use with Vitaros®, including use during oral or anal sex. Only latex material based condoms have been investigated for use with Vitaros®. Other materials may not exclude possible risk of damage to the condom. **Interactions:** Based on the nature of the metabolism of Vitaros® drug-drug interactions are considered unlikely. Not recommended for use with phosphodiesterase-5 (PDE-5) inhibitors as an additive increased cardiovascular risk cannot be excluded. Possible risk of priapism if used in combination with a penile implant or smooth muscle relaxant. Possible increased risk of hypotension (especially in elderly) when administered in combination with antihypertensive drugs and vasoactive medications. The effect of Vitaros® may be reduced if administered concomitantly with sympathomimetics, decongestants and appetite suppressants. When used in combination with anticoagulants and platelet aggregation inhibitors, there may be an increased risk of urethral bleeding, haematuria. **Fertility, Pregnancy & Lactation:** Pregnant

women should not be exposed to Vitaros®. It is not recommended to use Vitaros® while breastfeeding. It is not known whether Vitaros® has an effect on human male fertility. **Undesirable Effects:** *Common* (≥1/100 to <1/10): rash, urethral pain, penile pain, burning erythema tingling, throbbing or numbness, genital pain, erythema or discomfort, balanitis, penile oedema, erection increased, in partner: vulvovaginal burning sensation and vaginitis. **Other Serious Undesirable Effects:** *Uncommon* (≥1/1000, <1/100): hypotension, priapism, dizziness, syncope, urinary tract infection. Refer to the SmPC for details on full side effect profile and interactions. **Special Precautions for Storage:** Store in a refrigerator (2°C - 8°C), without freezing. Unopened sachets may be kept out of the refrigerator by the patient, at a temperature below 25 °C for up to 3 days prior to use; after this the product should be discarded if not used. **Presentation:** Vitaros® is supplied in individual sachets containing one Accudose™ container. Each single container contains 100 mg cream. Vitaros® is available in unit cartons containing four containers. **Basic NHS Price:** £40 per pack of 4 doses. **Legal Classification:** POM. **Marketing Authorisation Number:** PL 03194/0125. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd, Drayton Hall, Church Road, West Drayton, UB7 7PS, UK. Vitaros® is a registered trademark. **PI Approval Code:** VIT/1429/2018/UK(1). **Date of Preparation:** July 2018

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DYSPHAGIA

SWALLOWING, DYSPHAGIA AND MEDICINE

With dysphagia becoming a greater burden as the population ages, David G Smithard and Vruti Patel, Department of Elderly Medicine, Queen Elizabeth Hospital, Lewisham and Greenwich NHS Trust, highlight the medicine prescribing and administration considerations which must be acted on accordingly.

The taking of medication has become a way of life for the general population, with 48 per cent of the adult population taking at least one prescribed medicine (1), and with 90 per cent of older people taking at least one. Many more will be self-medicating. Medications can be provided in many different formats; the cheapest and most common being tablets or capsules.

Taking medications requires a person to swallow safely. Dysphagia is under-reported, particularly in the older population, where many people have slowly altered their diet (consistency and volume), or subconsciously changed the way they swallow (smaller bolus, taking fluids).

Dysphagia may be the result of a malignant process, neurological insult (stroke, head injury, tumour), progressive neurological disease (Parkinson's disease, Motor Neuron Disease or Multiple Sclerosis), as well as rheumatoid arthritis and cardiorespiratory disease.

Following investigations, clinical (speech and language therapist (SALT)) and instrumental (videofluoroscopy, fibreoptic endoscopic evaluation of swallowing or pressure / impedance), a management plan will be formulated. (2) The approach taken will depend on the underlying aetiology, with the same overall aim – to provide nutrition safely.

The questions that need to be asked are: will the swallow improve? If yes, how can we improve it? How should nutrition be provided, and who will follow the patient up?

If adequate nutrition can be taken orally, there is no need for enteral feeding. However,

there may be a need to alter the consistency of food and viscosity of fluids as indicated in the IDDSI guidelines (adopted in the UK). If not, then enteral feeding is often used, via a nasogastric or naso-jejunal tube or percutaneously via endoscopic placement or radiological placement.

Research is following many avenues, four of which are: a. basic science to understand the mechanism of swallowing; b. epidemiology and assessment; c. rehabilitation and recovery; d. safe delivery of medication. Unfortunately, it is often difficult to obtain funding.

EPIDEMIOLOGY AND ASSESSMENT

As alluded to, the prevalence of dysphagia and swallowing problems is not fully known, however, it's accepted as an increasing problem in the ageing population. Many studies use different assessment tools and different definitions of dysphagia. Further work using large databases will help, but this will only provide part of the information. A clear consensus on the definition of dysphagia, what is normal / acceptable in older people, and a minimum data set for studies are required going forward.

Screening for dysphagia is a minefield. Many 'screens of swallowing' are assessments. A screen needs to be simple and easy-to-use, with reasonable sensitivity and specificity. One such tool is the 4QT which relies on four simple questions. An even simpler way is to watch someone eating if time allows.

REHABILITATION AND RECOVERY

In head injury and stroke the ability to swallow may recover over time. In conditions where muscle weakness is an issue (frailty, under-nutrition, cardiorespiratory disease) what can be done to improve the swallow and the amount eaten?

A study in Japan noted that frail older adults who underwent dysphagia rehabilitation after admission were more likely to be taking a normal diet and eating more.

At present, many workers are investigating muscle strength exercises of the tongue and the suprahyoid muscles. There are several devices that can be used for tongue training, with evidence suggesting that the swallow will improve.

Suprahyoid muscle exercises, such as shaker manoeuvres, chin tuck against resistance, and laryngeal resistance have shown promising physiological results, mainly in a normal adult population. The Ablilex™ device and Iqoro are simple devices that have shown to have some

benefits, but further evidence is required.

MEDICATION

Medication errors are common when people have swallowing problems. (3) Staff and patients may crush, dissolve, or hide medications in food. These all raise legal and ethical challenges. Medication may get missed or not taken, putting people at risk.

Two things need to take place. Prescribers need to consider whether a particular medication is required, and the route medication is administered. Does an alternative formulation exist, such as a liquid, patch, melt / wafer, or granules that can be used instead? Will the dissolved, crushed, suspended medication interact with a feeding tube? How will thickeners added to liquids or liquid medications affect absorption of medications (4)? Who will do the research in these areas? Responsibility will rely on academic research as commercially the research will be expensive and falls between too many stools.

Secondly, clinical staff need to be educated as to the law on prescribing and manufacturing (crushing and mixing tablets), and alternatives to tablet formulations. Recently the Patient Association undertook some work and have produced a web page and a Charter (5) to educate care staff.

CONCLUSION

Further work is required to understand the prevalence and impact of dysphagia. More research needs to be undertaken to improve dysphagia identification, assessment, and rehabilitation. The impact of dysphagia management on medicine prescribing and administration needs to be better understood by the multidisciplinary team.

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It's a hard fact to swallow, but up to 69% of elderly patients have had problems taking tablets or capsules.¹

Studies have identified difficulties swallowing as a common cause of non-adherence.¹⁻³ Unfortunately, many patients don't report this troublesome issue to their healthcare professional.⁴

As a pharmacist, you are well placed to identify patients who are non-adherent because of difficulties swallowing during a chronic medication service (CMS). Simply asking patients whether they have trouble taking their medicines has the potential to improve the patient's care across primary care, secondary care and in the community.



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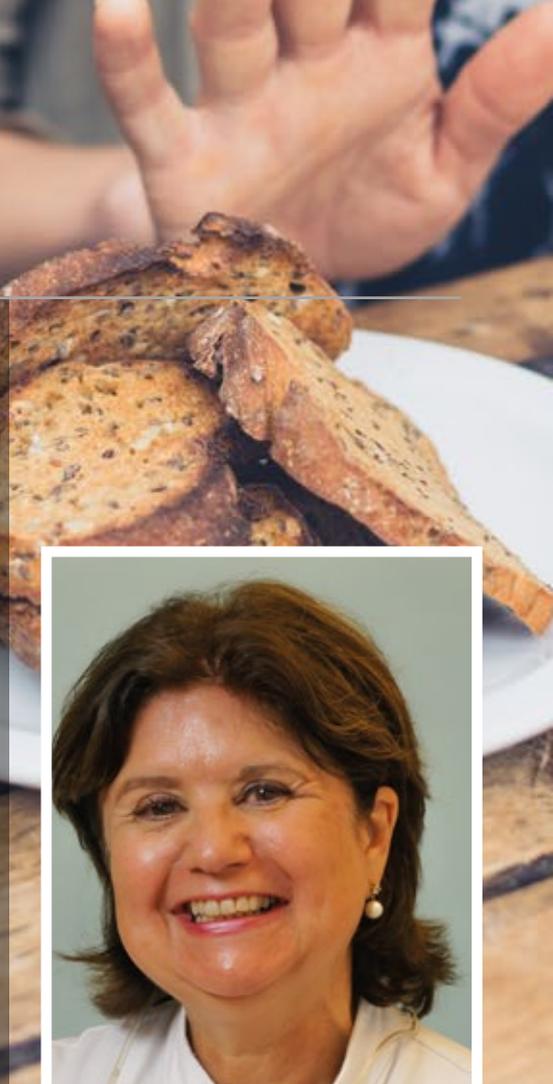
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COELIAC DISEASE

PAEDIATRIC COELIAC DISEASE: A TALL ORDER?

Coeliac disease is a frequent and life-long autoimmune condition, caused by an abnormal reaction of the immune system to gluten – a group of proteins found in grains such as wheat, barley and rye – that is common in the European diet. Despite its significant prevalence, many people are unaware of just how common it has become. Luisa Mearin, Secretary of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition, investigates how by boosting our understanding, we can reduce complications and pave the way to a brighter future for our young patients dealing with it.



Luisa Mearin

WHAT IS PAEDIATRIC COELIAC DISEASE?

Coeliac disease can occur at any age, including in babies during weaning (once gluten has been introduced to their diet), in children, and in adolescence. When a child with coeliac disease eats gluten, their immune system reacts by damaging the lining of the small intestine.

Paediatric coeliac disease is now the most common food-related chronic disease among children in Europe, with one-in-100 sufferers in the majority of European countries, and in areas of heightened prevalence, as many as eight-in-100. (1) However, most children with coeliac disease are not properly diagnosed, due to the complex clinical picture of the disease. (2) With this rising prevalence, undiagnosed paediatric coeliac disease leaves a large population at risk of developmental issues and long-term associated health complications.

It's a surprise to many experts that paediatric coeliac disease was considered a rare condition among children until recently. The reality is that it is commonplace among children of all ages, including adolescents, and this trend is only likely to continue moving into the future.

RISK FACTORS OF PAEDIATRIC COELIAC DISEASE

Certain groups are at a heightened risk of developing paediatric coeliac disease. Having a first-degree relative with the condition

makes you up to at least 10 times more likely to be a coeliac (3), and you are twice as likely to have the disease if you are female. (4)

Additionally, having type 1 diabetes, Turner syndrome, Down's syndrome, autoimmune thyroid disease, Williams syndrome, or autoimmune liver disease, increases the chances of having paediatric coeliac disease. (5)

Until recently we had no knowledge of how to stop paediatric coeliac disease from developing, finding no association with breast-feeding patterns, infection, or lifestyle factors, for instance. Prospective randomised research projects have shown that it's not possible to lower the risk by earlier or later introduction of gluten into the diet of young children.

Observational studies have also shown this for breast-feeding. However, recent studies within paediatric coeliac disease indicate that there may be ways to lower the risk of developing the condition through the diet. New research presented at the 52nd European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Annual Meeting held in June of this year suggested that high fibre intake during pregnancy reduces the risk of paediatric coeliac disease in children. (6) The Norwegian study, which assessed over 88,000 children between 1999-to-2009, found that the risk of the condition was eight per cent lower per 10g increase in fibre intake during pregnancy. The ESPGHAN look forward to

further studies in this field.

Secondary prevention by early diagnosis and treatment is also possible and in the first instance we should look to drive this forward. Screening programmes for young children offer an effective step in achieving this.

SIGNS AND SYMPTOMS OF PAEDIATRIC COELIAC DISEASE

Paediatric coeliac disease may present with a large variety of non-specific signs and symptoms. It's worth stressing the importance of diagnosis among those children with less clear symptoms, as well as those with obvious gastrointestinal indications. (7) Symptoms will not necessarily be severe, and in fact many children with the condition only present mild symptoms, such as abdominal pain, constipation, occasional vomiting, and flatulence. (8)

Key symptoms, which also act as the key health complications associated with paediatric coeliac disease, include chronic or intermittent diarrhoea, growth problems, weight loss, delayed puberty, amenorrhoea, iron-deficiency anaemia, nausea or vomiting, chronic abdominal pain, cramping or distension, chronic constipation, chronic fatigue, recurrent mouth ulcers, and abnormal liver tests.

COELIAC DISEASE

DIAGNOSIS AND TREATMENT OF PAEDIATRIC COELIAC DISEASE

In cases where a child is suspected of having coeliac disease, they should see a GP before a coeliac disease blood test is carried out to detect coeliac disease antibodies. (9)

Following a positive diagnosis, the only treatment is to completely remove gluten from the diet. This means that children with coeliac disease must strictly avoid eating any food containing gluten, including grains such as wheat, barley and rye, and some children may also be sensitive to oats. While this might seem unfortunate, one of the benefits of this treatment is that there is no need for any medicines or supplements, and with the

exception of products containing gluten, a normal healthy balanced diet can be adopted.

