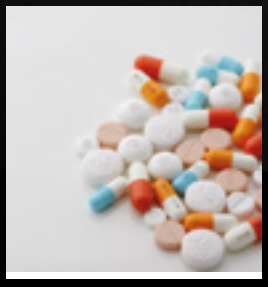
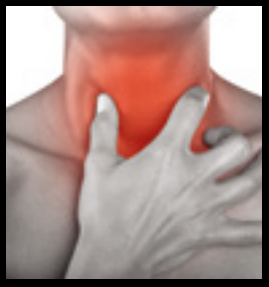
Scottish Pharmacy Review

ISSUE **122** - 2019

GROUP B STREP

A QUEST FOR CLARITY





invita D3®

COLECALCIFEROL

Licensed medicine for vitamin D deficiency

Weekly Invita D3.

Start as you mean to go on…

Week 1 > Week 2 > Week 3 > Week 4 > Week 5 > Week 6 > Week 7

Always prescribe InVita D3 by brand name

Product name and Composition: InVita D3 5,600 IU soft capsules: Each capsule contains colecalciferol (vitamin D3) 5,600 IU (equivalent to 0.14 mg vitamin D3). **InVita D3 50,000 IU soft capsules:** Each capsule contains 50,000 IU colecalciferol (equivalent to 1.25 mg vitamin D3). **InVita D3 50,000 IU oral solution:** 1 ml solution (1 single-dose oral solution) contains 1.25 mg colecalciferol, equivalent to 50,000 IU vitamin D3. **Indications: InVita D3 5,600 IU soft capsules:** The prevention and treatment of vitamin D deficiency in adults and adolescents with an identified risk. In addition to specific osteoporosis treatment of patients who are at risk of vitamin D deficiency, preferably in combination with calcium. **InVita D3 50,000 IU soft capsules, InVita D3 50,000 IU oral solution:** The treatment of vitamin D3 deficiency. **Dosage and administration: InVita D3 5,600 IU soft capsules:** Recommended dose is one capsule per week. Higher doses can be necessary to achieve desirable serum levels of 25-hydroxycolecalciferol (25(OH) D). Maximum 5 capsules per week. Renal impairment: InVita D3 should not be used in patients with severe renal impairment. Paediatric posology: InVita D3 is not recommended in children under 12 years of age. **InVita D3 50,000 IU soft capsules; InVita D3 50,000 IU oral solution:** Adults: Treatment of vitamin D3 deficiency (<25 nmol/l) 50,000 IU/week (1 capsule or 1 single-dose oral solution) for 6-8 weeks, followed by maintenance therapy (1400-2000 IU/day) may be required, such as 1 capsule or 1 single-dose 50,000 IU oral solution per month; follow up 25(OH)D measurements should be made approximately three to four months after initiating maintenance therapy to confirm that the target level has been achieved.) Higher doses and monitoring of serum 25(OH)D may be required in populations at high risk of vitamin D deficiency (including those who are institutionalised or hospitalised, dark skinned, obese, being evaluated for osteoporosis, with limited effective sun exposure due to protective clothing or consistent use of sun screens, using certain concomitant medication e.g. anticonvulsants or glucocorticoids, with malabsorption, including inflammatory bowel disease and coeliac disease and recently treated for vitamin D deficiency, and requiring maintenance therapy). Renal impairment: InVita D3 should not be used in combination with calcium in patients with severe renal impairment. Paediatric posology; pregnancy and breastfeeding: Due to lack of clinical data, InVita D3 is not recommended. **InVita D3 5,600 IU soft capsules, InVita D3 50,000 IU soft capsules**: swallow whole with water. **InVita D3 50,000 IU oral solution:** The single-dose oral solution should be either emptied into the mouth or onto a spoon, and swallowed orally; it can also be taken by mixing with a small amount of cold or lukewarm food/drink immediately prior to use. **Contraindications: InVita D3 5,600 IU soft capsules:** Hypersensitivity to the active substance or to any of the excipients; hypercalcaemia; hypercalciuria; nephrolithiasis; nephrocalcinosis; hypervitaminosis D. **InVita D3 50,000 IU soft capsules, InVita D3 50,000 IU oral solution:** Hypersensitivity to the active substance(s) or to any of the excipients; hypercalcaemia and/or hypercalciuria; nephrolithiasis and/or nephrocalcinosis; serious renal impairment; hypervitaminosis D; pseudohypoparathyroidism as the vitamin D requirement may be reduced due to phases of normal vitamin D sensitivity, involving the risk of prolonged overdose. Better-regulatable vitamin D derivatives are available for this. **InVita D3 50,000 IU soft capsules (only):** pregnancy; children and adolescents (under 18 years of age). **Warnings and precautions: InVita D3 5,600 IU soft capsules:** Use with caution in impaired renal function; monitor effect on calcium and phosphate levels. Consider the risk of soft tissue calcification. In patients with severe renal insufficiency, vitamin D in the form of cholecalciferol is not metabolised normally and other forms of vitamin D should be used. Use with caution in patients with sarcoidosis due to possible increase in vitamin D metabolism; monitor serum and urinary calcium levels in these patients. During long-term treatment, follow serum calcium levels and monitor renal function through serum creatinine measurements, particularly in elderly patients on concomitant treatment with cardiac glycosides or diuretics and in those with a high tendency to calculus formation. In case of hypercalciuria (exceeding 300 mg (7.5 mmol)/24 hours) or signs of impaired renal function, reduce the dose or discontinue treatment. The content of vitamin D (5,600 IU) in InVita D3 should be considered when prescribing other medicinal products containing vitamin D. Additional doses of vitamin D should be taken under close medical supervision; monitor serum calcium levels and urinary calcium excretion frequently. InVita D3 5,600 IU soft capsules contain Allura Red AC (E129) and Sunset Yellow FCF (E110) which may cause allergic reactions. **InVita D3 50,000 IU soft capsules, InVita D3 50,000 IU oral solution:** Use with caution in impaired renal function; monitor effect on calcium and phosphate levels. Consider the risk of soft tissue calcification. Exercise caution in patients receiving treatment for cardiovascular disease as concomitant administration of vitamin D with drugs containing digitalis and other cardiac glycosides may increase risk of digitalis toxicity and arrhythmia; strict medical supervision is needed, with serum calcium concentration and electrocardiographic monitoring if necessary. Use with caution in patients with sarcoidosis due to possible increase in vitamin D metabolism; monitor serum and urinary calcium levels in these patients. Allow for the total dose of vitamin D where patients consume treatments and / or foodstuffs enriched with vitamin D and for the patient's level of sun exposure. Possible risk of renal stones, especially with concomitant calcium supplementation; consider the need for additional calcium supplementation for individual patients. Calcium supplements should be given under close medical supervision. Oral administration of high-dose Vitamin D3 (500,000 IU by single annual bolus) was reported to result in an increased risk of fractures in elderly subjects, with the greatest increase occurring during the first 3 months after dosing. **Undesirable effects:** *Uncommon (>1/1,000, <1/100):* Hypercalcaemia and hypercalciuria. *Rare (>1/10,000, <1/1,000):* pruritus, rash, urticaria. *Not known (cannot be estimated from the available data):* Hypersensitivity reactions such as angio-oedema or laryngeal oedema. **NHS Price:** **InVita D3 5,600 IU soft capsules:** £2.50 per pack of 4 capsules. **InVita D3 50,000 IU soft capsules: £4.95 per pack of 3 capsules. InVita D3 50,000 IU oral solution:** £6.25 per pack of 3 x 1ml ampoules. **Legal Classification:** POM. **MA number: InVita D3 5,600 IU soft capsules:** PL 24837/0077. **InVita D3 50,000 IU soft capsules:** PL 24837/0074. **InVita D3 50,000 IU oral solution:** PL 24837/0076. **Marketing Authorisation Holder:** Consilient Health Limited, 5th Floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland. Further information is available on request from Consilient Health (UK) Ltd, 1 Church Road, Richmond upon Thames, Surrey, TW9 2QE or drugsafety@consilienthealth.com. **Date of preparation of PI:** April 2018 **Job bag number: UK/INV/0418/0117**

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 Consilient Health (UK) Ltd, No. 1 Church Road, Richmond upon Thames, Surrey TW9 2QE UK or drugsafety@consilienthealth.com

Date of preparation:
March 2019
UK/INV/0518/0120g

Consilient Health

SPR
ISSUE 122 – 2019

Medical Communications 2015
www.scothealthcare.com
www.pharmacy-life.co.uk

EDITOR
SARAH NELSON
sarah.nelson@medcom.uk.com

DIRECTOR
CHRIS FLANNAGAN
chris.flannagan@nimedical.info

NATIONAL ACCOUNT MANAGER
NICOLA MCGARVEY
nicola.mcgarvey@nimedical.info

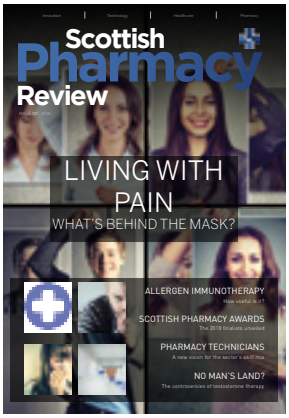
STUDIO MANAGER
DECLAN NUGENT
design@nimedical.info

ACCOUNTS MANAGER
DONNA MARTIN
accounts@nimedical.info

MANAGING DIRECTOR
BRIDGET MCCABE
bridget.mccabe@nimedical.info

IF YOU WISH TO CONTACT US BY TELEPHONE – **02890 999 441**

Subscription: £120 a year
Please note our new address.



To access the previous edition of SPR online, visit www.scothealthcare.com/previous-issue

WELCOME

Sarah Nelson Editor
sarah.nelson@medcom.uk.com

EDITOR'S LETTER

Welcome to the latest edition of Scottish Pharmacy Review!

The churning of all things Christmas may have halted in line with December's end, but the arrival of 2019 has also brought with it a word that seems to greet us upon every turn – ***'next'.***

The fog of political uncertainty – 'What's ***next?'.*** The pressure of self-improvement – 'Which resolution should I work on ***next?'.*** The reluctance to remain in one place – 'Where should I go ***next?'.*** Even my Netflix account urges me to click onto the '***next*** programme' before my episode has concluded; I'm still not 100 per cent sure how Friends ends.

But succumbing to forward-thinking panic is tiring, and we're so busy focussing on the next step, that we're not appreciating the first – which is the most important one of all. So, in this edition of SPR we're taking things back a bit.

This issue coincides with the results of the 2018 Scottish Pharmacy Awards. As wonderful as the proceedings were, we must bear in mind that the first steps paved the way for the bigger picture – from guests, sponsors, judges, and the work conducted by our winners who courageously showcased their efforts during entry. Check out the first half of our victors, and their paths to success (beginning on page 29).

Help patients take the first step in leading a healthier lifestyle – be it through nutritional intake or drinking habits (beginning on page 60), and begin your journey of addressing the challenges in obtaining diagnosis and delivering appropriate care for rare diseases (page 16).

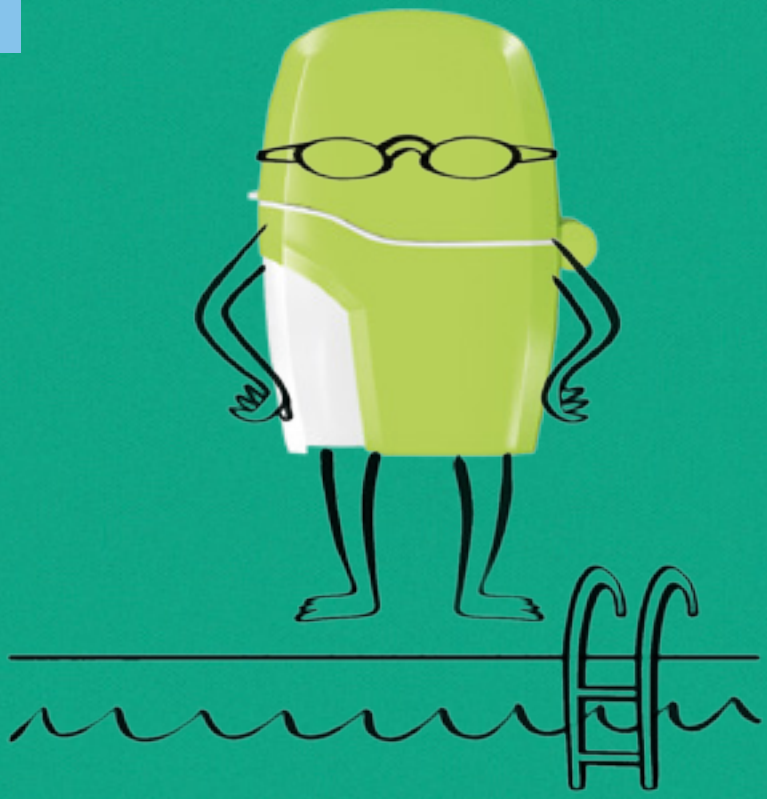
Also in this issue, we explore the profession's duty of candour (page 12), draw attention to the worrying finding that worldwide disability due to back pain has risen by more than 50 per cent since 1990 (page 48), and share the Scottish Medicines Consortium's recent updates (page 11).

That's not all – find out what a day in the life as the Chief Operating Officer for Right Medicine Pharmacy in Scotland entails as Richard Stephenson reflects on his responsibilities (page 14).

Happy reading!

@MEDCOMscot Medical Communications Ltd

TEVA Respiratory



It's not just about tiotropium,

it's about taking a dip in the pool

- 95% of patients felt confident or very confident about using Braltus®*[1]
- **Tiotropium** is a widely accepted LAMA for COPD[2]
- Ergonomic and compact inhaler with a clear capsule for visual confirmation of dose delivery to the patient[3]
- Braltus® Zonda® £25.80 *vs.* Spiriva® HandiHaler® (tiotropium bromide) refill pack £33.50 reduction in NHS spend of £7.70[4,5]

Braltus® tiotropium

For more information about Braltus® please visit **www.braltus.co.uk** and the **Braltus® ChatBot**

*100 patients with COPD who were switched to Braltus®, and had received Braltus® for an average of 16.5 months, were asked "Following instruction and guidance from your healthcare professional, how confident did you feel about using Braltus®?"[1]

Prescribing information

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Braltus® (tiotropium bromide) Inhalation Powder Abbreviated Prescribing Information

Presentation: Delivered dose: 10 mcg of tiotropium per capsule. Each capsule contains 16 mcg of tiotropium bromide, equivalent to 13 mcg of tiotropium. **Indications:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage and administration:** Inhalation use only. Must not be swallowed. Inhalation should be at the same time each day. *Adults:* Inhalation of the contents of one capsule once daily with the Zonda® inhaler. See SmPC for administration and instructions for use. *Children:* Not to be used in children or adolescents <18 years of age. *Elderly:* No special requirements. *Renal Impairment:* Mild: (creatinine clearance >50 ml/min), no special requirements. Moderate to severe: Use only if expected benefit outweighs the potential risk. *Hepatic Impairment:* No special requirements. **Contraindications:** Hypersensitivity to the active ingredient or any excipients. **Precautions and warnings:** Not to be used for the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy. Immediate hypersensitivity reactions may occur. As with other inhalation therapy, paradoxical bronchospasm may occur and treatment should be immediately discontinued. Use with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction; patients with recent myocardial infarction <6 months; unstable or life threatening cardiac arrhythmia; cardiac arrhythmia requiring intervention or a change in drug therapy in the past year; hospitalisation for heart failure (NYHA Class III or IV) within past year. Avoid getting the powder into eyes. The excipient lactose may contain trace amounts of milk proteins which may cause allergic reactions in patients with severe hypersensitivity or allergy to milk protein. **Interactions:** No formal drug interaction studies have been performed. Co-administration with other anticholinergic drugs not recommended. **Pregnancy and lactation:** Not recommended. **Effects on ability to drive and use machines:** No studies on the effects on the ability to drive and use machines have been performed. The occurrence of dizziness, blurred vision, or headache may influence the ability to drive and use machinery. **Adverse reactions:** *Serious:* Hypersensitivity reactions, anaphylactic reaction, bronchospasm, anticholinergic effects (glaucoma, constipation, intestinal obstruction including ileus paralytic as well as urinary retention), atrial fibrillation, supraventricular tachycardia, tachycardia. *Common:* Dry mouth. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** May lead to anticholinergic signs and symptoms. **Price:** £25.80 **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/1870 **Marketing Authorisation Holder:** Teva UK Limited, Brampton Road, Hampden Park, Eastbourne, BN22 9AG, United Kingdom. **Job Code:** UK/MED/18/0138. **Date of Preparation:** April 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 Teva UK Limited on 0207 540 7117 or **medinfo@tevauk.com**

References

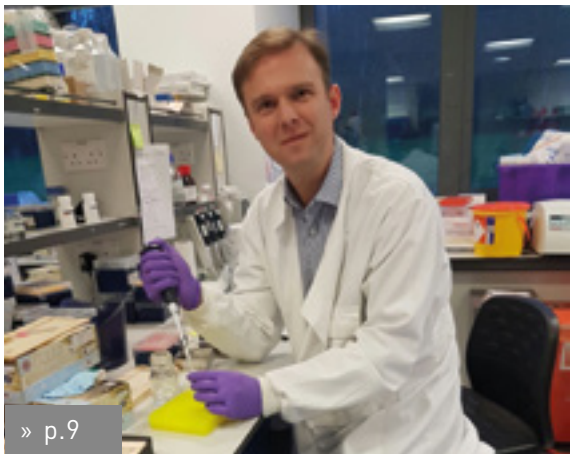
1. Braltus in real life. November 2018, prepared by Branding Science.
2. Karner C et al. Cochrane Database of Systematic Reviews. 2014; 7: 1-120.
3. Teva. Data on file. Teva market testing. 2015.
4. MIMS. Available at: https://www.mims.co.uk/drugs/respiratory-system/asthma-copd/braltus. Last accessed: January 2019.
5. Braltus Prescribing Information, UK/MED/18/0138. April 2018.

Date of preparation: January 2019 Approval code: UK/BRA/18/0018(1)

If you have any questions or wish to request further information, please contact us as follows: email at medinfo@tevauk.com or by post at Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX.

CONTENTS

ISSUE 122 – 2019


» p.9


» p.14


» p.19


» p.24


» p.29

LEPROSY

COULD LEPROSY BE CONFINED TO THE HISTORY BOOKS?

An international development charity has launched its most ambitious appeal yet to equip a hospital to rid Nepal of leprosy.

Head of Programmes for The Leprosy Mission, Siân Arulanantham, has said that leprosy isn't a disease confined to Biblical times – but a 21st Century problem that could be wiped out for good if stigma and ignorance surrounding the ancient disease are tackled, and there is government commitment in leprosy endemic countries to end the disease.

On 27th January The Leprosy Mission launched its Heal Nepal campaign in a bid to finally rid the country of leprosy. Thanks to UK Aid Match, every pound donated to Heal Nepal by 27th April will be doubled by the UK government.

Leprosy is a mildly-infectious disease that attacks the nervous system, leading to a loss of sensation in the hands and feet, and causing the eyelid muscles to stop working. Although leprosy is entirely treatable with a combination of three antibiotics, it too often goes untreated until a person is left with avoidable life-long disabilities, including blindness.

Regrettably prejudice surrounding leprosy sees it remain a stubborn disease to tackle in Nepal, with many people hiding the early symptoms for fear of being cast out of their homes, families, and communities.

Heal Nepal seeks to find, cure, and heal people with leprosy in a bid to rid the country from the ancient disease. It will train government health staff, as well as reaching people with leprosy through outreach teams before they develop permanent disabilities. If already disabled by the disease, care will be provided for months at Anandaban Hospital while their wounds heal or they undergo life-changing surgery.

The Leprosy Mission's Anandaban Hospital in Nepal was thrust into the spotlight in 2015 following the devastating earthquakes of 2015 that killed 9,000 people and destroyed more than a million homes.

Thanks to the amazing generosity of The Leprosy Mission supporters globally, staff from Anandaban Hospital were able to reach out to 18,000 earthquake victims, providing emergency medical care, food, and shelter.

Siân said that this has led to an extraordinary opportunity as, prior to the earthquakes, Anandaban Hospital was a hospital nestled away in the Himalayas that leprosy patients heard about through the grapevine. A place where they would receive first-class clinical care and, crucially, would be welcomed when they had nowhere else to go.

'In the aftermath of the 2015 earthquakes suddenly the hospital hidden away in the mountains became a beacon of light opening its doors to everyone,' explained Siân.

'We witnessed the most extraordinary turn of events. Leprosy patients giving up their beds for earthquake trauma patients and doing everything they can for them.

'This is so extraordinary as leprosy is such a feared and stigmatised disease in Nepal. Many of these leprosy patients wanting to help trauma patients at Anandaban Hospital were from the very same communities that had rejected them.

'Suddenly some of the fear was taken away from leprosy and people started to see it for what it is – a curable disease that, if treated in its early stages, will not lead to life-long disability.

'Thanks to the amazing efforts of the team at Anandaban Hospital there is now a huge opportunity to finally rid Nepal of leprosy and what a tremendous opportunity that is.'

Anandaban Hospital in Nepal was designated a Disaster Response Centre by the government of Nepal in the wake of the 2015 earthquakes as well as leading the world's fight against leprosy. In addition to being the national specialist leprosy referral hospital for Nepal, it is an International Leprosy Training Centre, training doctors and surgeons globally, and a world-class research centre partnering with the best researchers in its field, including those at the London School of Hygiene and Tropical Medicine.

Latest statistics from the World Health Organisation (published August 2018) reveal that there were 3,215 new cases of leprosy diagnosed and treated in Nepal in 2017. The Leprosy Mission, however, believes that this figure is just the tip of the iceberg, with thousands of cases going undiagnosed.

Heal Nepal will equip outreach teams to go into communities to find and diagnose people with leprosy before they develop disabilities.

All donations made to Heal Nepal by 27th April will be matched by the UK government. It costs £24 to find and cure a person from leprosy. So by giving £24, two lives are transformed!

Visit www.healnepal.org.uk or ring 01733 370505 to donate or to find out more.

Anandaban Hospital, Nepal

Matching your donations with UKaid

Leprosy patient, Ram, has new hope following reconstructive surgery at Anandaban Hospital

STIRLING PATIENTS BENEFIT FROM MAJOR CHARITABLE DONATION

A significant donation from a local charity is set to make the lives of rheumatology patients attending Stirling Community Hospital a little easier.

The act of generosity was extended by The Friends of Stirling Community Hospital, which donated almost £65,000 to NHS Forth Valley, with half of the funds being utilised for the purchase of a new ultrasound scanner for the rheumatology department.

The remaining amount will go towards the purchase of a new retinal screening scanner and teaching resources for the diabetic unit, along with a RemPod (a special pop-up display which helps to support reminiscence activities with patients who have dementia).

The new ultrasound scanner was officially presented to local NHS staff by Allan Dewar, Chair of the Friends of Stirling Community Hospital, who said, 'We are very pleased to have been able to purchase this equipment, particularly for Stirling. The Friends have been going for 70 years and over that time have gifted many items to a total of £850,000.'

NHS Forth Valley Chairman, Alex Linkston, shed light on the community's gratitude, remarking, 'This is an extremely generous donation which will make a real difference to local patients. Many people attending the rheumatology department are in pain and anything which can speed up their diagnosis and treatment is to be warmly welcomed.'

Allan Dewar, Chair of the Friends of Stirling Community Hospital (right), is pictured with Rheumatology Consultant, Dr Sara Else, and NHS Forth Valley Chairman, Alex Linkston

CALLS FOR GREATER AWARENESS OF LUNG CANCER RISK IN PEOPLE WITH COPD

Patients with COPD require increased support when understanding and acting on new chest symptoms, a study in the journal Psycho-Oncology has reported.

During this unique study – led by the University of Glasgow and University of Surrey – researchers investigated how the experience of COPD influences how individuals comprehend new or changing chest symptoms, and their decision to seek help from medical professionals.

With 40 people with COPD being interviewed, it was discovered that none of the participants were aware that having the condition put them at increased risk of developing lung cancer. Due to a lack of knowledge and support, participants often attributed chest symptoms to external factors, such as the weather or illness.

Researchers found that some participants didn't seek medical advice following the development of symptoms as they were keen to 'not make a fuss' and believed that poor health was something to be accepted when diagnosed with the condition. A stigma associated with continued smoking was also identified, as participants were found to be reluctant in seeking help, due to their belief that the doctor would blame their symptoms on smoking.

The patients also spoke about barriers in accessing care, which included scheduling appointments outside of usual working hours and difficulties in getting to the GP's surgery when symptoms present themselves.

Dr Katie Robb, Senior Lecturer at the University of Glasgow, warned, 'Healthcare professionals need to do more to educate those with COPD about their increased risk of developing lung cancer and be more vigilant when a patient with the illness presents changing symptoms.'

Highlighting the severity of these findings, and why a shift must occur, Jodie Moffat, Cancer Research UK's Head of Early Diagnosis, said, 'It's vital patients and their doctors stay alert to signs of cancer to ensure that any potential cancer is diagnosed as soon as possible. Symptoms of other diseases can mask cancer signs, so it's important patients know what to look out for. Changes to existing conditions, as well as new symptoms, should be checked out by a GP, and GPs need to be ready to consider cancer as an option.'

SKIN DEEP

Around 120,000 people in the UK have psoriatic arthritis, which, as well as psoriasis, causes inflamed, stiff, and painful joints. Yet against this backdrop of prevalence, many patients are still finding their journey with the condition to be plagued with confusion and both physical and psychological obstacles. To get to the bottom of this, and how the sector can help, SPR presents the clinical and patient views.

PSORIATIC ARTHRITIS: MY STORY

Fuelled by painful flare-ups, the physical symptoms of psoriatic arthritis can be a heavy weight for the patient to bear – however, the mental burden is just as hefty, if not more so.

Despite these forces of resistance, Rebecca North, 30, completed the London Marathon last year, after she was diagnosed with the condition less than two years ago and was left barely able to walk. Rebecca, who has always been a keen runner, was told by doctors that she would never run again. Here, she sheds a light on her psoriatic arthritis experience.

WHEN DID YOU FIRST NOTICE THE TELL-TALE SIGNS OF THE CONDITION? DID YOU IMMEDIATELY KNOW THAT'S WHAT IT WAS?

My first sign of psoriatic arthritis was a swollen toe (dactylitis) on my left foot, although with hindsight I had also suffered from pitted fingernails prior to the dactylitis. I had no idea it could be arthritis. Initially I thought I had stubbed the toe, but when it didn't get better, the pain grew worse and I started limping heavily. I went to see a GP who was unsure what it was. Many GP appointments, two trips to x-ray at A&E, and a few more swollen joints later, and four weeks after the first sign, finally psoriatic arthritis was suggested.

WHAT HAS YOUR EXPERIENCE OF PSORIATIC ARTHRITIS-RELATED SYMPTOMS BEEN LIKE?

My experience of psoriatic arthritis-related symptoms has been both physical and mental. I have dealt with a lot of inflammation, stiffness, fatigue, and extreme pain which I struggled to control for 18 months. I have 'hidden' symptoms, such as three 'hammer toes' that I am awaiting surgery on, and developing psoriasis in my toenails which was rectified by having all 10 permanently removed.

With every new ache and pain my mental health declined as I struggled to cope with the new body my life had given me.

PRIOR TO YOUR DIAGNOSIS, WERE YOU FAMILIAR WITH PSORIATIC ARTHRITIS?

Despite suffering from psoriasis my adult life I wasn't very familiar with psoriatic arthritis. I was vaguely aware from my basic research of psoriasis that it was possible to develop psoriatic arthritis, but I knew nothing more about it. I didn't know what the signs and symptoms were or generally what to look out for. I didn't know of anybody with the condition and it had never been mentioned to me by GPs.

WHAT WAS YOUR ASSESSMENT LIKE?

I was fortunate that my assessment at rheumatology occurred just 16 weeks after my first symptom. On arrival I was asked to describe the symptoms I had been suffering and give a brief medical history.

My joints were examined, and an ultrasound was performed on my toes. From all that I had told the rheumatologist, and from the inflammation that he could see and feel, a positive diagnosis was made. I was taken for blood tests and a chest x-ray, and informed that if all was well with these I would start medication (methotrexate) in a few weeks' time.

WHICH TREATMENT OPTIONS HAVE WORKED BEST FOR YOU?

Biologics have been the best medication for me. Initially I started methotrexate which didn't help my joints, made me permanently run down, and it gave me crippling fatigue. A very brief spell on sulfasalazine followed before my rheumatologist suggested that I try secukinumab, as both my psoriasis and inflammation of the joints had worsened. Just three weeks after I started injecting I could already feel a great improvement. The majority of my psoriasis had cleared, I was less stiff, and my pain levels had lessened. 10 months after I started secukinumab I am currently completely psoriasis-free with no inflammation.

TO WHAT EXTENT HAS PSORIATIC ARTHRITIS SHAPED YOUR LIFE?

Since my diagnosis psoriatic arthritis has shaped my life enormously; I almost feel like a different person to who I was pre-diagnosis. When I am in a flare it impacts on every aspect of my life, from my ability to leave the house to my mental health. Even when I am in good health it is still something that I am always aware of, from keeping on top of appointments and injection dates to being careful not to overdo it and cause myself extra fatigue.

WHAT EVERYDAY CHALLENGES DO YOU EXPERIENCE AND HOW ARE THESE OVERCOME?

One of the biggest everyday challenges I have had to overcome is to stay in employment. The ability to get to work and to stay in work has been difficult. When I have been in a bad flare or particularly run down I have had to take time off to stay at home and rest. I am incredibly thankful to have great colleagues and work for a company which understands my requirements and has allowed me to work flexibly so that I can attend all appointments and work from home when necessary while staying employed.

DO YOU HAVE ANY ADVICE AS TO HOW HEALTHCARE PROFESSIONALS CAN BETTER OPTIMISE THEIR MANAGEMENT OF THE DISEASE FOR PATIENTS GOING FORWARD?

From my experience, if a patient presents themselves with psoriasis then they should be asked if they are having any problems with their joints. So many psoriasis sufferers aren't aware that they might get arthritis and it then takes years to get a proper diagnosis, when early diagnosis is key. In all my years of seeing GPs and a dermatologist I was never once asked any questions about my joints. When I first went to my GPs with my swollen toe, not one of them made the link with my psoriasis despite them being aware of my medical history.

THROUGH EXPERT EYES

Hone your knowledge of psoriatic arthritis, and how it can be appropriately navigated, courtesy of SPR's chat with Paul Emery, a Versus Arthritis Professor of Rheumatology, and Director of Leeds NIHR Biomedical Research Centre, Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds.

Paul Emery

WHAT ARE THE DISTINGUISHING FEATURES OF PSORIATIC ARTHRITIS?

Psoriasis is a disease in which scaly red and white patches develop on the skin. Psoriasis is caused by the body's immune and inflammatory system becoming unregulated and affecting the skin. Some people with psoriasis also develop psoriatic arthritis, when the immune system attacks the joints as well. Like psoriasis, psoriatic arthritis symptoms flare and subside, vary from person-to-person, and even change locations in the same person over time. The diagnosis of psoriatic arthritis is suggested when patients have both psoriasis and arthritis, as about two-thirds of psoriatic arthritis will occur either after or at the same time as psoriasis.

In the presence of psoriasis, and the absence of auto-antibodies (indicating another diagnosis) a diagnosis is made. Some patients are unaware they have psoriasis: involvement of the scalp and nails predisposes to arthritis and may be previously undetected. For patients who don't have psoriasis, having a first-degree relative with psoriasis can also be considered the same importance as having psoriasis yourself, reflecting the fact that inherited factors play an important role. There are several distinct types of psoriatic arthritis, indeed these may be so characteristic that the diagnosis of psoriatic arthritis can be made even in the absence of skin disease.

WHAT CONTRIBUTES TO FLARE-UPS?

Often there is no obvious reason, but known triggers include stress, both psychological and physical. Psoriatic arthritis isn't infectious – people sometimes make the mistake of thinking it is – but it can be precipitated by infections including streptococcal throat infection. Being overweight is also a predisposing factor and there is a link with the 'metabolic syndrome' which includes hypertension, diabetes, gout, and hyperlipidaemia.

IS A MULTIDISCIPLINARY APPROACH BEING CONSISTENTLY EXECUTED FOR PSORIATIC ARTHRITIS?

In an ideal world that would be the case, but in practice, the majority of psoriatic arthritis patients are looked after in primary care, and when referred to secondary care, by a single specialist.