The role of the dietician is particularly important in advising parents and children in how to follow a healthy gluten-free diet appropriate for the age of the child.

PROMOTING AND ACHIEVING THE EARLY DIAGNOSIS OF PAEDIATRIC COELIAC DISEASE

Despite being relatively easy to detect and treat, diagnostic delays can often reach 10 years because symptoms can be non-specific, and other conditions may be diagnosed, like irritable bowel syndrome or 'functional disorders'. (10)

Another issue is that other conditions, like cancer and obesity, tend to dominate conversations over paediatric coeliac disease given their severity on young people. Certain children with coeliac disease suffer poorly before they get diagnosed, but even so, it's viewed as a condition which can be controlled by diet and does not involve any medication, which diminishes its standing as a focal point for health development. Consequently, paediatric coeliac disease is yet to achieve the same level of attention from the public or the medical community.

There is simply not enough coeliac-specific research being undertaken to match the growing demand. We launched a new appeal in the UK last year to try and pull together a £5 million fund to drive forward research because coeliac disease is not drug-treatable so does not command the commercial interests of big pharma. What we have had to do is make the case that actually, this is an important area and it is worth the investment. Our understanding of how the immune programme works in paediatric coeliac disease could be used as a model for many other autoimmune diseases, which is a strong case for extra investment. (11)

This in turn will support our wider ambitions for greater public awareness of the condition, healthcare professionals' understanding of symptoms and high-risk groups, and the establishment of national detection programmes for the early identification of paediatric coeliac disease.

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MEDICAL DEFENCE UNION



Dr Sally Old

At the Medical Defence Union (MDU), we regularly advise members on how to appropriately respond to issues arising from their activity on social media.

Used appropriately, social media is an effective tool to market yourself and your practice, communicate with other medical professionals, and makes it easier for patients to access healthcare information.

However, misguided online behaviour, such as a provocative image or a poorly-worded tweet, can result in social media becoming a minefield for medical professionals.

With this in mind, the MDU has just launched a new interactive e-learning module which is designed to help medical professionals maximise the benefits of using social media and appreciate its pitfalls while continuing to meet ethical and legal obligations.

The e-learning module features fictional social media scenarios that are based on common member queries and concerns, from interactions with patients and colleagues, to your professional image online.

Available to MDU members and non-members, the e-learning module tackles some of the common misconceptions and problems, as well as the benefits that social media can bring. Register for the e-learning module at www.themdu.com/learn-and-develop/social-media-e-learning.

HOLD THE PHONE

Dr Sally Old, Medico-Legal Adviser at the Medical Defence Union, investigates important issues for the sector to consider when using social media.

However, in the meantime, here are some key issues to consider when using social media:

MAINTAIN PATIENT CONFIDENTIALITY

The rules of confidentiality apply as much when posting online as they do to when you are chatting to a friend or family member.

In Doctors' Use of Social Media (2013), the General Medical Council (GMC) states that 'although individual pieces of information may not breach confidentiality on their own, the sum of published information online could be enough to identify a patient or someone close to them. You must not use publicly accessible social media to discuss individual patients or their care with those patients or anyone else.'

It's important to remember that when something is shared publicly through social media, it may not just be the patient and their friends and family who see it, but also employers, colleagues, national media, and regulatory bodies. This is the case, even if you are on a 'closed' professional forum.

Before posting, consider how you would feel if a colleague or patient saw what you had written, or if it was shared to a wider audience.

REMAIN PROFESSIONAL

Beware publishing comments which can appear unprofessional. It may be tempting to use social media to discuss something that happened at work but you can never be sure that others will share your opinions and your comments can also be taken out of context. The GMC guidance on social media states, 'You must not bully, harass or make gratuitous, unsubstantiated or unsustainable

comments about individuals online.'

Additionally, an unprofessional selfie or even the groups you join could harm your reputation and damage public trust in the profession so think twice before you post.

The GMC advises doctors to give their name if they identify themselves as a doctor in publicly-accessible social media and be open about conflicts of interest, such as having a financial stake in healthcare organisations or pharmaceutical and biomedical companies.

RESPECT BOUNDARIES

Also, be careful about which friend requests you accept. If a patient contacts you about their care or other professional matters through your private profile, the GMC advises you to 'indicate that you cannot mix social and professional relationships and, where appropriate, direct them to your professional profile.'

PROTECT YOUR PERSONAL SECURITY

Highly personal information is often accessible via social media for others to view even if you set your social media profile to private. As such, people have been caught out by security settings that have changed or require updates. Consequently, it is worth regularly reviewing the privacy settings for each of your social media profiles.

Social media can be a beneficial communication tool but remember not to take risks online that you would not take in the practice. The MDU recommends that you think carefully before you post.

For more information, visit www.themdu.com or follow them on Twitter: @the_mdu.

NEWS



RESPIRATORY

A BREATH OF FRESH AIR

An array of the industry's leading healthcare representatives gathered under one roof for a respiratory training day, 'Revisiting Respiratory – Actioning Asthma', in a bid to share knowledge, formulate new ideas, and ultimately better shape the future of asthma care.



Asthma UK estimates that 5.4 million adults and children in the UK are living with asthma. Sparked by this prevalence, it may be presumed that the disease is commonly and appropriately treated – but sadly this just isn't the case. As many as half of asthma sufferers aren't taking their prescribed medicines properly, leading to an individual experiencing a potentially life-threatening asthma attack every 10 seconds. The beliefs and attitudes of the patients themselves are also a cause for concern, as it's only with adherence that their needs will be adequately addressed.

An exciting training day recently provided a much-needed platform for the industry to confront these major issues – as well as an opportunity to address the other mechanisms underscoring asthmatic behaviour, and to reflect on the strategies which can enhance the approaches adopted by patients and healthcare professionals alike.

The event – 'Revisiting Respiratory – Actioning Asthma' – took place at Palm Court Hotel, Aberdeen, and attracted an extensive audience comprising representatives from different corners of the sector.

In line with the company's vision of educating healthcare professionals and promoting high quality asthma care, the meeting was organised and funded by Napp Pharmaceuticals Limited.

THE LINE-UP

Reflective of the complexity of asthma – and how important it is to undertake a multidisciplinary ethos – various speakers deriving from different backgrounds shared the respiratory-related lessons which they've picked up along the way.

Those presenting included:

- Dr Iain Small, GP, Peterhead, and NHS Grampian MCN Respiratory MCN Lead
- Professor James Chalmers, Respiratory Consultant, Ninewells Hospital, Dundee
- Dr Omar Usmani, Respiratory Consultant, Imperial College, London
- Deirdre Siddaway, Respiratory Nurse Specialist, Suffolk
- Dr Kris McLaughlin, GP, Stonehaven
- Dr Graeme Currie, Respiratory Consultant, Aberdeen Royal Infirmary, Aberdeen

THE DISCUSSION POINTS

Despite targeting asthma from different angles, one common thread tied all of the presentations together – the healthcare professional's fundamental role in equipping patients with the tools and insights to properly manage their condition.

In particular, harnessing the knowledge of children, adolescents, and their parents – and heightening engagement in this age group – in order to improve compliance, was identified as

a key area for attention. As a result, attendees were presented with tips as to how to effectively diagnose and treat these patients in question. A more in-depth exploration was also conducted in terms of what drives asthmatic behaviours – delving into the psychological and social reasons behind adherence to the medications.

Ensuring that the patient is prescribed the most effective inhalation device possible is a continuous process, and one which healthcare professionals must remain diligent about. Addressing how they can deliver this relevant information to individuals, Dr Omar Usmani, Respiratory Consultant, Imperial College, London, shared the benefits of using MDIs rather than dry powders; homing in on evidence indicating that the best health outcomes are derived from MDIs across all meta-analysis, in addition to the physics behind how devices work.

By drawing on the multiple issues highlighted throughout the day, Dr Kris McLaughlin, GP at Stonehaven, successfully summarised the important points to note when making the best decisions for patients; and how understanding their individuality is key to asthma optimisation. Dr McLaughlin also reiterated the significance of Respiratory Nurse Specialist at Suffolk, Deirdre Siddaway's talk on the National Review of Asthma Deaths, regarding how we must not be complacent with blue inhaler overuse from patients.

In reference to other change which must be executed immediately to mobilise results, Professor James Chalmers, Respiratory Consultant, Ninewells Hospital, Dundee, shed light on bronchiectasis. Increasing diagnosis of this condition needs to be considered now by primary care when they are looking at patients with suspected asthma / COPD, and they must be enlightened as to how to tell it apart and assist the individual.

As the day came to an end – concluding with closing remarks from Dr McLaughlin – the delegates departed with an optimistic outlook and a determination to implement this new evidence and advice into their real-life consultations. The future of asthma care is bright.

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flutiform® k-haler® (fluticasone propionate/formoterol fumarate). 50 µg/5 µg and 125 µg / 5 µg pressurised inhalation suspension
Prescribing Information United Kingdom. Please read the Summary of Product Characteristics before prescribing.

Presentation Pressurised inhalation suspension, in a breath-actuated pressurised aerosol inhaler.
Indications Regular treatment of asthma where the use of a combination product (inhaled corticosteroid [ICS] and long-acting β₂-agonist [LABA]) is appropriate: (i) for patients not adequately controlled with ICS and 'as required' inhaled short-acting β₂-agonist (SABA) (ii) for patients already adequately controlled on both an ICS and a LABA. For adults and adolescents aged 12 years and above. **Dosage and administration** For inhalation use. Patients should be shown how to use the inhaler correctly by a healthcare professional. Patients should be given the strength of flutiform k-haler containing the appropriate fluticasone propionate dose for their disease severity (note that flutiform k-haler 50 µg/5 µg per actuation is not appropriate in patients with severe asthma). The appropriate strength should be taken as two inhalations, twice daily (normally morning and evening) and used every day, even when asymptomatic. flutiform k-haler is not recommended in children under 12 years. Prescribers should be aware that in asthmatics, fluticasone propionate is as effective as some other inhaled steroids when administered at approximately half the total daily microgram dose. Patients should be assessed regularly and once asthma is controlled, treatment should be reviewed and stepped down to the lowest effective dose, or an ICS alone. ICSs alone are first line treatment for most patients. flutiform k-haler is not intended for initial treatment of mild asthma. For patients with severe asthma the ICS therapy should be established before prescribing a fixed-dose combination product. Patients on flutiform k-haler must not use an additional LABA. An inhaled SABA should be taken for immediate relief of asthma symptoms arising between doses. Patients should be advised to contact their prescriber when flutiform k-haler dose counter is getting near zero. **Contraindications** Hypersensitivity to the active substances or to any of the excipients. **Precautions and warnings** flutiform k-haler should not be used as the first asthma treatment, to treat acute asthma symptoms or for prophylaxis of exercise-induced asthma. It should not be initiated during an exacerbation, during significantly worsening or acutely deteriorating asthma, and should not be stopped abruptly. If a patient experiences serious asthma-related adverse events or exacerbations, they should continue treatment and seek medical advice. Patients should be reviewed as soon as possible if there is any indication of deteriorating asthma control. In case of sudden and progressive deterioration, seek urgent medical assessment. Caution in patients with: pulmonary tuberculosis; quiescent tuberculosis; fungal, viral or other infections of the airway; thyrotoxicosis; phaeochromocytoma; diabetes mellitus (consider additional blood sugar controls); uncorrected hypokalaemia; predisposition to low levels of serum potassium; impaired adrenal function (monitor HPA axis function regularly); hypertrophic obstructive cardiomyopathy; idiopathic subvalvular aortic stenosis; severe hypertension; aneurysm or other severe cardiovascular disorders; unstable or acute severe asthma and other conditions when the likelihood for hypokalaemia adverse effects is increased. There is risk of potentially serious hypokalaemia with high doses of β₂-agonists or concomitant treatment with β₂-agonists and drugs that can induce or potentiate a hypokalaemic effect. Monitoring of serum potassium levels is recommended during these circumstances. Formoterol may induce prolongation of the QTc interval. Caution must be observed when treating patients with existing prolongation of QTc interval. flutiform k-haler should be discontinued immediately if there is evidence of

paradoxical bronchospasm. Visual disturbance may be reported with corticosteroid use. Systemic effects with an ICS may occur, particularly at high doses for prolonged periods or when combined with potent CYP3A4 inhibitors, but are less likely than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density and cataract glaucoma. Children may also experience anxiety, sleep disorders and behavioural changes. Increased exposure can be expected in patients with severe hepatic impairment. Prolonged treatment with high doses of corticosteroids may result in adrenal suppression and acute adrenal crisis, particularly in children and adolescents or potentially as a result of trauma, surgery, infection or rapid dose reduction. flutiform k-haler contains a negligible amount of ethanol that does not pose risk to patients. **Interactions** Co-treatment with CYP3A inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nelfinavir, saquinavir, ketoconazole, telithromycin, cobicistat) should be avoided unless the benefit outweighs the increased risk of systemic side-effects. Caution is advised with concomitant use of non-potassium sparing diuretics (e.g. loop or thiazide), xanthine derivatives, glucocorticosteroids, L-Dopa, L-thyroxine, oxytocin, alcohol or other adrenergic drugs, including anaesthesia with halogenated hydrocarbons and digitalis glycosides, β-adrenergic drugs, known to prolong the QTc interval, such as tricyclic antidepressants or MAOIs (and for two weeks following their discontinuation), antipsychotics (including phenothiazines), quinidine, disopyramide, procainamide, antihistamines. **Furazolidone and procarbazine flutiform k-haler** should not normally be used with β-blockers including those that are used as eye drops to treat glaucoma. Under certain circumstances, e.g. as prophylaxis after myocardial infarction, cardioselective β-blockers could be considered with caution. **Pregnancy and lactation flutiform k-haler** is not recommended during pregnancy unless the benefits to the mother outweigh risks to the foetus. A risk to the breastfeeding infant cannot be excluded. **Side-effects** Uncommon (<1/100) but potentially serious side-effects: hyperglycaemia, agitation, depression, aggression, behavioural changes (predominantly in children), vision blurred, vertigo, palpitations, ventricular extrasystoles, angina pectoris, tachycardia, hypertension, dyspnoea, peripheral oedema. Please consult the SPC for a full list of side-effects and those reported for the individual molecules. **Legal category POM Package quantities and price** One inhaler (120 actuations) 50 µg/5 µg - £14.40 125 µg/5 µg - £28.00 **Marketing Authorisation numbers** PL 16950/0338-39 **Marketing Authorisation holder** Napp Pharmaceuticals Limited Cambridge Science Park Milton Road Cambridge CB4 0GW UK Tel: 01223 424444 For medical information enquiries, please contact medicalinformationuk@napp.co.uk. FLUTIFORM is a registered trademark of Jagotec AG, and is used under licence. K-HALER is a registered trade mark of Mundipharma AG. © 2018 Napp Pharmaceuticals Limited.

UK/FLUT-K-18011

Date of preparation: May 2018

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Napp Pharmaceuticals Limited on 01223 424444.

 flutiform® k-haler®
fluticasone propionate/formoterol

 NAPP

RESPIRATORY

UK/FLUT-K-19020; Date of preparation July 2019

ASTHMA

THE REAL WORLD OF ASTHMA AND ALLERGY

5.4 million people in the UK receive treatment for asthma, which equates to one-in-12 adults and one-in-11 children nationwide. Of these asthma patients, a huge number suffer from allergies which can trigger an asthmatic attack and exacerbate pre-existing symptoms – positioning them at the forefront of possible danger when a lack of awareness or planning comes into play. Shuaib Nasser, Consultant in Asthma and Allergic Disease at Cambridge University Hospitals NHS Foundation Trust, depicts why we must elevate patients' understanding of potential triggers, and ensure that they're prepared.



Shuaib Nasser

Allergic asthma accounts for up to 90 per cent of cases in children and young adults, and 50 per cent in adults. Many children do 'grow out of' their condition, yet, while the triggers that more commonly affect younger sufferers are food allergy and hay fever, among older sufferers there are different triggers to watch out for, of which infection can be a common one. These figures put the UK at one of the worst countries in Europe in terms of asthma rates, and data from Asthma UK shows that more people are suffering from attacks than five years ago.

HAVING THEIR SAY

In a new, real-world evidence study conducted on behalf of the British Society for Allergy and Clinical Immunology, in which 5,003 respondents took part, UK asthma sufferers were asked whether they were aware of their asthma triggers, with the aim to discover whether a better knowledge could help patients manage their condition. This study was a retrospective, non-interventional assessment of self-reported symptoms, in which participants completed an internet-based questionnaire and responses were collected electronically using a bespoke media platform.

The research showed that despite NICE guidance advising healthcare professionals to use 'IgE tests to identify triggers once a formal diagnosis of asthma has been made', over half of respondents didn't know what triggered their asthma, and almost 70 per cent had never been tested for allergies. 97 per cent of respondents, however, believed that a better understanding of their triggers could help them to manage their asthma. Of those who had been found to have allergic triggers, 92 per cent said that they had taken steps to reduce their exposure to their triggers and had benefitted as a result. Furthermore, two-thirds of respondents said that they didn't have a personalised asthma action plan (PAAP) despite NICE guidelines advising GPs to prescribe an 'asthma self-management programme, comprising a written personalised action plan' and a further third reported that they didn't attend an annual asthma review.





70 per cent of respondents reported fluctuations in the severity of their asthma over the course of the year. This suggests that identification of triggers in these patients may help to improve control. Common allergic triggers, at this time of year, in particular, include grass pollen as the most prevalent, as well as birch pollen. If symptoms are more severe during winter months, this could suggest a house dust mite or pet allergy. Other allergic triggers include fungal moulds (e.g. *Aspergillus*, *Alternaria*, and *Cladosporium*) or food.

THE IMPORTANCE OF EMPOWERMENT

If an asthma sufferer suspects that their asthma has an allergic trigger, it's important to advise them to begin to monitor their symptoms for potential triggers. Should they begin to document a pattern in the severity of their asthma, and this could be as simple as noticing a change in certain seasons, when travelling abroad, at home vs the office, or when visiting certain friends, then they should bring this up at their annual review. IgE testing can help to confirm or exclude suspected triggers and improve management of asthma using avoidance strategies.

Helping a patient to understand their triggers can empower them with new-found freedom to choose how they manage their asthma. For example, if an asthma sufferer is discovered to have pet dander as an allergic trigger, they can choose to make lifestyle adaptations to reduce contact with their own cat or dog, or pets belonging to others. This does not necessarily mean getting rid of their pet, however, actions such as regularly vacuuming and not allowing the pet in bedrooms, or on furniture, can have a substantial effect.

Encouraging asthma sufferers to take an interest in their condition is key and they are most often enthusiastic when it comes to learning about how they can play a role. Asking questions about their own health and how their actions affect symptoms leads to raised awareness of a patient's personal circumstances. In turn, this could inspire a desire to take control, self-manage, and reduce exposure to triggers through the use of achievable steps. A PAAP is just one example of how patients can be helped in managing a condition that, in some cases, can be life-threatening.

The cost of asthma to the National Health Service is £1.1 billion, of which over £660 million is spent on prescription drugs. Empowering asthma sufferers to monitor their own condition could lower the chances of attack, and in some case may allow reduced dosage of prescription medicines while maintaining better asthma control. Identification of individual asthma phenotypes and identification of triggers will give every asthma sufferer a deeper understanding of their own asthma, and in the longer-term improve compliance and more appropriate use of inhalers and other asthma medications.

It's important to remember that asthma is a serious condition, from which around three people every day die. Research carried out by Asthma UK has shown that around every 10 seconds, someone in the UK has an asthma attack, and one-in-11 people don't believe that asthma can kill. Evidence from this real-world study shows that too few asthma sufferers have their allergies and other non-allergic triggers identified. We should encourage those who take care of asthma sufferers to ensure that everyone with asthma has a PAAP listing personal triggers identified through careful history-taking and blood tests if required.

ABOUT THE AUTHOR

Shuaib Nasser is a Consultant in Asthma and Allergic Disease at Cambridge University Hospitals NHS Foundation Trust. His work on thunderstorm asthma, drug allergy and asthma deaths has improved patient care and led to a DH-funded national enquiry into asthma deaths. He set up and chaired the British Society for Allergy and Clinical Immunology (BSACI) Standards of Care Committee until 2012 and his efforts led to the publication of National Allergy Guidelines. He was a member of the Resuscitation Council Working Group that published guidelines on the management of anaphylaxis. He sat on the Royal College of Physicians National Review of Asthma Deaths Steering Group and chaired the NICE Drug Allergy Guideline. In 2011, he was awarded the William Frankland BSACI award for outstanding services to allergy. He served as President of BSACI from 2015-to-2018.

STROKE

NO TIME TO LOSE

Strokes don't just happen to older people – one-in-six of us will have a stroke at some point in our lives, and it can strike at any age, with a quarter of strokes occurring in individuals under 65. Andrea Cail, Director, the Stroke Association in Scotland, explores how this treatable and preventable disease requires urgent attention.



Andrea Cail

As a pharmacist, many members of your community will be at risk of, or affected by, stroke. You will know it strikes in an instant, without warning, and it can lead to devastating consequences – it's a leading cause of disability.

In Scotland, approximately 4,000 deaths happen each year as a result of stroke, and there are over 124,000 people in the community living with the effects of stroke and many, many more at risk of the disease.

The good news is that up to 80 per cent of strokes in Scotland could be prevented.

MAIN RISK FACTORS FOR STROKE

The largest number of people who have strokes are aged over 55 and the risk increases with age.

Lifestyle factors, too, play a significant role in increasing stroke risk.

Recognised advice is always to:

- Eat healthily – reduce salt and sugar intake
- Stop smoking
- Take regular exercise
- Reduce alcohol intake

Two of the major risk factors for stroke that can be managed are high blood pressure and atrial fibrillation – an irregular heartbeat. If diagnosed and treated promptly, thousands of strokes could be prevented every year.

HIGH BLOOD PRESSURE

We need more people in communities across Scotland to understand the link between high blood pressure and stroke. High blood pressure is growing in Scotland.

High blood pressure puts a strain on all the blood vessels, including the ones leading to the brain. High blood pressure often has no symptoms, so having it measured is the only way to tell if it is high. Normally, blood pressures will be taken by a GP or a community pharmacist and most people with high blood pressure will need to take medication to reduce it.

Changing lifestyle can also help to bring it down. The Stroke Association's booklet, 'How to Reduce Your Risk of a Stroke – Active Steps Everyone Can Take', is available to read and download for more information.

ATRIAL FIBRILLATION

Atrial fibrillation (AF) is the most common type of irregular heartbeat and can increase the risk of stroke five-fold. Having AF means that the heart may not be pumping as well as it should. As a result, blood clots are more likely to form in the heart, increasing the risk of having a stroke.

AF-related strokes are often the most severe and cause significant complex disability.

Some common symptoms of AF include:

- Palpitations (being aware of your heart beating fast)
- Breathlessness
- Chest pain
- Fatigue

Some people don't have any symptoms and AF is often only diagnosed during a general medical check-up or after a stroke or transient ischaemic attack.

If members of your community suspect their pulse is irregular, they can make an appointment with their GP who will test their pulse and refer their patient for further tests to confirm AF.

To find out more about AF and stroke risk, review or download the Stroke Association's information leaflet on AF by visiting www.stroke.org.uk/finding-support.

TREATING STROKE AS A MEDICAL EMERGENCY

Knowing the signs and symptoms of a stroke is vital to treat suspected stroke as a medical emergency. The FAST test helps people to recognise those signs:

Face: Can the person smile? Has their face fallen on one side?

Arms: Can the person raise both arms and keep them there?

Speech problems: Can the person speak clearly and understand what you say? Is their speech slurred?

Time: If you see any of these three signs, it's time to call 999

The Stroke Association want people to understand that by getting to hospital fast and being diagnosed and treated quickly, their stroke outcome can be significantly better.

To order FAST leaflets, wallets or posters, go onto the Stroke Association's website by visiting www.stroke.org.uk.

TAKING ACTION TO HELP PREVENT STROKE

As a member of the Cross-Party Group on Heart Disease and Stroke, we have been involved in some activities to improve diagnosis, treatment and care of AF and high blood pressure in Scotland. Both reports can be found at www.stroke.org.uk.

TWO INQUIRIES IN THE SCOTTISH PARLIAMENT

- Beating High Blood Pressure: Scotland's Silent Killer
- A Focus on Atrial Fibrillation in Scotland

For more information about the Stroke Association, visit www.stroke.org.uk, email info@stroke.org.uk, or call the stroke helpline on 0303 3033 100. For further stroke information, visit www.nhsinform.scot.



YOUR CHOICE FOR ELDERLY NVAF PATIENTS

LIXIANA[®] can be used across a broad range of elderly patients.¹⁻³ By offering a combination of clinical^{1,2,4} and practical^{3,5} benefits, LIXIANA[®] may help reduce the complexity in managing stroke prevention in your elderly NVAF patients.