However, it is important that multidisciplinary care is available when required for the complex patient. It's also important to point out that the majority of patients with psoriatic arthritis are well-controlled with straightforward measures and therapy. About one-in-20 patients with psoriatic arthritis has a severe progressive disease.

ARE THERE ANY DEVELOPMENTS WHICH OUR AUDIENCE SHOULD BE IN THE KNOW ABOUT?

There are many different areas of active research. These include the discovery and understanding of molecules mediating disease in skin, joints and entheses (the insertion of tendons / ligaments to bone). This work has led to specific new drugs being developed. Also, patients with psoriasis may have disease of the musculoskeletal system which isn't clinically apparent, but which can be detected by sensitive imaging. Various groups have started treating these patients, aiming to produce better long-term outcomes and perhaps even prevent some of the musculoskeletal disease.

IN TERMS OF THE FUTURE, HOW WOULD YOU LIKE TO SEE RESPONSES TO THE CONDITION PROGRESS?

Unlike rheumatoid arthritis, psoriatic arthritis patients don't get referred as often to secondary care. There is a need to make people more aware that there are effective therapies available. We must also be aware of the multiple morbidities of psoriasis and psoriatic arthritis including depression, so patients get access to appropriate therapy.

For more information, visit www.versusarthritis.org.

NEWS

PRODUCTS FROM THE AMAZON MAY HELP TO TREAT NEGLECTED DISEASES

University of Dundee researchers have been awarded £700,000 to investigate whether bacteria and other natural products found in the Amazon hold the key to formulating new drugs for neglected tropical diseases.

The Dundee team – led by Professor Kevin Read from the university's Wellcome Centre for Anti-Infectives Research – will work with colleagues in Brazil to identify novel drug targets and develop new therapies for visceral leishmaniasis and Chagas' disease.

The Medical Research Council / Newton Fund grant will enable Professor Read's team, alongside the collaborators in Brazil, to explore how small molecules isolated from bacterial symbionts of Amazonian insects can be exploited as potential treatments for these devastating diseases.

'There is a severe lack of robustly validated and exploitable drug targets in the parasites that cause these diseases,' explained Professor Read.

'One way to hopefully address this gap in our knowledge is to identify the target of the more chemically diverse natural product molecules known to be active against the parasites.'

He continued, 'We will be working with a team from the University of São Paulo to utilise their skills and experience of working with natural products from the Amazon region. Here in Dundee we will bring our vast expertise in drug discovery to try and find novel drug targets and deliver new treatments for these two diseases.'

New insights are especially necessary in today's age given that visceral leishmaniasis kills thousands of people every year – with some of the poorest countries in the world severely affected. Chagas' disease is also of considerable concern; affecting around six-to-eight million people in 21 endemic countries across the Americas.

Professor Kevin Read

NEW FUNDING FOR STUDENT PHARMACISTS

The Scottish government is investing in the next generation of pharmacists, with £2.85 million funding for 2018-to-2019, to support the current experiential learning that student pharmacists undertake in community pharmacies and hospitals, and to expand this into primary care, and other venues.

With student pharmacists heading out to experience experiential learning in new settings, such as primary care and NHS 24, this funding will allow them to put their learning from university into practice, which will ultimately result in better patient care.

The scheme, called Scottish Pharmacy Experiential Learning, is being organised in partnership between Robert Gordon University, the University of Strathclyde, NHS Education for Scotland, and other pharmacy stakeholders.

This new funding will allow the development and expansion of existing experiential learning to meet the requirements of pharmacists moving forward. Funding for training providers will help release facilitators to spend dedicated time supporting student pharmacists during experiential learning. Funding for students will cover travel and subsistence, if appropriate depending on the location of the placement, allowing them to experience remote and rural practice.

Commenting on the news, Chief Pharmaceutical Officer, Rose Marie Parr, said, 'This funding will enhance the experiential learning of student pharmacists, making the hands-on experience more fruitful and maximising support to students.

'It is vital that we continue to invest in our pharmacists of the future, so that the use of medicines can be optimised and ensure that patients continue to get the best results from their medicines. I would like to thank the universities and NHS partners for taking forward this exciting initiative.'

ENDOMETRIOSIS: HOLDING OUT HOPE

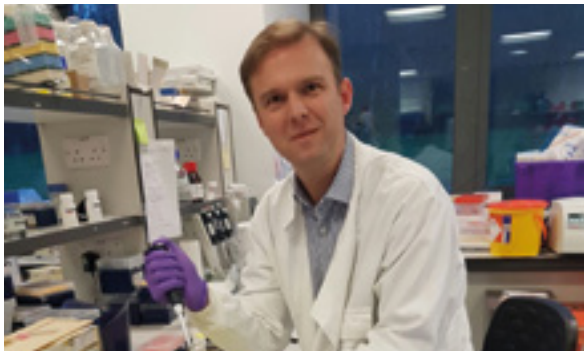
Endometriosis affects one-in-10 women – nearly two million women in the UK. It costs the UK £8.2 billion per year in the NHS budget and lost income, however treatments have barely advanced over the last 50 years. There is an urgent need for new treatments for endometriosis. However, promisingly, Wellbeing of Women – a charity dedicated to improving the health of women and babies – is helping to propel progress forward. Here, they provide a snapshot of some of the innovative research which they're funding, and which we should be aware of.

Endometriosis is a condition when endometrial cells, similar to the lining of the womb, grow outside the uterus, for example, in the pelvis, ovaries, or fallopian tube. Endometriosis is managed surgically or medically, but symptoms recur after surgery in 75 per cent of women and often have unwanted side-effects.

WHAT WE ARE DOING TO CHANGE THIS

There is a real gender bias in research as the disease gets dismissed as 'women's troubles.' Wellbeing of Women is one of the very few funders of research to find a new treatment.

RE-PURPOSING OF ANTI-CANCER DRUGS TO TREAT ENDOMETRIOSIS



Professor Andrew Horne

Our research with world-leader Professor Andrew Horne at the University of Edinburgh has already shown how endometriosis cells behave like cancer cells. Excitingly, his new project testing anti-cancer drugs on endometriosis tissue is showing promising results. This is the first glimmer of hope for a new treatment for the millions of women who have suffered in silence for years. With support from Wellbeing, the Edinburgh team have demonstrated non-clinical 'proof of concept' for a new non-hormonal treatment for endometriosis and have recently secured further funding to perform an exploratory clinical trial of the treatment in women (in collaboration with Ferring) to inform the design of a larger Phase III clinical trial and the development of a local drug delivery system.

UNRAVELLING THE ASSOCIATION BETWEEN ENDOMETRIOSIS AND AUTOIMMUNE DISEASE

Professor Krina Zondervan

Separately, Professor Krina Zondervan, at the University of Oxford, is investigating the link between endometriosis and autoimmune diseases to help identify women at risk and speed up diagnosis.

The team will use the UK Biobank (UKBB), a unique comprehensive national health resource, including data on 273,462 women aged 40-to-69 – of which 5,940 women have been diagnosed with endometriosis, and 14,897 women diagnosed with a variety of autoimmune diseases.

WOMEN'S HEALTH

In addition, they will look at large-scale datasets available on endometriosis and autoimmune diseases worldwide to investigate biological links. Using clinical, diagnostic, and genetic data from the UKBB, they will:

1. Assess the risk of different autoimmune diseases in women with endometriosis compared to carefully matched women without endometriosis
2. Investigate whether links between endometriosis and different autoimmune diseases have a biological basis by testing for shared genetics between the conditions
3. Use these genetic results to identify shared biological pathways and novel therapeutic target opportunities

Professor Zondervan said, 'The most common questions women with endometriosis ask their doctors are: 'What causes my disease?', and 'Does this mean I am at risk of other conditions?', as there have been several reports of women with endometriosis also suffering from chronic autoimmune diseases.

'We will investigate whether the connection between endometriosis and autoimmune diseases and investigate the biology underlying this connection to identify the mechanisms involved.

'This work will increase our understanding of fundamental disease mechanisms and enable us to develop urgently-needed patient-tailored treatments with fewer side-effects – including the potential to re-purpose treatments used in autoimmune diseases, for endometriosis.'

THE ROLE OF ENZYMES

Currently, diagnosis for endometriosis requires surgical intervention and the treatment strategies are contraceptive-based, which has implications for the patient's fertility.

Dr Helen Clarke, Liverpool Women's Hospital / University of Liverpool, is studying endometriosis cells in order to understand how they develop. The aim of the project is to pave a way for new treatments and diagnostics.

'Our preliminary data shows that human endometrial cells express one of the key enzymes identified, MAP4K4,' Dr Clarke said.

This enzyme causes the spread of the ectopic cells beyond the primary location.

'When a patient has cancer, the cells begin to rapidly multiply as normal cellular control mechanisms fail,' Dr Clarke continued.

'As the disease progresses, small deposits of cancer (metastases) can be found elsewhere in the body.'

Research has been able to identify key enzymes that may play a role in enabling cells to migrate and become invasive.

'This has not only the potential to be a target for cancer therapies, but also an effective treatment for endometriosis.'

UNDERSTANDING THE ENDOMETRIUM

In addition, Dr Alison Maclean, Liverpool Women's Hospital, was awarded £17,079 over three months to investigate endometrial cells to help improve the understanding of diseases such as womb cancer and endometriosis.

The endometrium is the inner lining of the womb and is a fascinating organ that has the remarkable capacity to shed its superficial layer each month during menstruation, called the functional layer, and regenerate the lost cells and tissue from the underlying layer, the basal layer. This occurs in response to fluctuating levels of the hormones produced by the ovaries: oestrogen and progesterone. This process is important, as it enables the human endometrium to facilitate a pregnancy.

However, faults can occur during this complex process of self-regeneration. As a result, gynaecological diseases can develop, such as endometrial (womb) cancer, which is now one of the most common gynaecological cancers in the Western world and is increasing in number, and endometriosis, which is a debilitating condition causing severe pain, and in some cases infertility.

This project will aim to use two new techniques to show that different types of epithelial cells exist in the endometrium and will use these techniques to isolate them and enable cell-specific research.

The long-term aim of this will be to identify cell types, which can cause certain diseases, and develop cell specific treatments, to improve the survival rates and quality of life of patients with endometrial diseases.

'I now plan to test the feasibility of using laser capture micro dissection to isolate RNA from EECs from the three aforementioned locations in full-thickness endometrial samples to examine the expression of the hormone metabolizing enzyme genes,' Dr Maclean said.

These samples will then be examined to discover the physical boundaries of EEC subtypes.

Dr Maclean hopes to find methods to identify and characterise EEC sub-populations. She said that this 'will enable us to perform cell-specific research to improve our understanding of diseases such as endometrial cancer and endometriosis.'

ABOUT WELLBEING OF WOMEN

Founded 54 years ago, Wellbeing of Women is one of the only charities finding cures and treatments across the breadth of female reproductive health, including pregnancy and childbirth, fertility, gynaecological cancers, and overlooked areas like endometriosis, polycystic ovary syndrome, and the menopause. Many of the routine tests and treatments that form everyday clinical practice can be traced back to our work, such as the use of ultrasound in pregnancy, and the importance of taking folic acid for the health of the unborn baby. We also funded Professor Henry Kitchener who linked HPV to cervical cancer which led to the HPV vaccination programme in schools, making cervical cancer preventable for the first time.

Only 2.48 per cent of publicly-funded research is dedicated to reproductive health and childbirth which makes our work vital.

For more information, and to find out how you can support Wellbeing of Women's work, visit www.wellbeingofwomen.org.uk.

WELLBEING OF WOMEN

CROSSING THE LINE

Discover the speed and scope of new medicines as SPR rounds up the latest entrants – granted the go-ahead by the Scottish Medicines Consortium – for use in NHS Scotland.

JANUARY 2019

MEDICINE	FOR THE TREATMENT OF...
Pertuzumab (Perjeta)	HER2 positive metastatic breast cancer (cancer that has spread to other parts of the body) or locally recurrent unresectable breast cancer (cancer that has come back locally after treatment and can't be removed by surgery)
Tofacitinib (Xeljanz)	Psoriatic arthritis, a painful and debilitating condition which causes red, scaly patches on the skin and inflammation of the joints
Ertugliflozin (Steglatro)	Type 2 diabetes as part of a package of treatment which includes diet and exercise to improve glycaemic control
Semaglutide (Ozempic)	Treatment of type 2 diabetes alongside a diet and exercise regime

FEBRUARY 2019

MEDICINE	FOR THE TREATMENT OF...
Tisagenlecleucel (Kymriah)	Acute lymphoblastic leukaemia in children and young adults who have not responded to previous treatment or in whom the condition has relapsed
Dabrafenib (Tafinlar)	Used in combination with another medicine, trametinib, for the treatment of stage III melanoma (skin cancer) in patients following surgical removal of the tumour
Tofacitinib citrate (Xeljanz)	Moderately-to-severely active ulcerative colitis, a disease which causes inflammation of the gut
Rivaroxaban (Xarelto)	Used in combination with aspirin in some patients with coronary heart disease, a condition that may lead to heart attacks or strokes

DUTY OF CANDOUR

SORRY SEEMS TO BE THE HARDEST WORD

Apologising to a patient when something has gone wrong can sometimes be daunting, but it is an important ethical duty for healthcare professionals and is the right thing to do. Dr Michael Devlin, Head of Professional Standards at the Medical Defence Union, directs our attention to the profession's duty of candour and how to successfully apologise.

Dr Michael Devlin

According to the General Medical Council (GMC), 'All healthcare professionals have a duty of candour – a professional responsibility to be honest with patients when things go wrong.'

There is also a statutory duty of candour in England and Scotland that requires organisations to tell patients when things have gone wrong that meet certain, defined, thresholds of harm. A candour requirement also exists for certain NHS bodies in Wales, such as NHS hospitals, that are subject to the statutory redress arrangements.

THE REQUIREMENTS OF THE STATUTORY DUTY OF CANDOUR

At its core, a duty of candour is an obligation to tell a patient when something goes wrong and causes them harm.

For the professional, ethical duty is straightforward: it applies wherever something goes wrong and causes harm or distress to the affected patient. But the complexity arises with the statutory arrangements in working out whether the patient safety incident reaches a threshold to trigger the duty. The thresholds vary in England depending on whether the organisation is a 'health service body', such as an NHS hospital, or 'any other registered person', such as a GP practice or independent clinic. The thresholds are slightly differently worded in the Scottish legislation – it can be confusing, but the important point for doctors and other healthcare professionals to take away is always to ensure that they follow their organisation's reporting procedures for patient safety incidents.

To illustrate how complex the threshold can be, instances which can trigger the duty of candour in a GP practice in England include:

- Pain or psychological harm which has or is likely to be present for 28 days
- An increase in the patient's treatment
- Changes to the structure of their body
- Shortening of their life-expectancy
- Impairment of function which has lasted or is likely to last at least 28 days
- The patient requiring further treatment to prevent death or to manage an injury which would lead to one of the above noted outcomes
- Death or a permanent lessening of function, which is defined as 'severe harm'

Bear in mind that as the treating clinician you may be asked to represent the organisation in meetings with the patient and / or their family. It is a good idea to contact your medical defence organisation for advice if you have any questions or concerns about preparing for this.

As well as being familiar with your organisation's duty of candour procedures, including how to report patient safety incidents, you should bear in mind that your professional, ethical obligations will still apply. Consequently, if you become aware of something that went wrong which could result in harm to a patient, you should, in line with GMC guidance, give patients a full and frank explanation, tell them what you propose to do to put it right, and apologise.

If the threshold for triggering the statutory duty of candour has been met, typically the organisation must then take the following steps as soon as reasonably practicable:

- Inform the patient (or their representative) in person
- Give them a full explanation of what is known at the time, including what further enquiries will be carried out
- Offer an apology
- Keep a written record of the notification to the patient
- Provide reasonable support to the patient, e.g. an interpreter to ensure that discussions are understood, or giving emotional support
- Follow notification in person with a written note of the discussion, and keep copies of correspondence

APOLOGISING TO A PATIENT

We are used to apologising in our personal lives and it should be no different in a professional setting. A common misconception is that healthcare professionals may inadvertently admit legal liability for a patient's harm if they apologise, but this is not the case. For example, in England and Wales, section two of the Compensation Act 2006 says, 'An apology, offer of treatment or other redress, shall not of itself amount to an admission of negligence'.

A similar provision exists in Scottish statute. A well-placed genuine apology can often, in the experience of the Medical Defence Union, resolve matters to a patient's satisfaction without the need for a formal complaint process to be invoked.