KEEPING THE ELDERLY IN MIND

LIXIANA[®] is a once-daily direct oral anticoagulant (DOAC) indicated for:

- Prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA)
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults

LIXIANA[▼] (edoxaban) 60 mg / 30 mg / 15 mg film-coated tablets prescribing information

Refer to the Lixiana Summary of Product Characteristics (SmPC) prior to prescribing

Presentation: 60 mg (yellow) / 30 mg (pink) / 15 mg (orange) edoxaban (as tosilate) film-coated tablets. **Indications:** Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. **Posology and method of administration:** NVAF: Recommended dose is 60 mg edoxaban once daily with or without food. Continue therapy long term. VTE: Recommended dose is 60 mg edoxaban once daily with or without food following initial use of parenteral anticoagulant for at least 5 days. Duration of therapy (at least 3 months) should be based on risk profile of the patient. For NVAF and VTE the recommended dose is 30 mg edoxaban once daily in patients with one or more of the following: moderate or severe renal impairment (creatinine clearance (CrCL) 15 - 50 mL/min); low body weight ≤ 60 kg; concomitant use of the P-glycoprotein (P-gp) inhibitors, ciclosporin, dronedarone, erythromycin, or ketoconazole. The 15 mg dose of edoxaban is not indicated as monotherapy, and should only be used during a switch from edoxaban to VKA in certain patients (see SmPC for full details). Edoxaban can be initiated or continued in patients who may require cardioversion. For transoesophageal echocardiogram guided cardioversion in patients not previously treated with anticoagulants, edoxaban should be started at least 2 hours before cardioversion to ensure adequate anticoagulation. Cardioversion should be performed no later than 12 hours after the dose of edoxaban on the day of the procedure. Confirm prior to cardioversion that the patient has taken edoxaban as prescribed. If a dose of edoxaban is missed, the dose should be taken immediately and then continued once daily on the following day. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Clinically significant active bleeding. Hepatic disease associated with coagulopathy and clinically relevant bleeding risk. Lesion or condition, if considered to be a significant risk for major bleeding including current or recent gastrointestinal (GI) ulceration,

presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities. Uncontrolled severe hypertension. Concomitant treatment with any other anticoagulants e.g. UFH, low molecular weight heparins, heparin derivatives (fondaparinux, etc.), VKA or DOACs except under specific circumstances of switching oral anticoagulant therapy or when UFH is given at doses necessary to maintain an open central venous or arterial catheter. Pregnancy and breast-feeding. **Special warnings and precautions for use:** **Haemorrhagic risk:** Caution in patients with increased risk of bleeding such as elderly on ASA. Discontinue if severe haemorrhage occurs. The anticoagulant effect of edoxaban cannot be reliably monitored with standard laboratory testing. A specific anticoagulant reversal agent for edoxaban is not available. Haemodialysis does not significantly clear edoxaban. **Renal impairment:** CrCl should be monitored at the initiation of edoxaban and afterwards when clinically indicated. Not recommended in patients with end stage renal disease or on dialysis. **Renal function and NVAF:** A trend towards decreasing efficacy with increasing CrCl was observed for edoxaban compared to well-managed warfarin. Edoxaban should only be used in patients with NVAF and high CrCl after a careful benefit risk evaluation. **Hepatic impairment:** Not recommended in severe hepatic impairment. Caution in mild or moderate hepatic impairment. Caution in patients with elevated liver enzymes (ALT/AST $> 2 \times$ ULN) or total bilirubin $\geq 1.5 \times$ ULN. Perform liver function testing prior to initiation and then periodically monitor for treatment beyond 1 year. **Surgery or other interventions:** discontinue edoxaban as soon as possible and preferably at least 24 hours before the procedure. If procedure cannot be delayed, the increased risk of bleeding should be weighed against urgency of the procedure. Restart edoxaban as soon as haemostasis achieved. **Prosthetic heart valves and moderate to severe mitral stenosis:** Not recommended. **Haemodynamically unstable PE patients or patients who require thrombolysis or pulmonary embolectomy:** Not recommended. **Patients with active cancer:** Not recommended in treatment and/or prevention of VTE. **Patients with a history of thrombosis diagnosed with antiphospholipid syndrome:** DOACs including edoxaban are not recommended. **Drug interactions:** Concomitant use of the P-gp inhibitors ciclosporin, dronedarone, erythromycin, or ketoconazole requires edoxaban dose reduction to 30 mg. Edoxaban should

be used with caution with concomitant P-gp inducers (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital, St John's Wort). Concomitant high dose ASA (325 mg) or chronic NSAIDs is not recommended. Concomitant ASA at doses > 100 mg and < 325 mg should be under medical supervision only. Very limited experience with dual antiplatelet therapy or fibrinolytics. Possibility of increased bleeding risk with concomitant SSRIs or SNRIs. **Adverse reactions:** **Common:** anaemia, dizziness, headache, epistaxis, abdominal pain, lower GI haemorrhage, upper GI haemorrhage, oral/pharyngeal haemorrhage, nausea, blood bilirubin increased, gamma GT increased, cutaneous soft tissue haemorrhage, rash, pruritus, macroscopic haematuria/urethral haemorrhage, vaginal haemorrhage, puncture site haemorrhage, liver function test abnormal. **Serious uncommon:** thrombocytopenia, hypersensitivity, intracranial haemorrhage (ICH), intraocular haemorrhage, other haemorrhage, haemoptysis, surgical site haemorrhage. **Serious rare:** anaphylactic reaction, allergic oedema, subarachnoid haemorrhage, pericardial haemorrhage, retroperitoneal haemorrhage, intramuscular haemorrhage (no compartment syndrome), intra-articular haemorrhage, subdural haemorrhage, procedural haemorrhage. **Legal classification:** POM. **Package quantities, marketing authorisation (MA) numbers and basic NHS costs:** 60 mg – 28 tablets – EU/1/15/993/018 – £49.00. 30 mg – 28 tablets – EU/1/15/993/005 – £49.00. 15 mg – 10 tablets – EU/1/15/993/001 – £17.50. **MA holder:** Daiichi Sankyo Europe GmbH, Zielstattstrasse 48, 81379 Munich, Germany.

References: 1. Giuliano RP *et al. N Engl J Med* 2013;369(22):2093–2104; and supplementary appendix. 2. Kato ET *et al. J Am Heart Assoc* 2016;5(5). pii: e003432. 3. LIXIANA[®] Summary of Product Characteristics. 4. Ruff CT *et al. Lancet* 2015;385(9984):2288–95. 5. Steffel J *et al. Eur Heart J* 2018;39:1330–1393.

be used with caution with concomitant P-gp inducers (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital, St John's Wort). Concomitant high dose ASA (325 mg) or chronic NSAIDs is not recommended. Concomitant ASA at doses > 100 mg and < 325 mg should be under medical supervision only. Very limited experience with dual antiplatelet therapy or fibrinolytics. Possibility of increased bleeding risk with concomitant SSRIs or SNRIs. **Adverse reactions:** **Common:** anaemia, dizziness, headache, epistaxis, abdominal pain, lower GI haemorrhage, upper GI haemorrhage, oral/pharyngeal haemorrhage, nausea, blood bilirubin increased, gamma GT increased, cutaneous soft tissue haemorrhage, rash, pruritus, macroscopic haematuria/urethral haemorrhage, vaginal haemorrhage, puncture site haemorrhage, liver function test abnormal. **Serious uncommon:** thrombocytopenia, hypersensitivity, intracranial haemorrhage (ICH), intraocular haemorrhage, other haemorrhage, haemoptysis, surgical site haemorrhage. **Serious rare:** anaphylactic reaction, allergic oedema, subarachnoid haemorrhage, pericardial haemorrhage, retroperitoneal haemorrhage, intramuscular haemorrhage (no compartment syndrome), intra-articular haemorrhage, subdural haemorrhage, procedural haemorrhage. **Legal classification:** POM. **Package quantities, marketing authorisation (MA) numbers and basic NHS costs:** 60 mg – 28 tablets – EU/1/15/993/018 – £49.00. 30 mg – 28 tablets – EU/1/15/993/005 – £49.00. 15 mg – 10 tablets – EU/1/15/993/001 – £17.50. **MA holder:** Daiichi Sankyo Europe GmbH, Zielstattstrasse 48, 81379 Munich, Germany.

Date of preparation of Prescribing Information: May 2019 EDX/19/0141

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Daiichi Sankyo UK Pharmacovigilance on 0800 028 5122, pharmacovigilance@daiichi-sankyo.co.uk

URINARY INCONTINENCE

A SENSE OF URGENCY

Affecting an estimated three-to-six million people across the UK – more than diabetes or asthma – urinary incontinence is a common condition impacting both men and women, yet it's not spoken about as much as it should be. Seeking to end the taboo and help patients shed their shame, The Urology Foundation suggests steps for steering the mental repercussions of urinary incontinence into mainstream conversation.

Whether it's due to the side-effects of surgery, the outcome of pregnancy, or the impact of obesity, urinary incontinence can feel like a life-sentence; inflicting both mental and physical challenges to a person's life.

MENTAL HEALTH AND INCONTINENCE GO HAND-IN-HAND

Research has shown that there is a strong link between urinary incontinence and mental health issues. The anxiety and embarrassment people feel while suffering from urinary incontinence can be really debilitating. Trips away from the home, even if it is a short trip into town, may require a huge amount of planning to know when and where they can access the toilets and monitoring how much fluid they can consume.

Urinary incontinence can even stop previously outgoing individuals from leaving the house because they are scared that they might leak and embarrass themselves. This can lead to depression as sufferers become more and more isolated from friends and family. In addition, a person may feel anger and frustration about the condition and why it's affecting them.

A DIFFERENT QUALITY OF LIFE

While not life-threatening, urinary incontinence threatens the general quality of life. Sufferers may suddenly become inactive, with fear of exercising or continuing with team sports. This can lead to weight gain, which can further exacerbate symptoms which they are already experiencing.

The sex lives of those living with urinary incontinence can also suffer as they try to hide the condition from a partner. In a recent survey conducted by The Urology Foundation (TUF), one-in-two Brits have stopped having sex because of a urology disease.



A FEAR OF BEING AWAY FROM THE TOILET

For Clare, life with an overactive bladder means that her bladder always feels irritated. She can go to the toilet and then, almost immediately after, feels that she must go again.

'I always have to plan ahead of time, always making sure that there is a bathroom wherever I'm going.'

'I've got quite a high-pressure job, and doing something like giving a presentation or sitting in a long meeting is a very stressful situation. It's just not socially acceptable to be getting up and going to the toilet all the time.'

'It can make my life really difficult. I'm an aspiring singer and auditions are a nightmare because I always feel as though I need to use the bathroom.'

Clare continued, 'The same is true of going out to social occasions. I can be sat around a table at a bar with people and everyone will be having a drink and I'll be making sure I hardly take on any liquid, and even then I'll find myself getting up to go to the bathroom and then you start to hear people saying things about you and why you keep getting up. It's horrible.'

'It affects you psychologically – you have to focus harder just to be like everybody else. There's always that one extra hurdle to overcome. It gives you anxiety, it limits your quality of life, and it makes you feel like an anomaly.'

BREAKING THE SILENCE

The impact which suffering in silence can have is far-reaching and impacts on one's mental wellbeing. But speaking up and talking to a GP or a specialist nurse is half the battle.

TUF is working hard to raise awareness of the help available, so that people can live their life well. Encouraging those affected by urinary incontinence to seek medical attention and examine why they might be suffering often goes a long way to resolving some of the problems.

ABOUT TUF

TUF is a UK-wide charity committed to improving the lives of patients with urological conditions by funding critical research and the training of urology professionals for the benefit of the patient. Diseases and cancers of the kidneys, bladder, prostate, and male reproductive organs are becoming more prevalent and devastating the lives of thousands of men, women and children.

TUF is committed to finding better treatments and cures and has invested millions in urology research programmes, as well as providing professional training grants and bespoke education courses. Recently TUF-funded scholars were involved with the UK's first robotic kidney transplants.

This September TUF is running Urology Awareness Month, a campaign dedicated to increasing knowledge and awareness about urological conditions and focussing on prevention, treatment, and management.

Research by the charity suggests that a quarter of UK residents would not seek medical advice for a urological condition because of embarrassment and that 20 per cent of people who are suffering from, or know someone suffering from, a urological condition, feel ashamed.

When their first antimuscarinic has failed,
why not take a different path?




Prescribing another antimuscarinic may be of minimal benefit after the first has failed.¹ So why not choose another route? BETMIGA is in a different class, relaxing the bladder via β_3 -adrenoceptors.² It can be just as effective as an antimuscarinic, but it doesn't have the same side-effect profile.³

BETMIGA is indicated for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.²

Prescribing information: BETMIGA™ (mirabegron)

For full prescribing information, refer to the Summary of Product Characteristics (SPC)

Presentation: BETMIGA prolonged-release tablets containing 25 mg or 50 mg mirabegron.

Indication: Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome.

Posology and administration: The recommended dose is 50 mg orally once daily in adults (including elderly patients). Mirabegron should not be used in paediatrics. A reduced dose of 25 mg once daily is recommended for special populations (please see the full SPC for information on special populations). The tablet should be taken with liquids, swallowed whole and is not to be chewed, divided, or crushed. The tablet may be taken with or without food.

Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SPC. Severe uncontrolled hypertension defined as systolic blood pressure ≥ 180 mm Hg and/or diastolic blood pressure ≥ 110 mm Hg.