An apology is more likely to be accepted if it is personal to the patient, relevant to their situation (as opposed to being a generic declaration of regret), and given in a timely manner. As a general rule, an apology is likely to be better received where this is face-to-face and part of a dialogue with the patient.

If you are unsure about the wording of an apology, contact your medical defence organisation for specific advice. There is no magic formulation of words when it comes to saying sorry for what happened: the Medical Defence Union's experience is that the successful apology is sincerely expressed in plain, unambiguous, non-technical language.

WIDER CHOICE, GREATER SAVINGS FROM THE ZERODERMA RANGE

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 new 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 39%, 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.'

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

Up to 31% cost saving per pack

Zeroveen is a non-greasy, silky, 2-in-1 moisturising cream and wash containing natural oatmeal. With proven 24-hour moisturisation[1], 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.

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

Up to 29% cost saving per pack

Zerolon Barrier Cream moisturises and protects damaged, intact or inflamed skin, and is suitable for use with incontinence pads[2]. Zerolon barrier cream is available in a 28g and 92g tube and only requires pea-sized amounts for application, and is resistant to wash off[2].

Survey shows the benefits of Zerodouble® Gel

Up to 16% cost saving per pack

Zerodouble Gel is a highly moisturising, double-action emollient gel. Results from a recent survey with over 300 members of the Psoriasis Association[3] 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.

QIPP TOOLKIT

By changing from proprietary emollient & barrier cream brands to the cost-effective Zeroderma range, the **NHS could save over £9 million[4] 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

Thornton & Ross
STADA GROUP
DERMATOLOGY

Thornton & Ross, Linthwaite, Huddersfield HD7 5QH
01484 842217
www.zeroderma.co.uk
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. HSCIC, November 2018.

ALL IN A DAY'S WORK

As Chief Operating Officer for Right Medicine Pharmacy in Scotland – and with a range of other roles also thrown into the mix – multitasking is an art exercised by Richard Stephenson on a regular basis. SPR checks in with just how he manages to strike this balance, and the worthwhile effects of doing so.

Richard Stephenson

Wow – where do I begin? My current role is Chief Operating Officer for Right Medicine Pharmacy in Scotland. I have been here for nine years now, and we are made up of 27 pharmacies across Scotland. It doesn't end there, though, as I also have two other posts that I am involved in, often on a daily basis. I am a Director for Edinpharm, which is a buying group of 127 pharmacies, and finally I volunteer as a Children's Panel Member and Trainer in the Central Belt.

I know – how do I fit it all in to my daily workload? With great skill it seems. An average day just does not exist in my job, and each day is immensely different, but I will try to give you an insight into a general day for me.

Usually I am on my emails on my phone from 6am onwards and at my laptop by 7am to see what's happening for the day ahead. I like to be prepared and ready for the curve-balls which may turn my day on its head – which is frequent! I can be on my emails and taking calls from early on and through to late at night as, let's face it, everyone is busy, and those queries from our team members are sometimes easier to do out-of-hours.

I am usually in the office for 8am if I'm not out visiting our pharmacies or at meetings, and the day will begin, of course, with a coffee to give me a little boost. I then check on the drivers before they leave for the day and catch up with the HR and operations team on where things are and what is planned for the day ahead. It is a good opportunity to make a plan for the day or week if I am going to be out and about.

I also add in to the mix a look at how our retail side is performing, and samples which have been sent in, offers from suppliers, and ideas from Claire, our Operations Manager, who now does most of the buying for retail.

The rest of the day could consist of external meetings around a wide variety of things, ranging from suppliers to utilities to other services, and that's before we add in any ad hoc work. I am also still very active in the development of our in-store till system (EPOS) and often have tele conferences with the developers to discuss where things are moving.

My Right Medicine Pharmacy workload is extremely varied and covers all business departments and reporting to the Directors on how things are going, and areas we may need to look into. Currently we are acquiring pharmacies and also relocating some of our existing pharmacies, so the demands of visiting recent takeovers to check all is going well and meeting new teams who are coming over to us soon, along with site visits to our relocations, can be tough to juggle. However, another recent change to our structure has seen us introduce a team of Area Support Managers to assist with the increasing workload; and also to support our teams across the group.

I also oversee and have become a lot more involved with Edinpharm which is a buying group in Scotland with around 127 members. My role here as a Director is to meet with suppliers and assist on negotiating deals and ensuring that we are doing our best for the members we serve. I come from a retail background so the transition to doing more of the 'pharmacy stuff' has been a learning curve indeed, but I'm enjoying the new challenge. I usually spend a couple of hours a day working on Edinpharm work, and plan meetings and emails around my Right Medicine Pharmacy role.

And if that wasn't enough, for the past four years I have also been a volunteer for the Children's Hearings System in Scotland which is a unique care and justice system for children and young people. One of its fundamental principles is that children and young people who commit offences, and children and young people who need care and protection, are supported through the same system.

It's one of a number of organisations which work together within the Children's Hearings System to deliver care, protection, and support services to children and young people in Scotland. Other organisations that work within the Children's Hearings System include social work, the police, education, and the Scottish Children's Reporter Administration.

The Children's Hearings System exists to ensure the safety and wellbeing of vulnerable children and young people. It does this through a decision-making lay tribunal called a children's hearing made up of members of the Children's Panel.

I generally undertake this role for one half day per month and I am often on-call for emergency hearings which may come up last minute too. I also train new panel members and existing panel members, which is generally on a Saturday, or an evening through the week, so it avoids taking up too much of my day job time. This role is an extremely rewarding part of my life and I am honoured to assist in making a difference to the young people of Scotland who require our assistance.

My day usually comes to a close around 6pm – meetings depending – and I can then focus on my diploma in Management and Leadership that I am currently working on via distance learning. Keeping my skills up-to-date is important, and the course has been demanding and slower than I would like, but I am determined to complete this during 2019, and already I have seen my skills and leadership improve from the work completed to date.

Community pharmacy is a really exciting place to be just now, and as services are increased and rolled out we need to be ahead of the changes by ensuring that our pharmacies are in good shape for this. I am extremely lucky to have a team of over 230 people across the group who are dedicated to the community they serve.

I am one of those people who loves what they do, but it's the people around me that makes this continue to be the case.

RARE DISEASES

IT'S TIME WE PAID ATTENTION TO THE ZEBRA IN THE ROOM

MEET HANNAH*

Hannah is a funny, bubbly, and dedicated medical student based in Manchester. Alongside her studies and numerous hobbies, she lives with neutrophilic panniculitis – a very rare auto-inflammatory condition that causes large painful nodules to form under her skin. The condition is also associated with extreme weight loss, fatigue, general malaise, and joint and muscle pain.

Despite these symptoms leaving Hannah completely disabled and housebound, it took her 10 long months to reach a diagnosis. She was passed from doctor-to-doctor, with many not believing that she was experiencing the symptoms she described, and given many wrong diagnoses.

Unfortunately, because it is so rare, there is no treatment for neutrophilic panniculitis. Hannah's condition is kept under control through a combination of immunosuppressant medication and steroids, but this can lead to severe infections.

In the four years following her diagnosis, she has been hospitalised with urinary sepsis, disseminated shingles, haemorrhagic cystitis, Influenza A, and pneumonia, to name just a few. These illnesses mean that Hannah frequently has to put her whole life on hold.

Hannah has come to know her body – and the early signs of upcoming infection – well. Yet she still comes up against doctors who are unwilling to accept her own assessments. This is understandably very frustrating: Hannah is left feeling that her doctors do not trust her despite her shortest hospital stays being when they are receptive to her knowledge.

Hannah's experience is far from an isolated case and her story is echoed across the rare disease community. Patients commonly feel as though they have to fight the healthcare system as well as their diseases, with physical, mental, and social knock-on consequences. Rare and unusual diseases can present huge challenges to doctors, but doctors must listen closely to the patients sat opposite them if they are to ensure their best care and treatment.

**Details of this story, including the name, have been changed to protect the identity of the person at its focus.*

With the rise of genomics and personalised medicine, treating people according to their specific needs is set to become more common. The impact of this shift will be no greater than in rare diseases, where 80 per cent of the 7,000 conditions are genetic, but only 400 have a licensed treatment. However, to make meaningful differences in patients' lives, this shift must be coupled with a more co-operative outlook among frontline healthcare professionals. Libbie Read, from Findacure, explores how you can become rare-savvy and build more productive relationships with rare patients.

Libbie Read

WHAT ARE RARE DISEASES?

Rare diseases are defined in Europe as conditions that affect fewer than one-in-2,000 patients. Chances are that you will have come across rare patients in your clinics: while individually rare, collectively these 7,000 diseases are estimated to affect one-in-17 people – or 3.5 million people in the UK. They include more common rare diseases, such as Duchenne muscular dystrophy and cystic fibrosis, down to the ultra-rare and even unique.

While rare diseases are diverse in terms of their symptoms and physical manifestations, they share challenges in obtaining diagnosis and getting access to appropriate care, support, and treatment.

THE RARE REALITY

A 2016 survey by Rare Disease UK (RDUK) found that the average rare disease patient consults with five doctors, receives three misdiagnoses, and waits four years before receiving their final diagnosis. In fact, one-in-10 patients surveyed had seen more than 10 doctors before getting a final diagnosis. Those with a positive diagnosis experience count themselves as 'lucky.'

This so-called 'diagnostic odyssey' can have a huge impact on the physical and mental health of patients. RDUK reported that a worrying number of respondents had difficulties convincing friends, family members, employers, and healthcare professionals that their unusual symptoms were real. It is common for patients to be accused of being a 'hypochondriac' or even diagnosed with psychiatric illness. Consequently, many rare patients become socially withdrawn and isolated.

Once a diagnosis has been reached, most patients are not able to access a treatment. There are only 400 licensed medicinal products in Europe for the 7,000 rare diseases. Playing trial-and-error with off-label therapies is an option, but this depends on their doctor's willingness to experiment with prescriptions that can have limited success.

On top of this, patients' care is rarely co-ordinated. Rare diseases regularly affect multiple systems of the body, meaning that patients can end up consulting multiple professionals from different hospitals in different cities.

Information is often not shared between health services and advice can conflict: some patients liken tracking and organising their health information to a part-time job. Travel can be burdensome too: according to RDUK, the average rare disease patient attends at least three clinics every quarter, travelling one-to-two hours for each.

Living with a rare disease is exhausting and isolating. Two-thirds of respondents said that their condition or caring responsibilities affect their ability to hold paid employment, and half said that it affects their education. Doctors and the wider scientific community have a large role to play in improving this situation, but you can't do it alone: you must work with patients, who are by nature experts in their conditions, if you are to achieve a meaningful difference.

WORK IN PARTNERSHIP WITH PATIENTS

Credit: Findacure and Barbara Asboth Photography

Doctors can't be expected to identify the majority of rare conditions; there are far too many to learn in an already jam-packed medical education. However, the traditional mantra, 'When you hear the sound of hooves, think of horses, not zebras' which is often taught at medical school is dismissive, top-down, and outdated. It can cause healthcare professionals to narrow their minds when confronted with something unusual.

Being open to the possibility of rarity – the zebras in the room – and working in co-operation with patients through diagnosis, and in accessing appropriate care and treatment, is crucial if you are to ensure the best for those in your care.

Here are some small steps you can take to help:

EXPERT PATIENTS: LISTEN AND LEARN

One of the biggest frustrations we hear from patients is that their doctors do not listen to them. Those affected by rare diseases have often conducted a high level of personal research into their conditions, and, given that they are faced with the symptoms on a daily basis, they have a lot of information that they can offer their doctor.

Our advice would be to do your research, but don't be afraid of saying that you don't know the answer and that you're willing to be taught. In particular:

- If you are new to the patient, believe that they have a rare disease and get curious about it. Ask them about their history, what their normal symptoms are, and how it affects their lives. This will help to build a positive and trusting relationship, but will also mean that you are ready to respond in times of relapse, deterioration, or unusual symptoms
- Research different treatment options and be flexible with the treatment plan. Listen to the patient's preferences for treatment, be willing to try new options, and record the outcomes
- Help the patient / parent share the outcomes of your appointments with the other healthcare professionals they regularly see, and support them if they are trying to co-ordinate their appointments
- If there is a treatment that patients are not able to access for financial reasons, support their fight through compassionate use, and other access schemes

WORK WITH PATIENT GROUPS

Patient groups are organisations that support patients and families affected by a particular condition or group of conditions. Their aims and priorities are highly varied: some focus on raising awareness of rare conditions among healthcare professionals and the public, others directly support patients and families, and ensure that they get the social benefits which they are entitled to, and others drive scientific and medical research forward.

In rare conditions, patient groups are incredibly powerful entities – they build geographically dispersed communities, break down isolation, and provide patients with hope. There is a lot you can do to support their goals in your medical capacity:

- Join their medical advisory boards
- Help them write health literature
- Allow them to forward questions seeking medical advice from their online forums
- Help them develop referral pathways or medical guidelines
- Help them collect data – e.g. by inputting to a registry or natural history study
- Contribute to outgoing communication about research and clinical trials

You can also help patients that come into your clinics research which support groups are out there. If you can't find one on the web, try Facebook and Twitter – some are very basic but are still vital sources of support.

CONTINUE YOUR PROFESSIONAL DEVELOPMENT

Some patient groups and specialist centres have developed disease-specific CPD-accredited courses or conferences that you can attend to become more rare aware. For instance, the AKU Society have developed a free e-learning module for the rare disease, alkaptonuria. You could also look at specialising your own career in a rare disease or set of rare diseases to reduce the travelling time for local patients.

CONNECT PATIENT ADVOCATES TO FINDACURE

If you know any rare patients who want to start their own patient groups, refer them to Findacure for support. Our training workshops and mentoring programmes help them grow their patient group, raise awareness of their condition, get research ready, and provide support to patients and families – all for free!

To find out more, visit www.findacure.org.uk/patient-group-training.

For more ideas about how you can become rare-savvy, you can read a selection of fantastic essays by medical students on the website and get involved with other organisations, such as Medics4RareDiseases, Rare Revolution Magazine, and Rare Disease UK.

NEWS

ENHANCED RESEARCH REPORTING METHOD TO IMPROVE PATIENT CARE

Patients could benefit from improved care and outcomes as a result of new research guidance developed as part of a University of Stirling-led study.

Experts have advanced an approach that enables the effective collation and analysis of qualitative studies – such as information garnered from patient interviews and focus groups. The study has led to the creation of the first ever tailored reporting guidance for the methodology, known as meta-ethnography, which will give researchers and healthcare bosses greater confidence in the findings of qualitative studies and, ultimately, aid the enhancement of patient care and services.

Dr Emma France, of the Faculty of Health Sciences and Sport and the Nursing, Midwifery and Allied Health Professions Research Unit, led the study, published in four journals.

'To create high-quality, patient-focussed health services, we need to consider why and how they work – and people's experiences of using them,' Dr France explained.

'Information about people's experiences of health services and care should play a major role in improving NHS services, but individual studies of this kind are often seen as anecdotal, so rarely influence decision-making.

'Pulling together evidence from many existing qualitative studies, including those using patient interviews or focus groups, can shed light on important factors, such as why patients or health professionals behave in a certain way, or what it's like to experience an illness.'

The new guidance contains 19 specific reporting criteria, supported by detailed explanatory notes – and includes recommendations on all aspects of meta-ethnography conduct and reporting, from selecting studies, to analysing data.

Free to use, the material will predominately be aimed at researchers, journal editors, and academics who review research articles to guide how meta-ethnographies should be reported.

Dr Emma France

MATERNITY AND NEONATAL CARE ON PATH TO IMPROVEMENT

New mums and their babies will receive additional support through a range of measures to transform maternity and neonatal services across Scotland, backed by a £12 million investment.

The new model for neonatal care will be tested in four sites to ensure that babies requiring the most specialist care receive the best start possible, as well as a range of initiatives to offer mums and other family members the support which they need.

All expectant mums will attain care from a primary midwife, alongside a small team, for their whole maternity journey, and support will be on hand to help parents with babies in neonatal units to provide as much day-to-day care for their new-born as possible.

Health Secretary, Jeane Freeman, visited Crosshouse Hospital in NHS Ayrshire & Arran, which will be one of the four units partaking in the testing of the new neonatal care model. By summer, babies from Crosshouse Hospital needing the most specialist care will be treated at the Royal Hospital for Children, before returning to their local neonatal unit. The new model will also be tested between the Edinburgh Royal Infirmary and Victoria Hospital in Kirkcaldy later this year.