Warnings and Precautions: **Renal impairment:** BETMIGA has not been studied in patients with end stage renal disease (GFR < 15 mL/min/1.73 m² or patients requiring haemodialysis) and, therefore, it is not recommended for use in this patient population. Data are limited in patients with severe renal impairment (GFR 15 to 29 mL/min/1.73 m²); based on a pharmacokinetic study (see section 5.2 of the SPC) a dose reduction to 25 mg is recommended in this population. This medicinal product is not recommended for use in patients with severe renal impairment (GFR 15 to 29 mL/min/1.73 m²) concomitantly receiving strong CYP3A inhibitors (see section 4.5 of the SPC). **Hepatic impairment:** BETMIGA has not been studied in patients with severe hepatic impairment (Child-Pugh Class C) and, therefore, it is not recommended for use in this patient

population. This medicinal product is not recommended for use in patients with moderate hepatic impairment (Child-Pugh B) concomitantly receiving strong CYP3A inhibitors (see section 4.5 of the SPC). **Hypertension:** Mirabegron can increase blood pressure. Blood pressure should be measured at baseline and periodically during treatment with mirabegron, especially in hypertensive patients. Data are limited in patients with stage 2 hypertension (systolic blood pressure ≥ 160 mm Hg or diastolic blood pressure ≥ 100 mm Hg). **Patients with congenital or acquired QT prolongation:** BETMIGA, at therapeutic doses, has not demonstrated clinically relevant QT prolongation in clinical studies (see section 5.1 of the SPC). However, since patients with a known history of QT prolongation or patients who are taking medicinal products known to prolong the QT interval were not included in these studies, the effects of mirabegron in these patients is unknown. Caution should be exercised when administering mirabegron in these patients. **Patients with bladder outlet obstruction and patients taking antimuscarinic medicinal products for OAB:** Urinary retention in patients with bladder outlet obstruction (BOO) and in patients taking antimuscarinic medicinal products for the treatment of OAB has been reported in postmarketing experience in patients taking mirabegron. A controlled clinical safety study in patients with BOO did not demonstrate increased urinary retention in patients treated with BETMIGA; however, BETMIGA should be administered with caution to patients with clinically significant BOO. BETMIGA should also be administered with caution to patients taking antimuscarinic medicinal products for the treatment of OAB.

Interactions: Caution is advised if mirabegron is co-administered with medicinal products with a narrow therapeutic index and significantly metabolised by CYP2D6. Caution is also advised if mirabegron is co-administered with CYP2D6 substrates that are individually dose titrated. In patients with mild to moderate renal impairment or mild hepatic impairment, concomitantly receiving strong CYP3A inhibitors, the recommended dose is 25 mg once daily. For patients who are initiating a combination of mirabegron and digoxin (P-gp substrate), the lowest dose for digoxin should be prescribed initially (see the SPC for full

prescribing information). The potential for inhibition of P-gp by mirabegron should be considered when BETMIGA is combined with sensitive P-gp substrates. Increases in mirabegron exposure due to drug-drug interactions may be associated with increases in pulse rate.

Pregnancy and lactation: BETMIGA is not recommended in women of childbearing potential not using contraception. This medicinal product is not recommended during pregnancy. BETMIGA should not be administered during breast-feeding.

Undesirable effects: Summary of the safety profile: The safety of BETMIGA was evaluated in 8433 patients with OAB, of which 5648 received at least one dose of mirabegron in the phase 2/3 clinical program, and 622 patients received BETMIGA for at least 1 year (365 days). In the three 12-week phase 3 double blind, placebo controlled studies, 88% of the patients completed treatment with this medicinal product, and 4% of the patients discontinued due to adverse events. Most adverse reactions were mild to moderate in severity. The most common adverse reactions reported for patients treated with BETMIGA 50 mg during the three 12-week phase 3 double blind, placebo controlled studies are tachycardia and urinary tract infections. The frequency of tachycardia was 1.2% in patients receiving BETMIGA 50 mg. Tachycardia led to discontinuation in 0.1% patients receiving BETMIGA 50 mg. The frequency of urinary tract infections was 2.9% in patients receiving BETMIGA 50 mg. Urinary tract infections led to discontinuation in none of the patients receiving BETMIGA 50 mg. Serious adverse reactions included atrial fibrillation (0.2%). Adverse reactions observed during the 1-year (long term) active controlled (muscarinic antagonist) study were similar in type and severity to those observed in the three 12-week phase 3 double blind, placebo controlled studies. **Adverse reactions:** The following list reflects the adverse reactions observed with mirabegron in the three 12-week phase 3 double blind, placebo controlled studies. Further information available from: Astellas Pharma Ltd., Medical Information: 0800 783 5018. For full prescribing information, please see the Summary of Product Characteristics, which may be found at www.medicines.org.uk

(cannot be established from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. The adverse events are grouped by MedDRA system organ class. **Infections and infestations:** Common: Urinary tract infection, Uncommon: Vaginal infection, Cystitis. **Psychiatric disorders:** Not known (cannot be estimated from the available data): Insomnia*, Confusional state*. **Nervous system disorders:** Common: Headache*, Dizziness*. **Eye disorders:** Rare: Eyelid oedema. **Cardiac disorders:** Common: Tachycardia, Uncommon: Palpitation, Atrial fibrillation. **Vascular disorders:** Very rare: Hypertensive crisis*. **Gastrointestinal disorders:** Common: Nausea*, Constipation*, Diarrhoea*, Uncommon: Dyspepsia, Gastritis, Rare: Lip oedema. **Skin and subcutaneous tissue disorders:** Uncommon: Urticaria, Rash, Rash macular, Rash papular, Pruritus, Rare: Leukocytoclastic vasculitis, Purpura, Angioedema*. **Musculoskeletal and connective tissue disorders:** Uncommon: Joint swelling. **Renal and urinary disorders:** Rare: Urinary retention*. **Reproductive system and breast disorders:** Uncommon: Vulvovaginal pruritus. **Investigations:** Uncommon: Blood pressure increased, GGT increased, AST increased, ALT increased. * signifies adverse reactions observed during post-marketing experience. Prescribers should consult the SPC in relation to other adverse reactions.

Overdose: Treatment for overdose should be symptomatic and supportive. In the event of overdose, pulse rate, blood pressure, and ECG monitoring is recommended.

Basic NHS Cost: BETMIGA 50 mg x 30 = £29, BETMIGA 25 mg x 30 tablets = £29

Legal classification: POM
Marketing Authorisation number(s): EU/1/12/809/001 – 018
Marketing Authorisation Holder: Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, The Netherlands.

Date of Preparation of Prescribing information: June 2019
Job bag number: BET_2019_0023_UK

Further information available from: Astellas Pharma Ltd., Medical Information: 0800 783 5018. For full prescribing information, please see the Summary of Product Characteristics, which may be found at www.medicines.org.uk

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Astellas Pharma Ltd. on 0800 783 5018

PSORIATIC ARTHRITIS

A CALL TO ACTION

Heighten your psoriatic arthritis awareness and hone your approach for supporting patients as Versus Arthritis presents the condition's causes, diagnosis details, and latest research.

As there are many forms of cancer and neurological conditions, there is no single form of arthritis; although 'arthritis' can be a general term people reference when discussing joint pain. The word arthritis is used to describe pain, swelling and stiffness in a joint or joints.

Arthritis isn't a single condition and there are several different types. There can be an overlap between how other conditions present and arthritis. People with a severe form of the dermatological condition psoriasis may also risk developing psoriatic arthritis which affects the joints. Due to how it presents itself, psoriatic arthritis can be mistaken for rheumatoid arthritis, osteoarthritis or gout.

Not everyone who has psoriasis will develop psoriatic arthritis. However, if joint pain becomes a concern within a few years of diagnosis of psoriasis, psoriatic arthritis may be the underlying cause. This is a sign to be aware of but there is no definite pattern to discovering that someone has the condition.

CAUSES

Knowledge of family history is important for patients to be correctly diagnosed. Some people may already be at risk of this type of arthritis because of genetics. Research suggests that an infection possibly acts as a trigger for psoriatic arthritis, but no specific infection has yet been identified. A variety of infections could possibly trigger the condition; for example, bacteria living in patches of psoriasis.

PAIN AND DISCOMFORT FROM JOINT INFLAMMATION

Psoriatic arthritis can affect any one of 78 major joints in the body – although some joints are more likely to be impacted than others.

The effect of inflammation on the immune system is a factor in both psoriasis and psoriatic arthritis. Each condition requires appropriate treatment to alleviate pain and discomfort in the joints.

SIGNS AND SYMPTOMS

People who have symptoms of psoriatic arthritis are referred to a rheumatologist who will make a diagnosis according to the signs and symptoms, which include a red, scaly rash; swollen, stiff and painful joints; swelling of fingers or toes (dactylitis). There may also be a thickening, discoloration and pitting of the fingernails. Pain and swelling at the back of the heel may also be present. People with many forms of arthritis can often experience fatigue.

Lifestyle choices can contribute to the development of psoriatic arthritis. Among these can be smoking, obesity and a lack of regular physical activity.

DIAGNOSIS

Blood tests, such as those for rheumatoid factor and the anti-CCP antibody, can help determine if someone has psoriatic arthritis. People with the condition tend not to have these antibodies in their blood, but people who have rheumatoid arthritis are more likely to test positive for them.

These tests can't confirm beyond doubt whether someone has psoriatic arthritis, but they can help when taking everything else into account. X-rays of your back, hands and feet may help because psoriatic arthritis can affect these parts of the body in a different way to other conditions. Other types of imaging, such as ultrasound scans and magnetic resonance imaging (MRI), may help to confirm the diagnosis.

TREATMENTS

Once a diagnosis has been made, topical treatments like ointments or light therapy may be used to treat psoriasis, while non-steroidal anti-inflammatory drugs (NSAIDs) can relieve pain and stiffness, or disease-modifying anti-rheumatic drugs (DMARDs) may be prescribed. These act on the causes of inflammation and may be prescribed to treat joint inflammation.

UPCOMING RESEARCH TO SUPPORT PATIENTS AND NON-CLINICAL RESEARCH

Versus Arthritis funded research into genetic differences in people with psoriatic arthritis, compared to psoriasis and rheumatoid arthritis.

This work, by the centre for genetics and genomics at the University of Manchester, will help to establish psoriatic arthritis as a condition in its own right. The benefit of these findings could lead to the development of drugs specifically for the condition.

The TIGHT COntrol of Psoriatic Arthritis trial will look at the benefits of early aggressive drug treatment for people with psoriatic arthritis, followed by an increase in drug dosage if initial treatment isn't working. It's hoped that patients treated in this way will require fewer hospital and community-based services than patients receiving the standard care.

Non-clinical studies funded by Versus Arthritis include research at the University of Glasgow into whether the molecule IL-37 can reduce inflammation in psoriatic arthritis and other inflammatory forms of the condition. If so, the molecule can be used to develop new treatments.

LIVING HEALTHIER LIVES WITH PSORIATIC ARTHRITIS

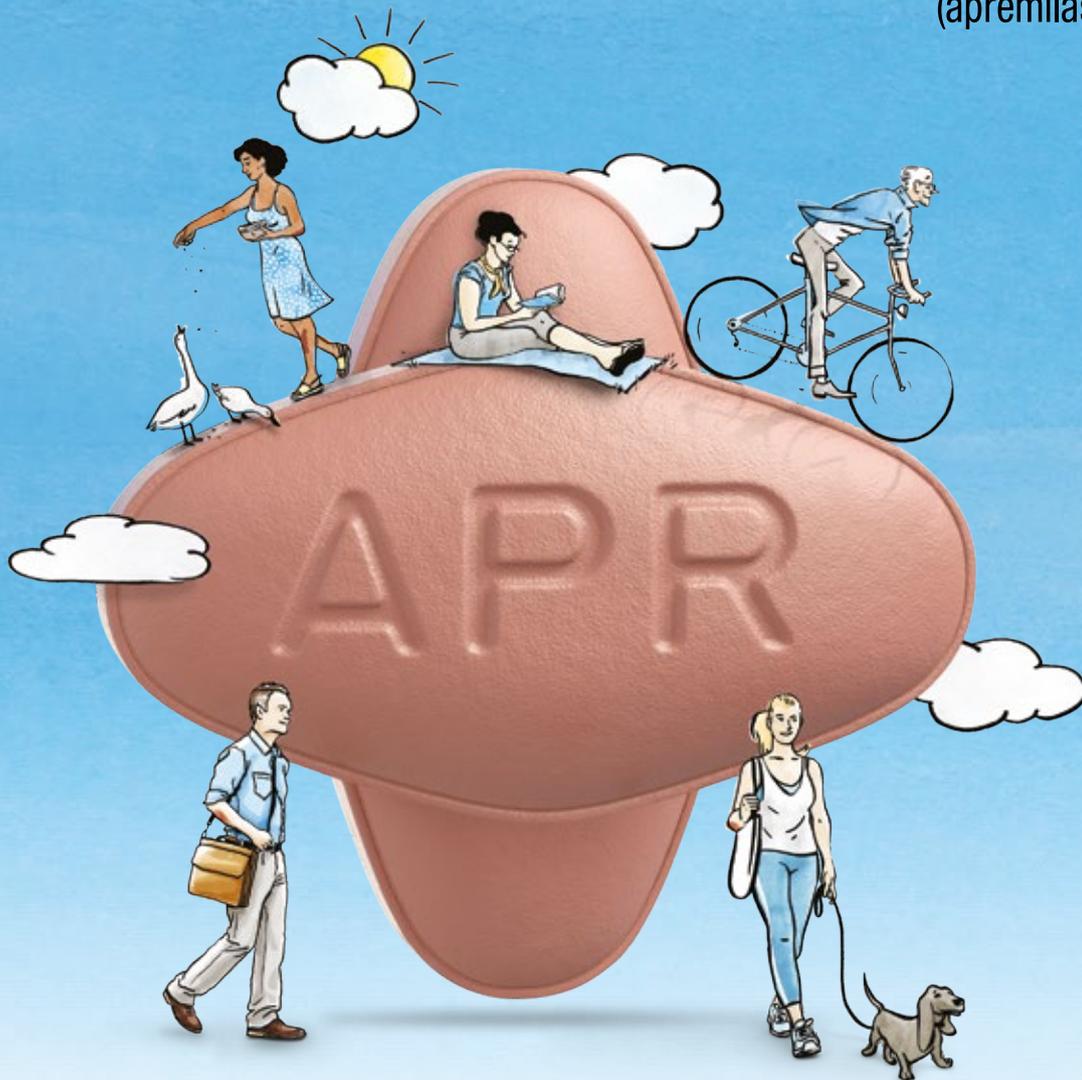
Like all forms of arthritis, psoriatic arthritis is a serious condition and people who are concerned about signs and symptoms should seek advice from their healthcare provider about individual treatment which is right for them. More information about how psoriatic arthritis can affect individuals can be found by visiting www.versusarthritis.org/about-arthritis/conditions/psoriatic-arthritis.

Both patients and healthcare providers can also access practical advice about additional support, including biological therapies, treatment pathways and more information about the latest research.

FURTHER GUIDANCE

More information about Versus Arthritis-funded research and research centres can be found by visiting www.versusarthritis.org/research/our-current-research/our-research-centres.

People who have psoriatic arthritis or who would like more information, help and guidance can contact the Versus Arthritis helpline by calling 0800 5200 520 for free (Monday-to-Friday; 9am-to-8pm).



RESULTS

— the way —

PATIENTS WANT THEM¹⁻⁶

OTEZLA is a targeted oral therapy for your patients with plaque psoriasis or psoriatic arthritis¹

OTEZLA, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy.¹

OTEZLA is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA).¹

Prescribing information can be found overleaf.

August 2019 PM-UK-OTZ-0298

Prescribing Information: OTEZLA® (apremilast) 10mg, 20mg and 30mg film coated-tablets.

Refer to the Summary of Product Characteristics (SPC) before prescribing

Presentation: 10mg, 20mg and 30mg film coated-tablets.

Indications: Psoriatic arthritis; OTEZLA® alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. Psoriasis; OTEZLA® is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA).

Dosage and administration: Treatment with OTEZLA® should be initiated by specialists experienced in the diagnosis and treatment of psoriasis or psoriatic arthritis. The recommended dose of OTEZLA® is 30mg twice daily taken orally, morning and evening, approximately 12 hours apart, with no food restrictions. The film-coated tablets should be swallowed whole. To reduce risk of gastrointestinal symptoms, an initial dose titration is required per the following schedule: Day 1: 10mg in the AM; Day 2: 10mg in the AM and 10 mg in the PM; Day 3: 10mg in the AM and 20mg in the PM; Day 4: 20mg in the AM and 20mg in the PM; Day 5: 20mg in the AM and 30mg in the evening; Day 6 and thereafter: 30mg twice daily. No re-titration is required after initial titration. If patients miss a dose, the next dose should be taken as soon as possible. If it is close to the time for their next dose, the missed dose should not be taken and the next dose should be taken at the regular time. During pivotal trials the greatest improvement was observed within the first 24 weeks of treatment. If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment should be reconsidered. The patient's response to treatment should be evaluated on a regular basis.

Special populations: Elderly patients: No dose adjustment is required for this patient population. Patients with renal impairment: No dose adjustment is needed in patients with mild and moderate renal impairment. The dose of OTEZLA® should be reduced to 30mg once daily in patients with severe renal impairment (creatinine clearance of less than 30mL per minute estimated by the Cockcroft-Gault equation). For initial dose titration in this group, it is recommended that OTEZLA® is titrated using only the AM doses and the evening doses be skipped. Patients with hepatic impairment: No dose adjustment is necessary for patients with hepatic impairment Paediatric population: The safety and efficacy of OTEZLA® in children aged 0 to 17 years have not been established. No data is available.

Contraindications: Hypersensitivity to the active substance(s) or to any of the excipients. OTEZLA® is contraindicated in pregnancy. Pregnancy should be excluded before treatment can be initiated.

Special warnings and precautions: Patients with rare hereditary problems of galactose intolerance, lapp lactase deficiency or

glucose-galactose malabsorption should not take this medicinal product. Severe diarrhoea, nausea, and vomiting associated with the use of Otezla has been reported. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older may be at a higher risk of complications. Discontinuation of treatment may be necessary. OTEZLA® is associated with an increased risk of psychiatric disorders such as insomnia and depression. Instances of suicidal ideation and behaviour, including suicide, have been observed in patients with or without history of depression. The risks and benefits of starting or continuing treatment with OTEZLA® should be carefully assessed if patients report previous or existing psychiatric symptoms or if concomitant treatment with other medicinal products likely to cause psychiatric events is intended. Patients and caregivers should be instructed to notify the prescriber of any changes in behavior or mood and of any suicidal ideation. If patients suffered from new or worsening psychiatric symptoms, or suicidal ideation or suicidal attempt is identified, it is recommended to discontinue treatment with OTEZLA®. OTEZLA® should be dose reduced to 30mg once daily in patients with severe renal impairment. OTEZLA® may cause weight loss. Patients who are underweight at the start of treatment should have their body weight monitored regularly. In the event of unexplained and clinically significant weight loss, these patients should be evaluated by a medical practitioner and discontinuation of treatment should be considered. Women of childbearing potential should use an effective method of contraception to prevent pregnancy during treatment. OTEZLA® should not be used during breast-feeding. No fertility data is available in humans.

Interactions: Co-administration of strong cytochrome P450 3A4 (CYP3A4) enzyme inducer, rifampicin, resulted in a reduction of systemic exposure of OTEZLA®, which may result in a loss of efficacy of OTEZLA®. Therefore, the use of strong CYP3A4 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin and St. John's Wort) with OTEZLA® is not recommended. In clinical studies, OTEZLA® has been administered concomitantly with topical therapy (including corticosteroids, coal tar shampoo and salicylic acid scalp preparations) and UVB phototherapy. There was no clinically meaningful drug-drug interaction between ketoconazole and OTEZLA®, OTEZLA® can be co-administered with a potent CYP3A4 inhibitor such as ketoconazole. There was no pharmacokinetic drug-drug interaction between OTEZLA® and methotrexate in psoriatic arthritis patients. OTEZLA® can be co-administered with methotrexate. There was no pharmacokinetic drug-drug interaction between OTEZLA® and oral contraceptives containing ethinyl estradiol and norgestimate. OTEZLA® can be co-administered with oral contraceptives.

Side effects: The most commonly reported adverse reactions in Phase III clinical studies have been gastrointestinal disorders including diarrhoea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache, and tension headache. The most common adverse reactions leading to discontinuation during the first

16 weeks of treatment were diarrhoea, and nausea. The overall incidence of serious adverse reactions was low and did not indicate any specific system organ involvement. Very commonly reported adverse events are listed as: diarrhoea* and nausea*. Common adverse events are listed as: bronchitis, upper respiratory tract infection, nasopharyngitis*, decreased appetite*, insomnia, depression, migraine*, tension headache*, headache*, cough, vomiting*, dyspepsia, frequent bowel movements, upper abdominal pain*, gastroesophageal reflux disease, back pain*, fatigue. Prescribers should consult the summary of product characteristics in relation to other side-effects. Hypersensitivity* and risk of triggering suicide* have also been reported. *At least one of these was reported as serious or could be considered serious

NHS list price: £265.18 per 14-day titration pack; £550 per pack of 56 tablets (30mg). **Legal category:** POM **Marketing authorisation numbers:** EU/1/14/981/001, EU/1/14/981/002 and EU/1/14/981/003. **Marketing authorisation holder:** Celgene Europe BV, Winthontlaan 6 N, 3526KV Utrecht, Netherlands. **For further information contact:** Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom Tel: +44(0)208 831 8300

Date of preparation: July 2018 **Approval code:** UK-OTZ180094

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to Celgene Drug Safety Tel: 0808 238 9908 Fax: 0844 801 0468

References:

1. OTEZLA (apremilast) 30 mg tablets. Summary of Product Characteristics. Celgene Europe BV.
2. Lebwohl MG, et al. *J Am Acad Dermatol.* 2014;70(5):871-881.
3. Shams K, et al. Poster Presented at: the 98th Annual Meeting of the British Association of Dermatologists (BAD), 3-5 July 2018; Edinburgh, UK (P014).
4. Eliasson L, et al. *Patient Prefer Adherence.* 2017;11:353-362.
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6. Mease P, et al. *Ann Rheum Dis.* 2018;77:201-202. OP0309.

Date of preparation: August 2019
PM-UK-OTZ-0298

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BEING OVERWEIGHT LINKED TO PSORIATIC ARTHRITIS SEVERITY

A new study has emphasised the need for weight loss interventions alongside treatment in patients with psoriatic arthritis.

The research, recently presented at the Annual European Congress of Rheumatology, has demonstrated significant correlation between body mass index and disease severity in psoriatic arthritis.

Psoriatic arthritis is a chronic inflammatory disease that affects the skin and joints, causing pain and disability. The disease often causes swelling of the fingers and toes, mainly because of joint inflammation.

Although psoriatic arthritis has been associated with an enhanced prevalence of obesity and being overweight, few studies have assessed the relationship between weight and the severity of disease in these patients.

‘Our results highlight the impact of obesity and need for lifestyle-directed approaches to manage weight in psoriatic arthritis in parallel to joint and skin-focused treatments,’ explained Dr Stefan Siebert, Clinical Senior Lecturer in Inflammation and Rheumatology, University of Glasgow.

IMAGING TESTS HELP REVEAL HEART RISKS IN PATIENTS WITH PSORIATIC DISEASE

Patients with psoriasis and psoriatic arthritis – psoriatic disease – face increased heart risks, according to a study published in *Arthritis & Rheumatology*, which indicates that ultrasound imaging of the carotid arteries can reveal the extent to which patients’ arteries are clogged, and also indicate their risk of experiencing future cardiovascular events.

The findings suggest that combining such imaging data with clinical and laboratory measures of traditional cardiovascular risk factors could improve risk predictions and identify which patients with psoriatic disease might benefit from more intensive heart-protective therapies.

‘Ultrasound is widely used in rheumatology settings as a point of care to detect joint inflammation. Our study suggests that ultrasound can also be used to identify patients that are at high cardiovascular risk who may be missed by the conventional methods, such as the Framingham risk score,’ said senior author, Lihi Eder, MD, PhD, of the University of Toronto.

‘This will allow early intervention, such as initiation of lipid lowering therapy, which will ultimately lower the risk of developing cardiovascular events.’



PARKINSON'S DISEASE

PARKINSON'S DISEASE: ON THE HORIZON

With the state of Parkinson's research both experiencing change and cultivating much change, Simon R W Stott, Deputy Director of Research at The Cure Parkinson's Trust, and Richard K Wyse, Director of Research and Development at The Cure Parkinson's Trust, highlight a few of the clinical trial programmes seeking to achieve disease modification, and outline some of the issues that those efforts face.



Simon R W Stott

These are the facts about Parkinson's that most readers will be familiar with: it is the second most common neurodegenerative condition after Alzheimer's. In the brain, it is characterised by the aggregation of certain proteins (such as alpha synuclein), and the degeneration of specific populations of neurons – most classically, the dopamine neurons in the substantia nigra. The loss of those particular cells is associated with the appearance of two or three motor features (bradykinesia, rigidity, and a resting tremor), but there are additional debilitating non-motor features that many sufferers also have to live with, including gastrointestinal issues, sleep disruption, and cognitive complaints. Currently there is no cure, and the primary treatments provide only short-term symptomatic relief.

What readers may not be aware of, however, is that Parkinson's is 'the only neurological disorder with increasing age-standardised rates of deaths, prevalence, and disability-adjusted life-years' (www.ncbi.nlm.nih.gov/pubmed/30287051). As the average age of on-set for the condition is over 65 years of age, Parkinson's represents a real public health burden for society at large as the overall population in Western societies continues to age. It will carry significant economic costs for society going forward unless better treatments are discovered.

Tremendous efforts are being made to find disease-modifying therapies for Parkinson's, by groups like The Cure Parkinson's Trust, the Michael J Fox Foundation, and the Silverstein Foundation. These efforts, however, are hampered by several rate limiting steps, such as the need for biomarkers and better methods of assessing / monitoring the condition.

WHAT'S HAPPENING?

Given the characteristic feature of protein aggregation in Parkinson's, many of the ongoing clinical trials are focussed on removing aggregated proteins like alpha synuclein from the brain. One method currently being clinically tested is 'immunotherapy' – boosting the body's immune system via the passive delivery of antibodies designed to target the aggregated form of the protein, or by active inoculation in the form of a vaccine.

Continued onto next page



PARKINSON'S DISEASE

The two leading immunotherapy clinical programmes are both conducting Phase II study at present – the Pasadena study being co-ordinated by Roche and the Spark study conducted by Biogen – both of which will be reporting results in the next few years. One issue with these approaches, however, is the limited amount of antibodies actually accessing the brain (less than two per cent of the injected total), and this has led to a number of biotech firms developing small molecule inhibitors of protein aggregation (such as NPT 088 from Proclara Biosciences), and these too are currently being clinically tested.