The Health Secretary explained, 'These steps to transform our maternity services will ensure mums, babies, and other family members are all supported from pregnancy to birth and after.

'To achieve this, we are looking at community maternity services right through to the care for the most premature babies, where we know outcomes are improved when they are in a unit with a higher throughput of cases and where support services, such as surgery, are nearby.

'We are committed to providing all mums, babies, and their families with the highest quality of care according to their needs, backed by this investment of £12 million.'

Professor Hazel Borland, NHS Ayrshire & Arran Nurse Director, further stated, 'We are delighted to welcome the Cabinet Secretary to Ayrshire Maternity Unit to hear first-hand about the fantastic work which is happening here to implement the Best Start: The Five-Year Forward Plan for Maternity and Neonatal Care in Scotland.'

SPOTLIGHT ON: NUTRITION AND CANCER

For patients, their ensuing cancer diagnosis journey is dotted with an array of lifestyle changes – and their dietary habits require particular focus. Be it during the treatment process itself, or to help reduce the disease's chances of recurrence, it's vital that the individual's body is being nourished with the necessary nutrients. Advice is at hand courtesy of Dietitian and Nutritionist, Andrea Davis, from Cancer Nutrition, who overviews how, and why, inadequate intake must be avoided.

Andrea Davis

Cancer is a disease that occurs when abnormal cells grow beyond their usual boundaries that can then invade adjoining parts of the body and spread to other organs. There are more than 200 different types of cancer (1), with it being the second leading cause of death globally, accounting for 9.6 million deaths in 2018, and this number is increasing. (2) Many people may be surprised to learn that one-in-two people in the UK will be diagnosed with cancer at some point in their lives. However, 50 per cent of people affected by cancer now survive for 10 years or longer. (1)

Nutrition plays a vital role in preventing the development of cancer in the first place, but also during cancer treatment and reducing the risk of cancer recurrence afterwards. It is estimated that a third of the most common cancers could be prevented by:

- Eating a healthy diet
- Increasing the physical activity we do
- Maintaining a healthy weight

Giving up smoking is the most important lifestyle change which someone can make to reduce their risk of cancer, then maintaining a healthy weight. The World Cancer Research Fund UK (WCRF UK) has produced 10 recommendations on dietary changes that people can make to reduce their risk of developing cancer. This is in addition to avoiding smoking and excess sun.

Cancer survivors can also follow this advice to reduce the risk of recurrence and other chronic health conditions, such as diabetes or heart disease.

Further practical advice is available from the WCRF UK website by visiting www.wcrf-uk.org.

Continued onto next page

CANCER

It is important to eat well and have a good nutritional intake during cancer treatment also. Good nutrition helps to improve tolerance to treatment, helps to maintain weight, muscle function and energy level, and aids recovery and the body's ability to fight infections.

Malnutrition is defined as a 'deficiency of nutrients such as energy, protein, vitamins, or minerals which causes measurable adverse effects on body composition, function, or clinical outcome.' (3)

Cancer patients may be malnourished at diagnosis or become malnourished as a result of the disease process and its treatment. In general, around 60 per cent of people affected by cancer are malnourished. (4) Its prevalence increases further in those with cancer of the gastrointestinal tract where around 80-to-85 per cent of people with pancreatic cancer, 80 per cent with oesophageal cancer, and 72 per cent with head and neck cancer are malnourished. (5, 6, 7) This is due to increased difficulties with eating, swallowing, digesting, and absorbing food due to the location of the tumour.

The side-effects of cancer treatment can also worsen these nutritional problems. Approximately 65 per cent of patients with cancer experience some nutritional problems, and up to 90 per cent of patients with advanced cancer suffer from anorexia.

Other common side-effects of treatment, resulting in a reduced food intake and worse nutritional status, include:

- Constipation – 14 per cent
- Vomiting – 11 per cent
- Diarrhoea – 14 per cent
- Swallowing difficulties – nine per cent
- Smells – seven per cent
- Mouth sores – one per cent
- No appetite – 38 per cent
- Early satiety – 27 per cent
- Pain – 23 per cent
- Taste change – 20 per cent
- Nausea – 19 per cent
- Dry mouth – 17 per cent

(8)

Unfortunately, cancer-related weight loss can't be simply defined as malnutrition.

It's been stated that, 'Cancer cachexia is a multi-factorial syndrome defined by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment. The pathophysiology is characterised by a negative protein and energy balance driven by a variable combination of reduced food intake and abnormal metabolism.' (9)

When a patient develops cancer cachexia, they have an abnormal metabolism due to an elevated resting metabolic rate, insulin resistance, lipolysis, and proteolysis which aggravates weight loss further and is provoked by systemic inflammation and catabolic factors. These may be host or tumour-derived. (8) Weight loss, impaired physical performance, and systemic inflammation in cancer patients are all independently associated with a poorer prognosis, increased toxicity to cancer treatments, and a reduced quality of life. (10, 11) In advanced cachexia, it is no longer possible to prevent weight loss due to very advanced or rapidly progressive cancer which is unresponsive to cancer treatment. At this stage, the aim is to minimise further weight loss, and the burden and risks of artificial nutritional support will likely outweigh any potential benefit. A multimodal approach focussing on symptom control, appetite stimulation, and nutritional counselling is best to manage this.

Oncology specialist dietitians work closely with other members of the multidisciplinary team to provide evidence-based, expert advice to cancer patients on how they can optimise their nutritional wellbeing and quality of life. We provide nutritional counselling to patients and their families / carers at any stage of their cancer treatment and rehabilitation. This includes providing practical information on foods to choose, portion sizes, and meal patterns which is tailored to the person's treatment and symptoms.

This leaflet from the WCRF UK provides practical tips on how to eat well and manage side-effects of cancer treatment: www.wcrf-uk.org/sites/default/files/Eat-well-during-cancer.pdf.

We also advise on when artificial nutrition, such as oral nutritional supplement drinks, enteral nutrition, or parenteral nutrition is appropriate to meet a patient's nutritional goal. Sometimes the prophylactic placement of feeding tubes will be arranged before cancer treatment starts if significant side-effects are expected which will impact on the person's ability to eat and drink sufficiently. Ideally, every cancer patient should be undergoing regular nutritional screening (for example, using the Malnutrition Universal Screening Tool) and referred to an oncology dietitian when they are at risk of malnutrition for advice and support to ensure that they can tolerate their cancer treatment as well as possible.

For more information, contact Andrea Davis at Cancer Nutrition via the details below:
Address: 519b Old York Road, London, SW18 1TF
Email: andrea@cancernutrition.co.uk
Website: www.cancernutrition.co.uk

CANCER NUTRITION
ANDREA DIETITIAN

REFERENCES

1. Cancer Research UK (https://www.cancerresearchuk.org/about-cancer/what-is-cancer)
2. World Health Organisation 2018 (http://www.who.int/en/news-room/fact-sheets/detail/cancer)
3. NICE Guidance: Nutrition Support in Adults 2006. Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition. CG 32.
4. Bozzetti F, Migliavacca S, Scotti A, Bonalumi MG et al (1982) Impact of cancer type, site, stage and treatment on the nutritional status of patients. Ann Surg 196:170–179
5. Ronga I, Gallucci F, Riccardi F, Uomo G. Anorexia-cachexia syndrome in pancreatic cancer: recent advances and new pharmacological approach. Adv Med Sci, 2014;1 1-6
6. Larrea J , Vega S , Martínez T , Torrent JM , Vega V , Núñez V (1992). The nutritional status and immunological situation of cancer patients. Nutricion Hospitalaria. 7(3):178-184
7. Goodwin W.J., Jr., Byers P.M. Nutritional management of the head and neck cancer patient. Med Clin North Am. 1993;77:597–610
8. Jann Arends, Patrick Bachmann, Vickie Baracos, Nicole Barthelemy, Hartmut Bertz, Federico Bozzetti, Ken Fearon, Elisabeth Hütterer, Elizabeth Isenring, Stein Kaasa, et al. ESPEN guidelines on nutrition in cancer patients. Clin Nutr. 2016 Aug 6 Published online 2016 Aug 6. doi: 10.1016/j.clnu.2016.07.015
9. Fearon KC, Voss AC, Hustead DS; Cancer Cachexia Study Group. Definition of cancer cachexia: effect of weight loss, reduced food intake, and systemic inflammation on functional status and prognosis. Am J Clin Nutr. 2006;83:1345-1350
10. Dewys WD, Begg C, Lavin PT, Band PR, Bennett JM, Bertino JR, et al. Prognostic effect of weight loss prior to chemotherapy in cancer patients. Eastern cooperative oncology group. Am J Med 1980;69:491e7
11. Jang RW, Caraiscos VB, Swami N, Banerjee S, Mak E, Kaya E, et al. Simple prognostic model for patients with advanced cancer based on performance status. J Oncol Pract 2014;10:e335e41

PHARMACIST SUPPORT ANNOUNCES NEW CHIEF EXECUTIVE

Pharmacist Support – the profession's independent charity – has announced the appointment of Danielle Hunt as its new Chief Executive.

Danielle had previously taken up the post of Operations Director at the national environmental charity, Keep Britain Tidy, during which she played a central role in leading it from its origins as mainly government-funded, to an entirely self-funded independent organisation, in addition to helping to raise millions through fundraising and service contracts.

Speaking of Danielle's appointment, Steve Lutener, newly-appointed Chair of the Pharmacist Support Trustee Board, commented, 'We are delighted to welcome Danielle to Pharmacist Support. The charity has undergone a period of significant growth over the past 10 years and Danielle's experience will ensure that the profession's independent charity continues to move forward with confidence. She has proven leadership qualities and service development expertise which will prove invaluable in the future.'

Discussing her new career pathway, Danielle said, 'I'm incredibly excited to be joining Pharmacist Support – leading the charity through its next phase of development. The charity has achieved a huge amount in the last 10 years, and this work has never been so important. I look forward to working with the staff, volunteers, the board of trustees, and others in the sector to develop the organisation and ensure we continue to support pharmacists and their families in the best way possible.'

Danielle Hunt

Steve Lutener

INCREASE IN MENTAL HEALTH WORKFORCE

The number of people able to access mental health support is now burgeoning, sparked by the announcement that 100 additional mental health workers in key settings have been recruited across Scotland as of January 2019. This puts the workforce on-track to reach 800 additional staff by 2022.

The figures are outlined in the latest quarterly progress report, which provides an update on the Scottish government's commitment to increase the number of mental health workers. This surge widens access to dedicated support in key settings, including A&Es, GP practices, police station custody suites, and prisons.

Hot on the heels of the news, Minister for Mental Health, Clare Haughey, stated, 'It's hugely encouraging that we are on-track to recruit 800 dedicated mental health staff by 2022, in line with the plans set out in our mental health strategy. I can speak from experience when I say a career helping support the mental health of people in need of care can be hugely rewarding.

'We are seeing an increasing demand for mental health support across Scotland in a variety of settings and I want to ensure we can provide the best possible care.

'Through our 10-year Mental Health Strategy we are committed to ensuring people get the right help at the right time, free from stigma, and where mental ill health is treated with the same commitment as physical ailments.'

Clare continued, 'I welcome the progress we have made so far, with 39-out-of-40 actions in our strategy either complete or underway. But I'm determined to go further. We must ensure our services reflect these changing needs and recruitment of over 100 additional mental health workers is a promising step.'

BEFORE YOU KNOW IT

A shocking report is blazing a new trail for Group B Strep medical care – and how it must be better honed to prevent the tragedy currently flooding the lives of far too many families throughout the region. According to the findings, newborn babies are needlessly dying or being left with potentially life-changing disabilities because the NHS is failing to prevent or treat infection caused by Group B Strep at birth, which kills one baby in the UK each week. Things must change. But how?

WHAT IS GROUP B STREP?

Group B Strep is a bacterium carried by many adults, commonly in the gut or in the vagina. Carriage is not an infection or illness, rarely causes any symptoms, and doesn't need to be treated. Carriage should therefore be regarded as 'normal'.

Group B Strep is the most common cause of life-threatening infection in newborn babies in the UK – and is carried by approximately 25 per cent of pregnant women without symptoms or side-effects. Many times, the first time that a significant proportion of parents hear of it is when their baby is sick in hospital with meningitis, sepsis, or pneumonia. Despite its potential severity, new and expectant mothers are often not informed about Group B Strep as part of routine care, which the Group B Strep Support charity is working to change. On average in the UK, two babies a day develop Group B Strep infection. Although most make a full recovery, every week one baby will die, and another will survive with life-changing disabilities.

REPORT REVEALS WORRISOME RISKS

A new report, The Cost of Group B Strep Infection, by the Group B Strep Support charity, looked at 32 legal cases of potential or admitted clinical negligence against the NHS, where a Group B Strep infection was suspected or confirmed. It found that, in nearly two-thirds of cases (62.5 per cent), a breach of duty of care by the NHS was responsible for the injury. The most common reasons for a breach were a negligent failure to give preventative antibiotics in line with clinical guidelines, or a negligent failure to spot the significance of emerging signs of infection. Signs missed in the babies included: the inability to feed or poor feeding; more than 10 per cent loss of weight following birth; and grunting and respiratory problems.

Shockingly, these cases, alone, cost the NHS nearly £40 million in compensation, with additional ongoing cases from the six law firms surveyed estimated to cost a further £10 million if successful.

According to maternity charity, Baby Lifeline's, new Mind the Gap report, which was published towards the end of last year, the NHS currently faces claims of £2.1 billion on maternity-related clinical negligence cases (2017-to-2018 figures), compared with the £1.9 billion per year that is spent on delivering babies.

TURNING WORLDS UPSIDE-DOWN

In the 32 cases studied, the three top reasons given for taking legal action were: dissatisfaction with the hospital's investigation or handling of their complaint; clinical failings around the time of birth or issues emerging later (e.g. the child not meeting developmental milestones); and the need for financial support for the continuing care of a child. Tragically, two mothers wanted answers to their questions because they felt responsible for the Group B Strep infection that had had a life-changing effect on their child.

Helen Richardson and Adam Rudd's daughter, Martha, suffered severe brain damage during her birth, after doctors at Royal Surrey County Hospital failed to diagnose devastating Group B Strep meningitis at birth. As a result, Martha, now nine years of age, has cerebral palsy, severe brain damage, and requires around-the-clock care. She is a life-limited child.

Just one day after Martha was born on 16th December 2008, Helen and Adam were told that their little girl had contracted Group B Strep meningitis during birth. Martha was so desperately ill that she was placed in an induced coma and spent the following two months in an incubator in hospital.

In November 2016 the High Court approved a structured seven figure multimillion pound settlement which will provide Martha with the care she needs for the rest of her life. This followed the Royal Surrey County Hospital NHS Foundation Trust admitting liability for Martha's injuries.

'Martha's illness turned our world upside-down,' said Helen Richardson.

GROUP B STREP

'She can be a very happy and content child who enjoys her life as much as she can, but this has destroyed her life and ours as a family.'

'Adam has had to give up his work to care for Martha and I work one day a week when Martha's health allows. Some people wrongly think compensation is a windfall, but it is not. It ensures Martha is able to access the support and care needed for her, for as long as she lives. We will continue to worry about her every day that she lives and we cry for the person she will never be,' continued Helen Richardson.

RECOMMENDED AREAS OF ACTION

The Group B Strep Support charity has said that the survey highlights the need for the NHS to improve the prevention, recognition, and treatment of Group B Strep in babies and, as a result, reduce related clinical negligence claims.

Its recommendations from the report are that:

- All NHS trusts should follow national guidelines on Group B Strep from the Royal College of Obstetricians and Gynaecologists and offer better training to staff involved in maternity and newborn care on preventing, spotting, and treating Group B Strep infection
- The NHS should review and improve its complaints and internal investigations processes by involving parents earlier and throughout the investigation.

The charity has produced an information leaflet, After your Baby's Group B Strep Infection, which provides guidance for those affected by Group B Strep infection.

TESTING FOR GROUP B STREP CARRIAGE

- Pregnant women can take a simple, safe test for Group B Strep between 35 and 37 weeks.
- The most effective test for Group B Strep is an enriched culture medium test (ECM test) and is available from several home-testing services and private clinics
- Although at present the NHS does not routinely test all pregnant women for Group B Strep carriage, in late 2017 the Royal College of Obstetricians and Gynaecologists updated their guidance and recommended that women who tested positive in their previous pregnancy should be offered testing specifically for Group B Strep, using the ECM test, in their next pregnancy. As a result, the ECM test is increasingly becoming available in NHS hospitals intravenous

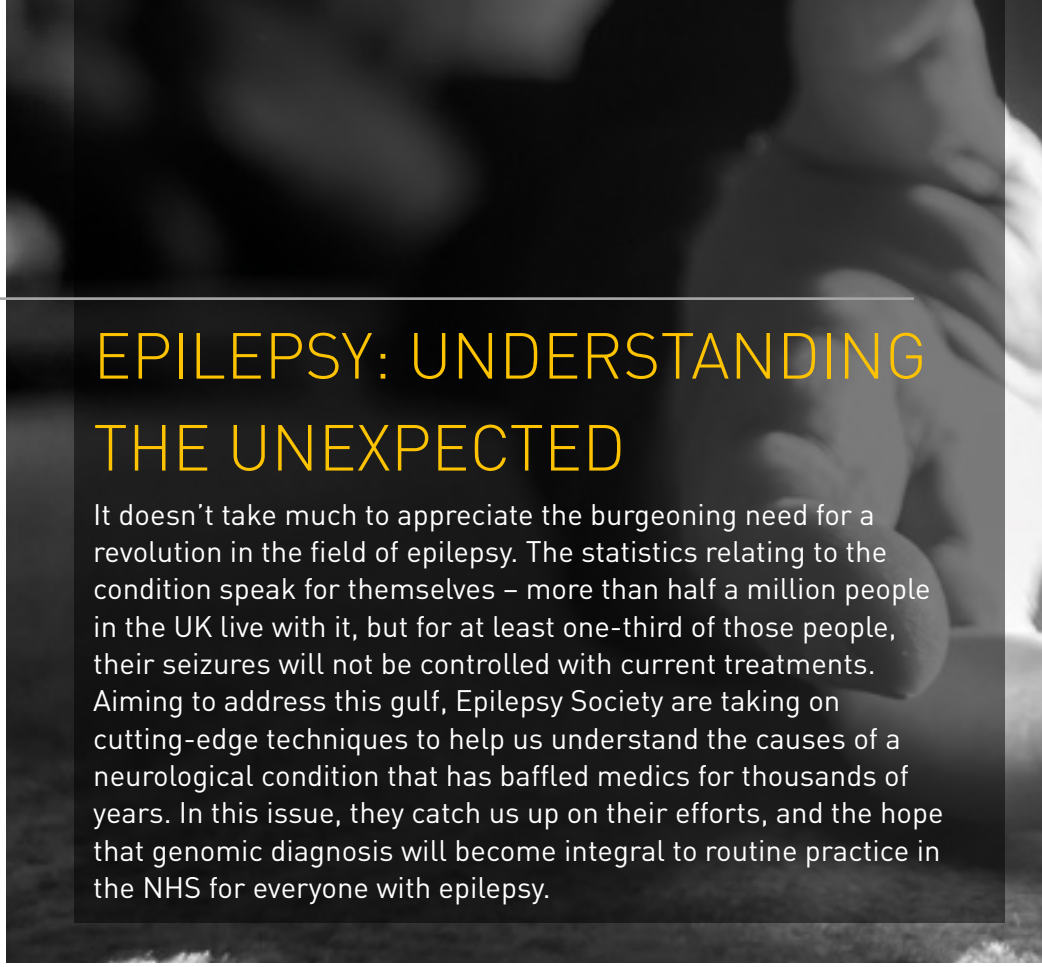
PREVENTATIVE MEDICINE IN LABOUR

- Most Group B Strep infections in newborn babies could be prevented by identifying carriers during pregnancy and offering them antibiotics during labour
- Giving women antibiotics (usually penicillin) in labour reduces the risk of a baby developing a Group B Strep infection by up to 90 per cent

KEY GROUP B STREP FACTS

- Group B Strep causes a range of serious infections, including sepsis, pneumonia, and meningitis – it's the most common cause of severe infection in newborn babies and of meningitis in babies under three months of age
- If left untreated, a Group B Strep infection can kill a newborn baby within hours
- On average, two babies each day in the UK develop a Group B Strep infection and each week, one baby dies from Group B Strep, and another is left with a life-changing disability
- Most Group B Strep infections in newborn babies can be prevented by testing during pregnancy and providing intravenous antibiotics during labour to women whose test results are positive.
- The UK doesn't routinely test for Group B Strep, unlike America, Canada, Germany, France, and Spain
- Even Bangladesh, Iran, Lithuania and Trinidad and Tobago routinely test pregnant women for Group B Strep
- The test would cost the NHS just £11, and costs from £35 privately

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



EPILEPSY: UNDERSTANDING THE UNEXPECTED

It doesn't take much to appreciate the burgeoning need for a revolution in the field of epilepsy. The statistics relating to the condition speak for themselves – more than half a million people in the UK live with it, but for at least one-third of those people, their seizures will not be controlled with current treatments. Aiming to address this gulf, Epilepsy Society are taking on cutting-edge techniques to help us understand the causes of a neurological condition that has baffled medics for thousands of years. In this issue, they catch us up on their efforts, and the hope that genomic diagnosis will become integral to routine practice in the NHS for everyone with epilepsy.

DNA sequencing is helping Epilepsy Society to understand more about the genetic contribution to different types of epilepsy

MRI AND EPILEPSY

More than 20 years ago we led the way using magnetic resonance imaging (MRI) in the diagnosis of epilepsy, investing in the country's only MRI scanner dedicated to the condition. This enabled doctors to look deep inside the brain in order to identify structural anomalies that could be the cause of a person's seizures.

Initially this was only available for those with the most severe forms of epilepsy. Today MRI is part of routine practice across the NHS for the diagnosis of all people with epilepsy. As well as directing diagnosis and treatment, it has led to many people undergoing safe and life-changing brain surgery for their seizures – the closest we can get at the moment to a cure for epilepsy.

Now, scientists at the charity are working in partnership with University College London and University College London Hospital to carry out ground-breaking genomic research which they believe could further enhance our current understanding of the genetic landscape of different types of epilepsies. And they hope that genomic diagnosis, based on a person's DNA, will trail a similar blaze to MRI and become part of routine practice across the NHS for all people with epilepsy.

THE CURRENT LANDSCAPE OF TREATMENT

In the last 100 years the number of medications available to treat epilepsy has increased to more than 26, with newer drugs tending to be better tolerated and causing fewer side-effects. However, doctors can still only prescribe based on the best evidence available, and for many people, a diagnosis of epilepsy means an odyssey of multiple different drugs in different combinations, and at varying doses before the optimum treatment is found.

Our goal is to achieve the right drug at the right dose from the point of diagnosis, but the current reality is very different, and the need for more individualised treatments screams loud and clear. This is where we hope that pioneering genomic research at Epilepsy Society, University College London, and University College London Hospitals NHS Foundation Trust, will make the difference, bringing hope for up to 200,000 people in the UK with drug-resistant epilepsy.

A PERSONALISED DIAGNOSIS

We believe that genomics is the missing element in the toolkit required for the diagnosis of the type of epilepsy and personal treatment for each type of epilepsy.

We know that sequencing and analysing all three billion letters of a person's genetic code can tell us more about a person's epilepsy than any other single technique. And this is pivotal. Not only do we hope that it will enable us to determine the cause of their seizures, but it will also help us to predict their response to anti-epileptic medication and their susceptibility to Sudden Unexpected Death in Epilepsy.

We have already established an innovative epilepsy genomics clinic at our Chalfont Centre in Buckinghamshire, where we see and diagnose people who are thought to have an underlying genetic cause for their epilepsy.

The clinic has been running for more than a year, investigating individual genetic pre-disposition to epilepsy, and then trying to shape its treatments for the individual.

It also provides the opportunity to counsel patients and their families where there may be a chance of other family members being affected, or of children having similar difficulties. And it ties in closely with the research which we are doing into the epilepsies.

Genetic diagnosis can lead to a change in

medication, diet, or supplements, although in some cases we don't yet have the required knowledge to redirect treatment. This is where we hope that our research will enhance our knowledge of the underlying genetic architecture of epilepsy, leading to better treatments for more people.

WHAT IS GENOMICS?

Initially we began by sequencing just a small part of the DNA at Epilepsy Society, focussing on the exome, or 10 million letters that carry the most significant sequences of DNA – those that direct the body to make proteins essential for it to function.

This has helped us to make progress in recognising epilepsy syndromes, defining them genetically, and understanding them biologically. Now we are looking at the whole genome in order to increase our understanding and identify risk factors and therapeutic markers which could potentially lead to the development of new medications.

Alongside sequencing, we are using some of the most sophisticated equipment to help analyse genetic data. 3D stereo photogrammetry is helping to demonstrate how a genetic contribution to epilepsy can have a subtle, but significant, impact on facial structure, and in turn help us to understand an individual's genome; optical coherence tomography can show the impact of epilepsy on the thickness of the retinal fibres at the back of the eyes; and transcranial magnetic stimulation is helping to analyse brain activity without the need for electrodes or needles.

Our translational research programme has already begun sequencing 5,000 genomes and is currently focussing on more severe forms of epilepsy characterised by uncontrolled seizures and issues such as learning disabilities. In these more extreme forms of epilepsy, it can be easier to pinpoint the malfunctioning genes. In less challenging epilepsies, it can be more challenging to pick out the genetic variants.

Approximately 1,000 genomes have been sequenced as part of the Genomics England 100,000 Genomes Project and we are now at the exciting stage of interpreting the data alongside each person's phenotype, including their health and the history of their epilepsy.

SUDDEN UNEXPECTED DEATH IN EPILEPSY

We are also looking at Sudden Unexpected Death in Epilepsy (SUDEP) – the most common cause of death in epilepsy. Every year, 600 people lose their life to SUDEP in the UK and the impact on friends and families is devastating. Scientists believe that there may be multiple mechanisms involved in SUDEP.

We want to increase our understanding of the risk factors for SUDEP by identifying genetic changes which could increase a person's susceptibility. We will be sequencing the genomes of 100 people who have died of SUDEP or who are thought to be at risk. We hope that this will help us to identify those at greatest risk and put in place risk-reducing measures that will enable them to better manage their heightened vulnerability.

Our researchers also work collaboratively with other epilepsy experts across the world, pooling data and expertise to grow our understanding of the underlying causes of epilepsy. Big data is essential for recognising meaningful patterns and changes in an individual person's genetic make-up that could be significant to their epilepsy.

NEW BREAKTHROUGHS

In recent months we have seen two significant breakthroughs which are helping to elucidate the epilepsy landscape.

We are part of a large collaboration which has been looking at the DNA of 15,000 people with epilepsy across the world, and this has enabled us to identify 16 new regions in the brain that are thought to be associated with the more common epilepsies. This is a particularly exciting development as we begin to extend our knowledge beyond that of the more severe syndromes.

Working as part of the International League Against Epilepsy Consortium on Complex Epilepsies, we have pinpointed 21 genes in these regions that are thought to be contributory factors. The research could lead to the development of new treatments for epilepsy and the repurposing of 166 existing drugs which could be suitable for treating seizures.

And in the largest neuro-imaging study of people with epilepsy, we have shown how epilepsy can affect the volume and thickness of certain regions of the brain. The changes are very subtle and their significance is not yet fully understood, but have even been seen in people with different types of epilepsy, such as idiopathic generalised epilepsy, which is typically characterised by a lack of visible changes in the brain. The study, carried out by the global ENIGMA-Epilepsy consortium and led by our scientists, pooled data from 24 centres across Europe, North, and South America, Asia and Australia.

Although it is not yet possible to know from the study whether changes in the brain are caused by the seizures or an initial insult to the brain, the results are helping to draw a neuroanatomical map of areas of the brain that are key for future studies which will lead to a greater understanding of epilepsy.

We are fortunate at Epilepsy Society that our research work is integrated with our clinical practice. But most of all, we are lucky to have so many people with epilepsy who are willing to be a part of our ground-breaking research. Our discoveries are their discoveries. Our goal of personalised medicine based on a person's genetic make-up and individual circumstances will only ever be achieved thanks to their wish for better diagnosis and treatments, and their confidence in us to deliver.

For more information about Epilepsy Society, visit www.epilepsysociety.org.uk/epilepsy-research.

For referrals to Epilepsy Society's specialists, assessment centre, or therapeutic drug monitoring service, visit www.epilepsysociety.org.uk/getting-referral.

Epistatus® is licensed for use in the treatment of prolonged, acute convulsive seizures in children and adolescents aged 10 to less than 18 years, who have been diagnosed with epilepsy[1]

EPISTATUS®
10mg in 1mL Oromucosal Solution
Midazolam (as maleate)

Epistatus is approved for use by both the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC)

Epistatus is presented ready-to-use in a novel, pre-filled, single-dose syringe, in a volume of 1mL[1], to provide carers with the confidence that they are administering the correct dose.[2]

Epistatus has been developed specifically for buccal administration and comes in a robust, tamper-resistant pack, which is UV-resistant to maximise shelf life.[1] It is portable and can be carried by patients at all times.[2]

"It is of great value to have a second licensed formulation of a buccal rescue medication for patients with epilepsy, especially the availability of single dose prescription in those patients whose prolonged seizures are infrequent, which means we can avoid doses going to waste when past their shelf life."

Dr Joseph Anderson, Consultant Neurologist
Royal Gwent Hospital, Newport

"It is also a great reassurance to our team that potentially devastating supply chain problems are now mitigated against by the availability of a second supplier of buccal midazolam."

Dr Joseph Anderson

Get support for the inclusion of Epistatus on your local formulary for prolonged, acute convulsive epilepsy seizure treatment in children aged 10 to less than 18 years old because Epistatus:

- offers a likely reduction in product wastage for patients with low frequency of seizures relative to use of multipacks in which the full supplied dose may not be required.[3]
- the NHS price for a single 10mg in 1mL pre-filled syringe is £45.76.

Community Pharmacists can obtain Epistatus 10mg/1mL pre-filled syringes exclusively via Alliance Healthcare.

Hospitals can order Epistatus 10mg/1mL pre-filled syringes directly from Veriton Pharma Ltd at www.veritonpharma.com

For further information about Epistatus 10mg oromucosal midazolam pre-filled syringe, or to find out more about a budget model to calculate the financial impact of prescribing multipack buccal midazolam versus single-pack Epistatus visit www.epistatus.co.uk.

References:

1) Epistatus 10mg Oromucosal Solution. Summary of Product Characteristics.
2) Data on file – Excerpts from Epistatus Patent Application.
3) Data on file (item code EDM/1030/2017), Veriton Pharma Ltd 2017.