Another method of clearing aggregated protein from neurons involves increasing autophagy. One such clinical trial programme, being conducted here in the UK (and supported by The Cure Parkinson's Trust), is repurposing the expectorant Ambroxol for Parkinson's. Pre-clinical research has suggested that this respiratory drug can not only raise levels of a lysosomal enzyme called glucocerebrosidase, but also increase exocytosis. These properties help with the breakdown and disposal of aggregated proteins and accumulated waste. A Phase II clinical trial has recently been conducted, the results of which are shortly to be announced.

A second drug that has evidence of increasing autophagy is the cancer drug Nilotinib which is also being repurposed for Parkinson's in a Phase II clinical trial (also supported by The Cure Parkinson's Trust). Numerous research groups have demonstrated that this c-ABL inhibitor has beneficial effects in models of Parkinson's, and a small Phase I pilot clinical study provided supportive data justifying the larger, ongoing evaluation of this drug.

Mitochondrial dysfunction is a recognised feature of Parkinson's and enhancing the performance of these 'cellular power stations' has been a continuous theme in research into the condition. A number of clinical trials are now evaluating the utility of various compounds for their ability to support and enhance mitochondrial function. One of these trials, being conducted in Sheffield, is the UP study – 'UDCA in Parkinson's'. Ursodeoxycholic acid (or UDCA) is a bile acid that is used in the treatment of gallstones. Previous pre-clinical research has demonstrated that UDCA also improves mitochondrial function in various models of Parkinson's, and this has led to the initiation of the study in Sheffield.

One of the most exciting areas of clinical research for Parkinson's at present, however, is the Exenatide / Bydureon clinical trial programme. This is a frontline treatment for diabetes that is being repurposed for Parkinson's based on evidence that GLP-1 agonists exhibit neuroprotective properties in multiple neurodegenerative models. The Cure Parkinson's Trust has supported this research effort since the pre-clinical stage, and in 2017 the results of a Phase II study indicated a stabilisation of motor features over a 40-week period in 20 people receiving the treatment (compared to the control group who continued to worsen). A major Phase III clinical trial will be initiated in September this year with the goal of testing efficacy of this weekly treatment in a cohort of 200 individuals with Parkinson's.

One final aspect of Parkinson's research that is experiencing significant progress is cell replacement therapy. When a person is diagnosed with Parkinson's, they have lost approximately 60 per cent of their dopamine neurons in the substantia nigra. Replacement of these lost cells is an obvious potential remedy. The Cure Parkinson's Trust has supported a clinical trial of foetal cell transplantation in Cambridge (UK) called Transeuro. It is apparent from that study, however, that cells multiplied and grown in culture have an advantage to the limited supply (and ethical dilemma) of foetal-derived cells. In addition, significant progress has been made in the development of protocols which allow researchers to differentiate bonafide dopamine neurons from embryonic stem cells.

This important progress has given rise to five ongoing clinical trial programmes for stem cell-derived cell transplantation in Parkinson's, with additional interested parties preparing to initiate their own trials.

CHALLENGES AHEAD

All of this clinical activity may sound exciting and raises hopes for disease-modifying therapies in the near future, but these clinical trial programmes face some significant challenges. One of the main issues plaguing clinical trial efforts has been the lack of biomarkers for Parkinson's. Currently, clinical rating scales and brain imaging methods are utilised in efforts to determine disease modification. Inter-rater variability and discrepancies between clinical results and image analysis render these methods rather blunt instruments, and treatment effects need to be large for positive results to be determined, while more subtle effects may be missed completely.

Alternative methods of assessment are being tested though. For example, technology is gradually being utilised in order to provide more objective measures. Tech firms are using artificial intelligence to assess video recordings of clinical assessments, providing more quantitative scores compared to the clinician estimations. In the forthcoming Bydureon Phase III trial, a smart phone app will be used by a large portion of the participants to collect data and monitor their Parkinson's features over the length of the trial, and similar technology is being utilised in the Pasadena immunotherapy trial being conducted by Roche in America.

In addition, novel techniques are being employed to evaluate the biological effect of treatments in trial participants. For example, analysis of brain-derive exosomes provided post hoc evidence of target engagement in the Phase II Bydureon trial, demonstrating that the drug was having a biological effect in the individuals in the treatment group. These exosomes can be collected from a blood sample, providing a simple, not-so invasive measure of biological activity in the brain.

Clinical trial design is also being reconsidered. The Cure Parkinson's Trust is currently supporting the Australian Parkinson's Mission, which involves four drugs being tested in a large five-arm clinical trial. This study design allows multiple treatments to be tested and compared against each other and a single placebo arm, offering a more efficient use of resources. And many new clinical trials are targeting specific subtypes of Parkinson's. For example, the Phase II Ambroxol study mentioned included participants with a specific genetic form of the condition.

Any important feature of all of these clinical trials is the acknowledged requirement for added value in each study. Gone are the days when a clinical trial tested a drug and reported solely on the success or failure of the outcome. Each new trial now collects additional data – from blood samples and DNA, to the testing of new rating scales or assessment tools. And all of this information is feeding back into our understanding of Parkinson's, and improving our ability to conduct these studies.

MANAGING EXPECTATIONS

While all of these developments provide reasons for optimism for the Parkinson's community – both patients and researchers – it is important to manage expectations. Neurodegenerative conditions have had a long and disappointing history of efforts to get new disease-modifying therapies approved for clinical use. And while there has never been so much research activity, the prudent course forward is to focus on what can be learned from each study and how it can be applied to improving our knowledge of Parkinson's and the lives of those living with the condition.

RURAL PHARMACY

GOING THE DISTANCE

An abundance of opportunities awaits the pursuit of a career in community pharmacy in rural areas. Noel Wicks, of Right Medicine Pharmacy, shares his own experience, and how both professional and personal fulfilment can be attained.

With the most recent batch of pharmacy graduates eager to get out there and get practicing for the first time, I started thinking about what a great set of opportunities they have ahead of them here in Scotland.

There's a huge variety of experiences available with different roles and locations to suit everyone's taste. I've been lucky enough to work in lots of different community pharmacies, and even primary and secondary care. In doing so I've managed to find those things I needed to get at work to fill my particular bucket and make pharmacy less a job and more of a passion.

For me it was about working with a good team who could get behind a 'can do' mindset. It was about being able to make a difference as often as possible at the point where it was needed, and I guess, finally, it was about building relationships with the people we were helping.

In nearly 20 years of practicing, some of my best experiences have been in some of our more rural locations across Scotland. In general, there tends to be less provision in remote areas which in turn generates a greater need and more opportunities to be able to make a difference when and where it's needed most.

Often in these smaller communities, people are frequent visitors to the pharmacy and it's great to be able to quickly build relationships,

not just with patients and customers, but also with the other local healthcare providers.

These relationships form an enormous bedrock of opportunity to really put to work all that pharmaceutical knowledge that perhaps we don't have the platform to use as much as we might wish. It also means that the increasing number of services we have available through our pharmacies can be deployed with great effect and perhaps more rewardingly the results are clearly visible.

Of course, rural practice isn't for everyone, and while working in some of Scotland's most amazing settings is nice, there's no denying that it can present a new set of logistical challenges both professionally and personally. However, there can also be enormous benefits from the sort of lifestyle that goes with being in and around these areas because, as one of our pharmacists rightly pointed out, 'Where else could I so easily go and climb a different Munro every weekend?'

I think ultimately in everyone's pursuit of professional and work satisfaction it's important for pharmacists (both new and not-so-new) to find out what fills their bucket at that time in their life. I, for one, thoroughly enjoyed my experiences and the opportunities afforded me in my stints in rural pharmacies and have no doubt there will be more in the future.



Here at Right Medicine Pharmacy we are constantly growing our business and with that we are always looking for amazing new team members to come and join us!

We are confident we have something to suit everyone...

- Whether you are newly qualified or have years of experience and simply looking for a new challenge.
- Whether you want to work on relief & experience a mix of different branches or be based in one branch.
- Whether you are looking for a 12 month fixed term contracts or a permanent vacancy for a bit more stability.

With opportunities from Wick to Dumfries and branches across Scotland we are positive we have the right vacancy for you! Interested? Read on...

We can offer a supported first year to any newly qualified pharmacists by providing a mixture of responsible & second pharmacist cover days, your very own mentor, a supportive Head Office team and a variety of training days both internally and external opportunities as well. This may even suit a return to practise pharmacist.

We offer a very competitive salary, 5 weeks annual leave, company bonus scheme, pension scheme as well as other exciting extras to prove you will never just be a number to us! Relocation packages are also available for many of our vacancies.

Are you interested in joining us? Do you have any questions? Get in touch with Richard on richard@rightmedicinepharmacy.com to discuss the ideal job you are looking for and let us work our magic.

JUVENILE IDIOPATHIC ARTHRITIS

IN THIS DAY AND AGE

One-in-1,000 children and young people are living with juvenile idiopathic arthritis; a type of arthritis that causes widespread pain, stiffness and fatigue. SPR presents clinical and patient views about being diagnosed with arthritis during childhood and adolescence.



Francesca White

FRANCESCA'S STORY

24-year-old Francesca White has lived with juvenile idiopathic arthritis (JIA) for eight years. She has battled severe pain, alongside multiple surgeries and treatments, which at times have taken their toll on her mental wellbeing. The condition has had an impact on Francesca's education and social life, and she has missed out on plans with friends and family due to the pain and fatigue, which has often left her feeling isolated and excluded.

Despite the physical and emotional impact of JIA on Francesca's life, she maintains an extremely positive outlook and always finds the strength to make the most of any situation. She has just finished reading Psychology at the University of Greenwich and looks forward to a career in counselling to help other people experiencing some of the challenges she has overcome.

Speaking to SPR, she offers an insight into her life since being diagnosed.

WHEN DID YOU OR YOUR PARENTS FIRST NOTICE SYMPTOMS OF THE CONDITION? DID YOU IMMEDIATELY KNOW THAT'S WHAT IT WAS?

I was officially diagnosed with JIA when I was just 16 and preparing for my GCSE exams. I'd been feeling poorly for years before this, and doctors suggested that it might be growing pains, stress, and all sorts of other things. I

think maybe because I was so young, no one mentioned arthritis.

Finally, I was diagnosed at the Versus Arthritis Centre for Adolescent Rheumatology at Great Ormond Street Hospital, and within two weeks I was on treatment to start coping with the disease. It was a huge shock and my family and I had to adjust massively.

WHAT HAS YOUR EXPERIENCE OF THE SYMPTOMS OF JIA BEEN LIKE? HOW HAS THE CONDITION IMPACTED ON YOUR LIFE?

When I was first diagnosed, I found it really tough. It was almost like a bereavement. I had lots of ideas about what I wanted to do, but being unwell from a young age meant I had to reconsider things, which was difficult to get my head around.

There have been extended periods of time where I haven't been well enough to go out. After surgeries it has been particularly difficult as recovery can take months and surgeries to my jaw have knocked my confidence, as they make my face look and feel completely different. Generally, pain and discomfort make me feel grumpy and down, which can be hard for friends and family to see.

Starting methotrexate and trying to get through my GCSEs was horrible. While the medication lessened the joint pain, it didn't control the arthritis completely.

When I started studying Biomedical Sciences at University of Westminster, my arthritis was really bad and made it too difficult for me to continue living away from home while studying. I moved back home and applied for an Open University course in Counselling and Psychology, which I've just finished.

I have now applied to study a doctorate in Counselling Psychology. I'm particularly interested in mental health interventions at the stage of diagnosis for people with arthritis. I've learned from my own experiences how important this is.

WERE YOU OR YOUR FAMILY FAMILIAR WITH THIS CONDITION IN CHILDREN PRIOR TO YOUR DIAGNOSIS?

No, I wasn't familiar with children having arthritis. I don't think my mum and dad were familiar with JIA either. My diagnosis came as a real shock to us all even though my dad has psoriatic arthritis. We just never thought it would happen to me so young.

HOW ARE YOU MANAGING YOUR CONDITION NOW?

Most of the pain in my joints is quite well-controlled with medication now, but over the years I've had periods of remission and very severe flare-ups and lots of surgery. As my jaw joint is the worst affected, it can be difficult to eat and speak.

I've been on lots of different medications, including steroids, methotrexate and biologics. I like to research each one to make sure that I fully understand the differences in available drugs and therapies. Information has been important for my family too as it can be daunting changing medication because of side-effects.

WHAT TREATMENT OPTIONS HAVE WORKED BEST FOR YOU?

So far, Humira has been the most effective treatment. I have been on it for around five years now and although I still get flares, especially during stressful times, overall my arthritis has been more controlled.

WHAT SUPPORT CAN YOU RECOMMEND TO OTHER YOUNG PEOPLE AND FAMILIES WITH THE CONDITION?

I've had counselling over the years to come to terms with JIA. This has been, and is still, such an important coping mechanism for me. I can talk to someone about my condition and develop strategies for the harder times. Also, the charity Versus Arthritis have provided support. With their help, I have been able to meet other young people with arthritis. It's

JUVENILE IDIOPATHIC ARTHRITIS

lovely because I can talk to them and they totally get it.

I've found support groups on social media helpful too. On those days when I can't do anything it's nice to feel like I'm not the only one. There are other people my age, or younger than me, who are going through a very similar thing. Of course, I have extremely supportive friends and family. I made it very clear when I went back to university for the second time that I might struggle, and they've been amazing.