EDM-1069-2018
Date of Preparation: November 2018

Epistatus Prescribing Information
EPISTATUS® 10mg oromucosal solution midazolam (as maleate). Please consult Summary of Product Characteristics before prescribing. **Presentation & composition:** oromucosal solution. Each 1mL of solution contains 10mg of midazolam (as maleate). Excipients with a known effect: ethanol 197mg/mL, liquid maltitol 675mg. **Indication:** Treatment of prolonged, acute, convulsive seizures in children and adolescents aged 10 to less than 18 years. Epistatus must only be used by parents / caregivers where the patient has been diagnosed to have epilepsy. **Dosage:** For children and adolescents aged 10 to less than 18 years the standard dose is 10 mg (1.0 mL). Carers should only administer a single dose. If the seizure has not stopped within 10 minutes after administration, emergency medical assistance must be sought. Patients should be kept under supervision by a carer who remains with the patient. A second or repeat dose when seizures re-occur after an initial response should not be given without prior medical advice. **Administration:** For oromucosal use only. Using the pre-filled oral syringe provided, administer, over a period of 2-3 seconds, approximately half of the prescribed dose to each buccal cavity. For detailed instructions please refer to the Summary of Product Characteristics. **Contra-indications:** Hypersensitivity to midazolam, benzodiazepines or to any of the excipients. Myasthenia gravis; severe respiratory insufficiency; sleep apnoea syndrome; severe hepatic impairment. **Warnings & Precautions:** Caution in patients with chronic respiratory insufficiency (may further depress respiration). For oromucosal use only. Take care to avoid the risk of choking. Midazolam should be used with caution in patients with chronic renal failure or impaired hepatic function (may accumulate); or cardiac function (may decrease clearance). Debilitated patients are more prone to the central nervous system (CNS) effects of benzodiazepines and, therefore, lower doses may be required. Midazolam should be avoided in patients with a medical history of alcohol or drug abuse. May cause anterograde amnesia. Contains maltitol and ethanol. **Interactions:** Please consult the Summary of Product Characteristics for full details. Midazolam is metabolized by cytochrome P450 3A4 isozyme (CYP3A4). Inhibitors and inducers of CYP3A4 may increase and decrease the plasma concentration respectively. In the presence of CYP3A4 inhibition the duration of effect of a single dose of oromucosal midazolam may be prolonged; careful clinical monitoring is recommended. Midazolam may interact with other hepatically metabolized medicinal products. Co-administration with other sedative / hypnotic agents and CNS depressants, including alcohol, is likely to result in enhanced sedation and respiratory depression. Additional alcohol intake should be strongly avoided. **Pregnancy and lactation:** Midazolam may be used during pregnancy if clearly necessary. The risk for new-born infants should be considered in the event of administration in the third trimester. Midazolam passes in low quantities into breast milk (0.6%); it may not be necessary to stop breast-feeding following a single dose. **Driving and machines:** midazolam has a major influence on the ability to drive or use machines. The patient should be warned not to drive or use machines until fully recovered. **Side effects:** Respiratory depression occurs at a rate of up to 5% although this is a known complication of convulsive seizures as well as being related to benzodiazepine use. Common: sedation, somnolence, depressed level of consciousness, respiratory depression, nausea & vomiting. Uncommon: pruritus, rash, urticaria. Following injection, additional adverse reactions have very rarely been reported (including respiratory arrest and cardiac arrest); these may be of relevance to oromucosal administration. Consult the Summary of Product Characteristics before prescribing. **Legal classification:** POM **NHS Price:** 10mg in 1mL prefilled syringe - £45.76 **Marketing authorisation number:** PL 16786/0003 **Marketing authorisation holder:** Veriton Pharma Limited, Unit 16, Trade City, Avro Way, Brooklands Business Park,Weybridge, Surrey, KT13 0YF, United Kingdom. **Date of last revision:** October 2017.

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 Veriton Pharma Limited. Tel +44 (0) 1932 690325

EPILEPSY AND ANTI-SEIZURE DRUGS: WHAT'S TO COME?

2018 was a momentous year for people with epilepsy. News stories emphasised the hope of cannabis-derived medications, and the risk of drugs, such as valproate in pregnancy. Rhys Thomas, Intermediate Clinical Fellow, Newcastle University, and Honorary Consultant in Epilepsy, Royal Victoria Infirmary, Newcastle upon Tyne, and Donald Craig, Margie Jackson Epilepsy Fellow, Royal Victoria Infirmary, Newcastle upon Tyne, select contemporary issues regarding anti-epilepsy therapies, as well as discuss developments to illustrate the hopes and challenges for future improvements in epilepsy care.

Rhys Thomas

WHAT ARE SEIZURES?

Seizures are clinical events that occur due to poorly organised electrical discharges in the brain. These electrical disturbances can occur at any stage of life, with the highest incidence occurring in early life and the elderly. There are many different seizures, from brief alterations to extended convulsions with impaired awareness and autonomic disturbances.

Every brain is susceptible to seizures in a fluid concept termed a 'threshold'. Seizures can be 'provoked' in numerous temporary situations, such as electrolyte disturbances or head trauma. The circumstances leading to seizures in one individual will not inevitably lead to seizures in the next, even within close family members.

WHAT ARE THE EPILEPSIES?

Epilepsy is the occurrence of repeated unprovoked seizures. The pattern of electrical discharges in the brain can be observed by an electroencephalogram (EEG), leading to broad categorisation of focal and generalised epilepsies. There are sub-groups of epilepsy syndromes, arising in certain circumstances, such as during sleep, or on exposure to patterns of light.

Epilepsies can improve as the brain ages, regarded as self-limited when seizures resolve spontaneously. The conditions that include epilepsy as a central feature are wide, with seizures co-occurring with a number of diverse co-morbidities. All healthcare services will have patients who have seizures, or are affected by the consequence of an epilepsy therapy.

DRUG CHOICES – THERAPY FOR EVERY SEIZURE?

In the UK, around one-in-10 will experience a single seizure in their lifetime. The first step is to manage any modifiable factors, for example, provoking medications or poor sleep.

Investigations inform decision-making, so simply starting an extended course of medication for every seizure may not be helpful, and most likely, harmful.

One per cent of the population will experience recurrent seizures that merit anti-epileptic therapy. There are over 30 drugs currently listed in the British National Formulary listing standard doses, with regimes in paediatrics varying compared to adults. The choice of therapies is ideally considered in the context of co-morbidities and co-prescribed medications.

Drugs called 'anti-epileptics' but are more correctly 'anti-seizure' and do not represent a true class of medications but rather a collection of drugs – often serendipitously identified as anti-seizure agents.

Combinations of anti-epileptic drugs present further challenges to balance both efficacy and adverse effects. That two-thirds of patients can be seizure-free with the use of medication should be celebrated as an achievement. However, there is a great need to continue to improve therapies, both for patients whose seizures are 'controlled', and in those who are limited by ongoing seizures.

FUTURE NOW – USING EXISTING DRUGS BETTER

'Next generation' drugs, such as eslicarbazepine (in the same 'family' as carbamazepine and oxcarbazepine) and brivaracetam (with levetiracetam), report better tolerability. They are not first-line but cost-efficacy may be justified by projected future NHS cost savings. Long underappreciated co-morbidity costs, such as atherosclerosis, sleep, and psychiatric symptoms could have enhanced weighting in future analysis.

There is strong hope that precision medicine will deliver better choices to improve both efficacy and reduce adverse effects. This is already realisable with currently available pharmacogenomics. The metabolism of many of commonly used anti-epileptics, such as phenytoin, can be partially predicted through knowledge of liver cytochrome enzyme profile. Carbamazepine is one of the first-line recommendations for drugs in focal epilepsy in the UK. There can be a high incidence of severe cutaneous reactions, predictable by testing of human leukocyte antigen status. This is recommended in certain countries in South East Asia prior to prescription. The extra diagnostics and delay, limits rather than improves, choice, but there is exciting work to move this process closer to point-of-care testing.

FUTURE SOMETIME – EVEROLIMUS

Once a genetic diagnosis was a laboured process, but this is being rapidly simplified, and improvements in diagnostics to identify aetiologies are celebrated. There are few approaches aimed at a reversal of underlying processes and drugs are then employed to suppress seizures and minimise symptoms. An example of a potential of targeted, truly anti-epileptic therapy may be everolimus for tuberous sclerosis (TS).

This drug influences mTOR protein signalling that has been shown to delay the growth of kidney and brain lesions. Whether everolimus improves seizures compared to conventional blunt medication in this rare but severe epilepsy remains to be established in head-to-head studies. In the UK the drug is approved but control of large TS-related lesions called SEGAs but licensed but not commissioned as an anti-epilepsy drug pending further review.

EPILEPSY

RECENT FUTURE DRUGS – STIRIPENTOL AND RUFINAMIDE

Many of the recent drug introductions are subject to particular prescription restrictions. These reflect the ages and populations of the licensing trials where they are used as adjuvants in severe syndromes. Examples are stiripentol in Dravet Syndrome (sodium channel malfunction), and rufinamide in Lennox Gastaut Syndrome (a network epilepsy with a particular EEG signature).

These drugs are consequently difficult to practically access, even in larger centres, with the potential bottlenecks being diagnosis and familiarity with the drugs. The applicability of these narrowly approved medications to the wider epilepsy community may continue to be unknown. There is unlikely to be sufficient data or trials supported to enable widespread adoption outside of the current niche usage.

CANNABIS DERIVATIVES

There has been widespread public attention to the potential introduction of cannabis-derived medications. There is hope that this will find a place in the treatment of many pharmaco-resistant epilepsies. At present larger trials have been in the paediatric patients in combination with multiple co-prescribed drugs and the wider applicability is unclear.

There have been promising results, but the overall numbers using recognised preparations remains small. The mechanism of action remains under investigation as cannabidiol may not exert its anti-seizure effect at cannabinoid receptors. No trials of drugs containing the more psychoactive THC extract have reported in epilepsy. There is concern that political considerations may obscure the opportunity for real-world research because of the high profile of cannabis-derived drugs.

FENFLURAMINE – RE-PURPOSING

Fenfluramine was originally introduced as an appetite suppressant. It was noted to have a serotonergic mechanism before being withdrawn due to cardiovascular adverse effects. Research use in epilepsy was interrupted and then re-instituted under special licence in open label studies in patients with sodium channel genetic abnormalities causing epilepsy.

How the serotonergic mechanism relates to the sodium channel malfunction is unclear and there may be heterogeneity of response depending on subtle differences in genetics. Re-purposing of drugs with established licenses for other indications is welcome if therapies increase in neurological rare diseases where pharmaceutical investiture is often halting.

RETIGABINE

Retigabine was a welcome addition with a novel mode of action on potassium channels that was soon withdrawn after unforeseen discolouration of skin. This was an unfortunate mis-step as there were hopes that this differing biological mechanism would provide more scope to prescribe anti-epileptics combinations by awareness of their mechanism of action.

VALPROATE

Dedicated pregnancy registries led to collection of data that identified that high dose valproate use is potentially harmful to cognitive development of a foetus. This led to advice that valproate should now be prescribed only if pregnancy is discouraged. (www.gov.uk/guidance/valproate-use-by-women-and-girls) Valproate is very effective and switching to alternative agents requires careful consideration.

NEURO-STEROIDS

The central action of steroids on the brain is undoubted, as can be seen by the occurrence of catamenial epilepsy. Attempts to influence seizures with contraceptive hormonal manipulation has been less successful. There are neuro-steroid derivatives that have progressed to published trials but have not yet become commercially available. An interesting avenue has been the use of the neurosteroid allopregnanlone as an adjuvant therapy in refractory status epilepticus in trials.

DIETS

Starvation has been known since antiquity to reduce seizures. An example where dietary manipulation is an essential component of treatment is the GLUT1 deficiency syndrome where brain-barrier glucose transporters malfunction.

Various ketogenic regimes that are high in fat, low in carbohydrate increase alternative energy utilisation to reduce seizures.

Identifying metabolic deficiencies and prescribing individualised dietary additives could represent another avenue for therapies. Biotin and pyridoxine vitamin responsive seizures are clear examples of success. In the UK, where the responsibility to develop and the drive to license potential nutraceuticals will emerge from is not defined at present.

DEVICES

Devices implanted in the chest can electrically stimulate the vagal nerve to influence susceptibility to seizures. The selection of patients remains empirical and the ideal combination of drugs with stimulation is under investigation.

'Deep brain' implantable seizure modifying devices are available, highly specialised, but have no UK accessibility. Wearables may contribute biomedical data, such as skin sweat and sleep data, to predict and intervene before seizures occur with more responsive drug regimens rather than routine dosing. Until exciting developments in minimally-invasive surgery – lasers, optogenetics, gene therapy, focused radiotherapy, MRI guided ultrasound – becomes more than horizon therapies, the drive will remain to improve the selection and tolerability of drug therapies.

SUMMARY

The breadth of epilepsy treatments extends beyond the 'big four' anti-epilepsy drugs of carbamazepine, lamotrigine, levetiracetam, and valproate. Pragmatic UK-led head-to-head studies, such as SANAD and awaited SANAD-2, remind us that novel drugs may not be superior to established agents.

However, there is much to be optimistic about – regarding the opportunities currently available and soon-to-be-available – for helping to better control epileptic seizures, with the aim of improving quality of life for people with epilepsy.

TALES OF TRIUMPH

Against the backdrop of winter's chill, the Scottish Pharmacy Awards shone a light on the scorching and bright talent which the sector has to offer.

An air of jubilation swept through Scotland towards the end of last year – signally that the coveted Scottish Pharmacy Awards had once again been clinched.

The annual celebration – which took place at Hilton Glasgow Hotel, William Street – yields its positive impact on the pharmaceutical industry by recognising the exceptional workers among us, and springing their accomplishments into the spotlight.

This year Rachel McTavish took on presenting duties and effortlessly commanded a ballroom abuzz with 300-plus guests, made up of pharmacy students, esteemed service leaders, and representatives spanning the different health boards.

There were 11 accolades in total distributed throughout the evening – which was rounded off with the Special Recognition Award.

Funds were raised on the evening for the 2018 nominated charity, Pharmacist Support, which works for pharmacists and their families, as well as former pharmacists and pharmacy students, to provide help and guidance in times of need.

All the winners and their stories of success will be split across this edition of Scottish Pharmacy Review, as well as our next issue later in the year – don't miss it!

The categories which the winners secured victory in were:

- Advances in Travel Health and Vaccine Services in Community Pharmacy
- Student Leadership Award
- Respiratory Project of the Year
- Hospital Pharmacy Team of the Year
- Innovations in Prescribing, Quality and Efficiency in Scotland
- Pharmacy Practice of the Year Independent
- Innovative Use of Technology in Community Pharmacy
- Innovations in Clinical Development in Cardiology Pharmacy
- Education and Self Development in Community Pharmacy
- Community Pharmacist of the Year Independent
- Special Recognition Award

WINNER

RESPIRATORY PROJECT OF THE YEAR

Bernadette Brown and Team – Cadham Pharmacy, Glenrothes

Sponsored by Teva Respiratory

Having launched as a health centre in 2017, the team have been admirable in their passionate pursuit of patient care – and mission to change the hearts and minds of the public to choose Pharmacy First for long-term conditions.

The centre is nestled in the ex-mining town of Glenrothes; a setting which has sparked a high prevalence of respiratory disease among those living in the area. This has subsequently boosted demand for the respiratory services offered in the primary care setting – leading to difficulty in patients obtaining annual respiratory reviews and being able to access GP / nurse appointments when experiencing acute exacerbations. A further cause for concern has been the significant number of young professionals who prefer weekend appointments, and thus frequently don't attend at their GP practice.

Eager to address these vital gaps in the delivery of care, the team were spurred into action to provide accessible respiratory clinics with highly skilled pharmacists / nurse independent prescribers in the community pharmacy setting which would improve patients' healthcare outcomes, and ultimately relieve the burden on the primary care setting.

The team's innovative insight has particularly risen to the fore via their heavy investment in resources to enable the safe and effective running of the clinics. In line with this, the consultation room is highly equipped with a tympanic thermometer, pulse oximeter, blood pressure monitor, peak flow meter, and FeNO machine, which grant the ability to conduct a thorough physical assessment of the patient's symptom / disease control.

The results of these assessments help guide the pharmacy towards their prescribing decisions and formulation of well-rounded patient management plans. The ACT score is also utilised to assess disease control and to act as a tool in which an open discussion can be carried out with the patient regarding the extent to which their respiratory disease affects their life. Placebo inhaler devices have been helpful, too, in examining individuals' inhaler techniques, and assisting in the explanation and demonstration of good inhaler technique to all patients.

Central to the team's success is the importance which they place, not just on the individual's current wellbeing; but on how their condition may be shaped in the future – and on how they can self-manage it. Building on the public's awareness, the team have been employing the Let's Talk Respiratory educational programme, and stickers which attach to the inhalers as a go-to reminder as to how they should be properly used. Meanwhile, the information digital 55-inch iPad boards play videos focussing on asthma inhaler technique, and support public health education on all topics, including COPD.

The members of the pharmacy flourish on an individual basis in addition to as a team. When comprising patient management plans, they all follow appropriate local and national guidelines for prescribing to ensure that the treatment plans are evidence-based. Each pharmacist conducting the clinics uses a patient-centred approach to all consultations, and invokes patient collaboration throughout the decision-making process. This method therefore inspires patients to take responsibility for their condition; improves adherence to prescribed treatment; and bolsters healthcare outcomes.

The uptake of new opportunities for the advancement of learning is continuously rife, in which the pharmacy has now involved some of the healthcare staff, and obtained support from pharma companies, to complete on-site inhaler technique accredited courses. Two staff members have also been recruited who have benefitted themselves from the asthma journey, and know first-hand how it can change their thinking.

Looking to the future, the team are intending to further propel respiratory care into the spotlight for the benefit of patients – in which asthma and COPD will become greater societal priorities, and the Cadham team will continue their high standard of work.