DO YOU HAVE ANY ADVICE FOR HOW HEALTHCARE PROFESSIONALS CAN BETTER MANAGE JIA FOR PATIENTS GOING FORWARD?

I would encourage GPs to always consider arthritis as a possible diagnosis for children if they present with any of the symptoms, like I did. I would also ask them to really take the time to fully explain the condition and what is likely to follow for the patient and their families or carers. A diagnosis can be life-changing and the mental impact can be very challenging.

Personally, I found it hard adjusting to a new way of life with a condition I felt I had very little control of. The pain and fatigue can be severe. I've mentioned the effect on mental health – I felt silly for feeling down. I was never really asked how I was coping with the disease; instead questions were focussed specifically on the pain or side-effects of treatments. Mental health awareness is essential, and I think more could be done to support young people and families at every stage of their journey.

THROUGH EXPERT EYES

SPR speaks to Dr Flora McLane, Consultant Paediatric Rheumatologist at Great North Children's Hospital, and spokesperson for charity, Versus Arthritis, to find out more about the condition. Dr McLane offers her expert insight into JIA, including the diagnosis and treatment options.



Dr Flora McLane

WHAT ARE THE DISTINGUISHING FEATURES OF JIA?

JIA usually presents with a combination of stiffness, swelling and / or pain affecting one or more joints. Young people with systemic on-set JIA may be very unwell around the time of diagnosis, but children with other subtypes are usually well in themselves. Fatigue is very common and unusual tiredness may be something that parents and carers may notice first.

For healthcare providers to make a diagnosis of JIA, a series of indications should be present. These are the child having arthritis for more than six weeks with symptoms evident before their 16th birthday. Other conditions that can cause arthritis should be excluded, for example, an infection. It's possible that exposure to infection may trigger the on-set of arthritis in some children.

The cause of JIA is not completely understood. We know that it's an autoimmune disease, indicating that the immune system is overactive. This causes inflammation (arthritis) in one or more joints and sometimes in the eyes, which can occur at any time.

HOW DIFFICULT IS THE DIAGNOSIS PROCESS?

We observed that an arthritis diagnosis can be shocking for the parents and carers of children with JIA. This is usually because they are children and arthritis is considered an older person's condition. That being said, there is often a sense of relief, to finally bottom out what is causing ill health. It's a mix of emotions but we try to be as supportive as possible.

The diagnostic process for JIA can be very involved. If blood tests and x-rays are normal they can help to rule out other causes of chronic arthritis. This is where we would be looking at infection. Joint pain in children is relatively common and most is mechanical in origin. It's not associated with underlying disease. Considering all of this, it can be difficult for families and healthcare providers to distinguish between joint pain that is benign and pain that isn't. As a result, JIA diagnosis can be delayed.

WHAT'S THE LONG-TERM OUTLOOK FOR JIA? WHAT ARE THE MAIN TREATMENT AVENUES?

The aim of treatment is to completely control the arthritis and reduce symptoms to prevent long-term joint or eye damage. Obviously,

all children and young people with JIA should have the opportunity to live as well as possible. The positive news for patients is that long-term outcomes are usually very good for anyone who has access to a full multi-disciplinary team and modern treatment and therapies.

Steroid medications work immediately and are usually used at the on-set of JIA or during a disease flare. It's found that steroid injections to affected joints are often well-tolerated and cause few side-effects, but each patient is an individual and it's important to develop the right treatment plan for them. If four or more joints are affected, steroid injections alone are unlikely to control the disease in the longer-term. This is when systemic immune suppressing medications, such as methotrexate, will usually be commenced. While, it's a very effective drug for arthritis, half of young people will need an additional or alternative medication. Examples of these are biologic medicines, such as etanercept, adalimumab, and tocilizumab which support in managing inflammation.

HOW CAN THE CONDITION IMPACT ON A CHILD'S LIFE?

A diagnosis can be life-changing. Young people and their families typically need support in managing the impact of JIA. Support is really necessary in several areas: physio, occupational therapy, clinical psychology are all essential to ensure that young people maintain good physical and psychosocial health. Life and personal development shouldn't be put on hold because of a diagnosis.

HOW PROGRESSIVE HAS SOCIETY'S UNDERSTANDING OF JIA BEEN?

Although the majority of young people with JIA are open about their illness, many report a persistent lack of understanding by others when it comes to their illness and its symptoms. JIA can be 'invisible' to peers, teachers, and employers. Increasing public awareness of JIA remains a priority, with the aim of better informing families, schools, healthcare professionals and policymakers.

For more information about JIA, or another form of arthritis, visit www.versusarthritis.org.

Learn more about the impact of musculoskeletal conditions using the charity's guidance for healthcare providers www.versusarthritis.org/about-arthritis/healthcare-professionals/musculoskeletal-impact-toolkit.

BACK TO BASICS

The surge in pain-centred studies may be leading to an enlightened sector – but it can also result in overwhelmed sufferers, struggling to understand their symptoms. The Chartered Society of Physiotherapy is therefore helping you to simplify back pain for patients, and dismantle a few false beliefs along the way.

WHAT CAN CAUSE BACK PAIN?

In most cases, it's not possible to identify the exact cause of back pain. It is important to know that any kind of structural damage is rare. While it can be painful and upsetting, this type of back pain usually gets better quickly. It can be managed through advice and remaining active.

Many physical or psychological factors can cause back pain, and often a combination of these are involved.

They could be:

- Physical factors – such as ‘protecting’ the back and avoiding movements, or a simple strain
- Psychological factors – including a fear of damage or not getting better, feeling down or being stressed
- More general health and lifestyle factors – like being tired and rundown, not getting enough good quality sleep, being overweight, or not getting enough physical activity
- Social triggers – such as difficult relationships at work or home, low job satisfaction, or stressful life events, like a family death or illness

Crucially, it's important for the individual to know that all pain is 100 per cent real and never ‘all in their head’, even when factors like stress or mood are involved.

Each of the factors can turn up the volume on their pain and gaining a greater understanding of when that can happen puts the patient in a stronger position to recognise them and learn how to turn down the dial again.

Sometimes there are specific causes for back pain, especially when there is leg pain, pins and needles, or numbness too. This can be caused by irritation or compression of the nerves in the back.

SYMPTOMS TO BE AWARE OF

These symptoms are very rare, but an individual should contact a doctor if they experience any of them:

- Difficulty passing urine or having the sensation to pass water that is not there
- Numbness / tingling in the genitals or buttocks area
- Loss of bladder or bowel control
- Impaired sexual function, such as loss of sensation during intercourse
- Loss of power in their legs

- If they are experiencing pain that runs down the back of both legs
- Feeling unwell with their back pain, such as a fever or significant sweating that wakes them from sleep

COMMUNICATION IS KEY

A quiz has been designed as a tool to assist clinicians in learning what messages can be helpful or unhelpful when communicating with people seeking care for back pain. It also highlights the importance of their communication style.

To access the video, visit www.lowbackpaincommunication.com.

THE MOMENT OF TRUTH

The Chartered Society of Physiotherapy is at hand to bust myths and reinforce what the latest evidence says is best for your patient's back.

Myth One: Moving will make the back pain worse

Truth: People fear twisting and bending but it's essential to keep moving. Gradually increase how much you are doing, and stay on the go

Myth Two: I should avoid exercise, especially weight training

Truth: Back pain shouldn't stop you enjoying exercise or regular activities. In fact, studies found that continuing with these can help you get better sooner – including using weights where appropriate

Myth Three: A scan will show me exactly what is wrong

Truth: Sometimes it will, but most often it won't. Also, even people without back pain have changes in their spine so scans can cause fear that influences behaviour, making the problem worse

Myth Four: Pain equals damage

Truth: This was the established view, but more recent research has changed our thinking. Modern physio takes a holistic approach that helps people understand why they are in pain

For more information, and to see more myths and facts, visit www.csp.org.uk/mythbusters.

MIND YOUR BACK

 Mentholatum

Mind Your Back is a campaign to help prevent and manage back pain by following **5 simple S.T.E.P.S.**

STRETCH

THERAPY

EXERCISE

POSTURE

STRENGTHEN



To find out more and to follow our simple stretch and strengthening videos visit:

www.mindyourbackuk.com



Deep Relief Anti-inflammatory Gel and Deep Relief Joint Pain Gel are medicines for muscular aches and pains. Deep Heat Pain Relief Heat Patches, Deep Freeze Pain Relief Cold Patch and Deep Freeze Pain Relief Glide-on Gel are medical devices. Deep Heat Muscle Massage Roll-on Lotion is non-medical. Always read the label.

SCOTTISH MEDICINES CONSORTIUM

CROSSING THE LINE

With a raft of newly-licensed medicines springing into the sector, the Scottish Medicines Consortium has issued its latest advice – revealing what's been accepted for use in NHS Scotland.

MAY 2019

MEDICINE

Abemaciclib (Vernezios)

Pembrolizumab (Keytruda)

Cariprazine (Reagila)

FOR THE TREATMENT OF...

Advanced or metastatic breast cancer in two different settings

Advanced melanoma (a form of skin cancer)

For the second-line treatment of schizophrenia in adult patients where the symptoms are diagnosed as being 'predominantly negative'

JUNE 2019

MEDICINE

Patisiran (Onpattro)

Brigatinib (Alunbrig)

Durvalumab (Imfinzi)

Nivolumab (Opdivo)

Benralizumab (Fasenra)

FOR THE TREATMENT OF...

Hereditary transthyretin (hATTR) amyloidosis

A rare, advanced form of non-small cell lung cancer in patients who have not responded to another cancer medicine, called crizotinib

The maintenance treatment of locally advanced non-small cell lung cancer

In combination with another medicine, ipilimumab, for the treatment of advanced renal cell carcinoma, a form of kidney cancer

Severe eosinophilic asthma (a type of asthma characterised by an excess of inflammatory cells known as eosinophils) which isn't well-controlled with other treatments

JULY 2019

MEDICINE

Palbociclib (Ibrance)

Daratumumab (Darzalex)

Arsenic trioxide (Trisenox)

FOR THE TREATMENT OF...

In combination with another medicine, fulvestrant, it was accepted following consideration through the Scottish Medicines Consortium's Patient and Clinician Engagement process, which is used for medicines to treat end-of-life and very rare conditions

Multiple myeloma

In combination with another medicine, tretinoin, for the treatment of acute promyelocytic leukaemia



How much could you save with the Zeroderma range?

The Zeroderma range now includes five creams, one ointment, one gel, two bath additives and a barrier cream. All Zeroderma products are gentle on the skin and do not contain the harmful irritant sodium lauryl sulfate (SLS).

Zeroderma products are similar in formulation to around 35% of emollients currently prescribed by Health Boards and offer cost savings of up to 55%, with no compromise on patient care. Around 80% of formularies and prescribing guidelines already include at least one Zeroderma product.

The Zeroderma emollient & barrier cream range is available on prescription.

A CCG who recently started using the Zeroderma range commented:

“Emollient prescribing has been a useful area to address as part of QIPP. The focus has been on optimising patient care by offering emollient products that patients are happy to use. Feedback from GPs has been positive and changes have been simple to implement. Patient care has not been compromised and changes to the product prescribed have been acceptable to most patients.”



Thornton & Ross, Linthwaite,
Huddersfield HD7 5QH
01484 842217
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zeroderma@thorntonross.com

Zeroveen® Cream – a 2-in-1 emollient containing natural oatmeal.

Zeroveen is a non-greasy, silky, 2-in-1 moisturising cream and wash containing natural oatmeal. With proven 24-hour moisturisation¹, Zeroveen has both occlusive and humectant properties, as it contains glycerol to actively draw moisture into the skin. The 500g airless pump dispenser offers less than 2% wastage.

Up to **31%** cost saving per pack



Zerolon® Barrier Cream – helps to prevent irritation from bodily fluids.

Zerolon Barrier Cream moisturises and protects damaged, intact or inflamed skin, and is suitable for use with incontinence pads². Zerolon barrier cream is available in a 28g and 92g tube and only requires pea-sized amounts for application, and is resistant to wash off².

Up to **30%** cost saving per pack



Survey shows the benefits of Zerodouble® Gel

Zerodouble Gel is a highly moisturising, double-action emollient gel. Results from a recent survey with over 300 members of the Psoriasis Association³ showed that 97% liked the feel of Zerodouble Gel, 91% said it was as good as or better than their current emollient and 84% wanted to continue using Zerodouble Gel.

Up to **16%** cost saving per pack



QIPP TOOLKIT

By changing from proprietary emollient & barrier cream brands to the cost-effective Zeroderma range, the NHS could save over £8 million⁴ p.a.

A QIPP & emollients toolkit developed by Medicines Management teams contains everything needed to implement product changes at practice level. To estimate your potential local savings and find out more please visit: qipp.zeroderma.co.uk

For FREE samples for patient evaluation please email: zeroderma@thorntonross.com

1. Study to determine the effect of two moisturisers; data on file. 2. Testing of wash-off resistance, dressing adhesion and absorption; data on file. Thornton and Ross. 2018. 3. Data on file. T&R. 2015. 4. HSCOC, April 2019.

Proud of our working partnerships



Spend time with any member of the Qdem team and you will feel the pride in the partnerships we have developed.

Learning from each other is the key to developing effective partnerships, which are pivotal to the continued success of our mission ' delivering quality medicines with a value proposition to the NHS'.