'Winning this award means that all the hard work; sending the kids back to university; and getting diplomas in Respiratory is really important. But what especially matters is getting to talk to the public, and being able to help them to understand how they can manage their own health better. It means the world to us that we can help them.'
Bernadette Brown and Team
Cadham Pharmacy
(Glenrothes)

'We're delighted to be able to sponsor an award that recognises outstanding contribution to pharmacy in Scotland. Respiratory can be a significant burden of illness, so it's brilliant to see initiatives like this.'
Mark Osborne
Teva Respiratory

Respiratory Project of the Year Award winner, Bernadette Brown and team, Cadham Pharmacy (Glenrothes), with Mark Osborne, Teva Respiratory, and Graeme Bryson, Director of Pharmacy (NHS Dumfries & Galloway)

TEVA Respiratory

WINNER

HOSPITAL PHARMACY TEAM OF THE YEAR

Leanne Miller, Jude Madeleine and Oncology Pharmacists – NHS Highland

Sponsored by Ethypharm

From their first formation to continued fruition, resilience has been a major factor underscoring the small team, which comprises five pharmacists providing care for cancer patients across NHS Highland. This is all the more impressive against the challenges which they have effectively contended with – such as the geography of the Highlands; an area the same size of Belgium, and the difficulties encountered in recruiting consultant oncologists and haematologists. The pharmacy staff are thus a hugely valuable asset in supporting the medical and nursing teams in the provision of optimal care to patients.

The team work closely with Macmillan nurses in peripheral hospitals, such as Wick, Skye, Western Isles, and Fort William to deliver pharmaceutical care to their patients in the absence of specialist oncology pharmacists in these areas. In the last five years they have established a clinical pharmacy service within oncology outpatient clinics and the outpatient chemotherapy unit – which has garnered a flurry of positive feedback from the multidisciplinary team and patients alike, demonstrating how the offering has significantly improved patient experience and patient safety.

A key course of action undertaken by the team entailed one of the members initiating audit work; looking at the impact of immunotherapy in patients with metastatic melanoma. This was a large retrospective audit over two years which followed the patient journey, toxicities from treatment, and treatment outcomes. From this data it was identified that patients with symptomatic brain metastases at presentation often had poor treatment outcomes – and the lead consultant for melanoma patients has subsequently changed practice based on the audit results. This patient group are now offered palliative care rather than treatment, where outcomes were poor and toxicities experiences outweighed the benefit.

Collaboration has been – and continues to be – an integral part of the team's success, whereby they work closely with pharmacy colleagues across the North of Scotland Cancer Network (NOSCAN) through the development of joint guidelines, clinical management guidelines, and the sharing of project work. In fact, NHS Highland have led the work on several supportive guidelines for the NOSCAN, including immunotherapy toxicity guidelines, treating chemotherapy-induced diarrhoea and constipation guidelines and tumour lysis guidelines – enabling the NOSCAN to become more compliant with government guidelines on the safe delivery of systemic anti-cancer treatment.

The wider landscape of healthcare learning has been bolstered by the team's example and willingness to pass their knowledge on. In line with this, they offer education and training to primary care pharmacists and technicians and nursing staff within NHS Highland on cancer treatment.

For example, NES educational evenings have been carried out, and work with the ECHO Project during the last two years has been conducted, led by the Highland Hospice, to deliver training on chemotherapy toxicities. Hot on the heels of this, the staff received excellent responses from nursing and community pharmacy teams regarding how they have massively contributed to the building of their confidence in dealing with chemotherapy-induced toxicities, and assisting their understanding of cancer treatments.

Future opportunities for enhanced awareness are also being adopted, in which the team are presently in the process of working with community pharmacists in NHS Highland to implement community dispensing of abiraterone and enzalutamide.

Another core goal which has been put in place is the implementation of a homecare scheme for lanreotide injections which are used to treat neuroendocrine cancers. Currently, patients are required to travel to their nearest cancer centres for a quick subcutaneous injection every month; and, in some cases, this journey can be over three hours. By instigating the homecare scheme there is a VAT saving in these drugs, but most importantly, patients can either be trained to self-administer or have a trained nurse administer this drug at the patient's home, avoiding unnecessary journeys to hospital.

'We're thrilled to have won but we couldn't do the job without our whole team. Thank you.'
Leanne Miller, Jude Madeleine and Oncology Pharmacists (NHS Highland)

'It's great to be able to sponsor this award. It's fantastic to see how the collaborative work of the team has benefitted patients.'
Kevin Waton
Ethypharm

Hospital Pharmacy Team of the Year Award winner, Leanne Miller, Jude Madeleine and Oncology Pharmacists (NHS Highland), with Kevin Waton, Ethypharm, and Sandra Melville, Lead Pharmacist, Oncology and Acute Care, Lorne and Islands Hospital (NHS Highland)

Ethypharm

WINNER

INNOVATIONS IN CLINICAL DEVELOPMENT IN CARDIOLOGY PHARMACY

Joanne McGeoghie – Post-MI LVSD Pharmacist Up-titration Clinics, Angus, The Abbey Practice, Arbroath

Sponsored by Daiichi-Sankyo

Joanne's strong work ethic and expert insight have resulted in the service emerging as a formidable – and valued – force for both patients and healthcare providers.

The project's roots were first forged when Tayside were approached as part of a Scotland-wide roll-out of post-MI LVSD teach and treat, which was developed and successfully advanced across NHS Greater Glasgow & Clyde. Paul Forsyth, Lead Pharmacist in Cardiology / Heart Failure in Greater Glasgow & Clyde, was instrumental in identifying the national need for the development of this service. Paul and Joanne then reviewed local patient data of post-MI patients across Tayside to demonstrate the low achievement in the optimisation of secondary prevention in post-MI patients with all grades of LVSD. Joanne subsequently proceeded to sort out the logistics of starting the clinic, with Paul's assistance, and the support of Stuart Hutcheon, Clinical Lead for Cardiology, and Gordon Thomson, Lead Pharmacist for Clinic Development.

Angus was selected as a prime area to commence the clinics due to the fact that a cardiology clinic was already routinely running in Arbroath, and, as a new prescriber, Joanne recognised the worth of having the support of cardiology medical staff if needed for any complex patients. In addition, the Angus cardiac rehab nurses aren't prescribers and there was a notable service gap for a specialist cardiology prescriber to assist in ensuring the up-titration of medications, even more so than other areas where some nurses do act as prescribers.

The cohort chosen encompassed patients with all grades of LVSD as the clinic would allow capacity for the number of patients even with mild LVSD. From here, Joanne's intention was to prioritise patients and see individuals with moderate-to-severe LVSD first, then as clinic space allowed, allocate mild, asymptomatic patients.

Joanne's thorough nature and unfaltering focus have filtered into her provision of a comprehensive service. During the process patients are referred by cardiac rehab nurses, with Joanne then reviewing the patient's discharge, ECHO, and any relevant clinical information available. Following this, she phones the patient; aware of the importance of building trust with the individual from the very first interaction.

A clinic appointment is allocated usually within the first four weeks post-MI, and when patients are seen in clinic, Joanne allows a 30-minute appointment time to discuss all of their post-MI medication, along with compliance and symptoms, and she conducts a clinical assessment of the patient too. If appropriate, a polypharmacy review is undertaken in the first appointment with the patient – with Joanne acknowledging that compliance with their post-MI medication will be enhanced if they can plan to rationalise any other medication; particularly any cardiac medication that is no longer valuable to the patient's future quality of life or morbidity now post-MI.

If appropriate – which most often it is – Joanne prescribes an up-titration or initiation of ACEi, beta blocker or MRA (or other appropriate LVSD medication treatment) on a prescription that the patient is able to take away at that time to take straight to a community pharmacy.

Data collation from the first nine months of the clinic is now in progress, which will pave the way for the quantitative results being finalised. However informal qualitative feedback from both healthcare professionals and patients has been incredibly positive; centring on how important they've found the clinic to be, and the beneficial nature of having medications efficiently and attentively increased to suit the individual needs.

'The work is an example of how health boards can come together to bounce ideas off eachother and be collaborative. I'm very appreciative – thank you.'
Joanne McGeoghie
Post-MI LVSD Pharmacist Up-titration Clinics, Angus, The Abbey Practice (Arbroath)

'We're delighted to support such an important award. Cardiovascular is an area in which pharmacy can make a real difference to patients' lives.'
Joanne Jervis
Daiichi-Sankyo

Innovations in Clinical Development in Cardiology Pharmacy Award winner, Joanne McGeoghie, Post-MI LVSD Pharmacist Up-titration Clinics, Angus, The Abbey Practice (Arbroath), with Joanne Jervis, Daiichi-Sankyo, and Iain Speirits, Pharmacist, Clinical Cardiology (Primary Care) / Heart Failure Specialist (NHS Greater Glasgow & Clyde)

Daiichi-Sankyo

WINNER

COMMUNITY PHARMACIST OF THE YEAR AWARD (INDEPENDENT)

Sam Falconer – Townhead Pharmacy, Kilwinning, NHS Ayrshire & Arran

Sponsored by Consilient Health

Integrating the traditional path of the pharmacist with the changes trickling through the profession is a tricky feat – but one which Sam has been able to seamlessly navigate.

One of the major tasks which Sam has encountered has been balancing his time management between the dispensary, and his role as an independent pharmacist prescriber, providing care to patients.

With this in mind, on a daily basis he attains responsibility for managing a busy dispensary while running clinics and distributing advice to patients. His regular duties range from checking surgery prescriptions, waiting prescriptions, blister packs, and methadone prescriptions, to dealing with problems, such as items being out-of-stock. The recent addition of a dispensary robot and two ACTs has presented the opportunity for Sam to further exercise his organistional skills and delegate more tasks – simultaneously enabling him to concentrate more on patient-facing services, like his common clinical conditions clinic, Pharmacy First service, and respiratory clinics.

In line with the shifting face of pharmaceutical care, Sam assigns great importance to not just maintaining, but further developing, his own skills and knowledge to ensure that he possesses the ability to deliver up-to-date and appropriate advice. This path has incorporated the completion of NES courses on consultation skills, and common clinical conditions, as well as respiratory, cardiovascular, and musculoskeletal. He has also participated in additional training with GPs, nurses, and ENT consultants.

The number of consultations performed within the pharmacy has rapidly increased so during a recent refit the team opted to increase the number of consultation rooms from one to two. This has ensured that there is always a private area to have a conversation with a patient even when a clinic is taking place.

Reputable for his professional and confidential nature, Sam has gained the trust of his patients, in which they feel comfortable regularly seeking advice. This therefore allows him to identify care issues relating to long-term medical conditions, and as an IPP he can alter medication where appropriate. Also advantageous is that through Sam's unique position he can directly access the patient's notes from within the pharmacy – giving him more background to the care being provided to the patient, and offering the chance to input any interventions he can make for the GPs, nurses etc. to see.

Tapping into the needs of the population, the pharmacy actively promotes a healthy lifestyle by offering national services, such as smoking cessation, and emergency hormonal contraception. The team have also extended their offerings to include a weight management programme, a healthy heart clinic (blood pressure and cholesterol monitoring), and flu vaccination in order to further boost public health. During several charity events recently hosted the team also promoted exercise by bringing along fitness equipment – such as exercise bikes and activity steppers – into the pharmacy. In addition to this, they engaged with the local primary school by getting them to name the new dispensary robot.

As Chair of the Kilwinning Locality Planning Forum, it's part of Sam's role to interact with the local community in line with the objective of bettering public health. He has recently presented talks at local support groups, schools, businesses, GP surgeries, and health and social care partnership forums regarding services such as smoking cessation and sexual health.

The teamwork culture endorsed by Sam has boosted the morale of the pharmacy staff. One of the measures implemented in this strategy is the daily morning meeting in which problems and learning opportunities are identified.

These are employed to create a monthly 'lesson' which he creates and presents to the staff – generally made up of a short presentation followed by a group discussion. The team have also recently completed the Patient Safety Climate survey and used this to reflect on their practices and identify learning opportunities. Additionally, Sam has successfully trained an ACT and new technician through challenging courses.

'I'm ecstatic and truly grateful. Thank you very much.'
Sam Falconer
Townhead Pharmacy, Kilwinning (NHS Ayrshire & Arran)

'Congratulations to Sam for winning what was a very tough competition.'
Nicola Quinn
Consilient Health

Community Pharmacist of the Year Award (Independent) winner, Sam Falconer, Townhead Pharmacy, Kilwinning (NHS Ayrshire & Arran), with Nicola Quinn, Consilient Health, and David Thomson, Lead for Community Pharmacy Development & Governance (NHS Greater Glasgow & Clyde)

Consilient Health

WINNER

ADVANCES IN TRAVEL HEALTH AND VACCINE SERVICES IN COMMUNITY PHARMACY

Jane Rorison and Team – Ogg & Company Pharmacy, Ayr

Sponsored by Scothealthcare.com

Jane's eagerness to veer down the path of travel care was sparked during the completion of her independent pharmacist prescribing course in 2013 / 2014, and upon her interaction with a former colleague, now working in London, who ran a travel clinic within a busy community pharmacy.

Recognising that the route presented her with the ideal opportunity to harness her travel-related passion to aid patients, Jane found a PGD which would allow her to prescribe anti-malarials without requiring a prescribing qualification. As a result, in March 2014 she carried out training with the PGD company and began advising and offering an anti-malarial service.

Intent on utilising her skills to their full potential, Jane set about raising awareness – a quest which was assisted by the fact that Ogg & Company Pharmacy is located in Ayr; a large town with an array of pharmacies and GP practices in which she has harvested great relationships with since taking over as the manager of Oggs in February 2013. Following her training, Jane conducted meetings with all of the practice managers, informing them about the new travel service, and as a result of these existing relationships, Oggs promptly emerged as a go-to referral place for GP practices to send patients.

The accessibility of the service has been a prime reason for the site's soaring popularity; vastly improving the previous requirements during which patients had to carry out an online consultation, or take the one-hour journey to the nearest pharmacy offering travel services in Glasgow.

Always seeking opportunities for the advancement of her skills, once the anti-malarial prescribing service became more established, Jane began to notice that she couldn't offer patients all the advice and treatment necessary to allow them to go on their trips fully covered, as she was unable to deliver a vaccination service.

Discovering an effective solution for improving this gap in provision, after completing her independent pharmacist prescribing course, Jane participated in a two-day course run by TREC Travel Health that would grant her the chance to train to be able to offer a vaccination service. The nurse-led training company covered all bases, from risk assessment and disease, to vaccination schedules, and spurred on her passion in getting established. Refusing to rest on her laurels, Jane attended another TREC course in March 2017 to reflect on her practice after two years and to update her knowledge on any changes.

Equipped with the new-found vaccination ability, the demand for the travel clinic proceeded to surge – leading to Jane's desire to offer the yellow fever vaccination. She thus researched and completed a training day with Health Protection Scotland in November 2016 to be able to offer the yellow fever vaccine; subsequently rounding the service off and allowing the pharmacy to fulfill all of the patient's needs in one go.

Since March 2015 the travel clinic service, and its facilitation of the continuity of care, has continued to grow, with significant support from local practices and other GP practices throughout Ayrshire.

With an eye on the future footing of patient care, Jane has trained another pharmacist in the company so that he can offer the travel clinic in another branch. Once this clinic is fully developed it means that if she isn't available in the pharmacy the staff have a trusted team member that they can contact in her absence for advice.

Although the intention was originally to run a travel vaccination clinic, having the independent prescriber qualification and an experience in carrying out vaccinations has led to a number of other services, which are going from strength-to-strength.

'I'm completely and utterly delighted. I can't believe it. I'm so passionate about the travel clinic which I run, and it means so much to get an award for it.'
Jane Rorison
Ogg & Company Pharmacy
(Ayr)

'The passion of the service really came through – as well as how it looks at the needs of the patients. It makes all the difference.'
Liz McGovern
Specialist Pharmaceutical Health
(NHS Greater Glasgow & Clyde)

Advances in Travel Health and Vaccine Services in Community Pharmacy Award winner, Jane Rorison, Ogg & Company Pharmacy (Ayr), with Liz McGovern, Specialist Pharmaceutical Health (NHS Greater Glasgow & Clyde)

SCOTTISH PHARMACY AWARDS 2018

DRINKS RECEPTION

CAPTIONS:

1: GRAEME BRYSON AND JILL NOWELL

2: KIRSTIN AND JAMIE MACCONNACHER

3: KATIE WAGHORN AND GEORGE INNES

4: KEVIN WATON, KEN SUTHERLAND, AND DAVID ORR

5: THE OGG & COMPANY PHARMACY TEAM, AYR

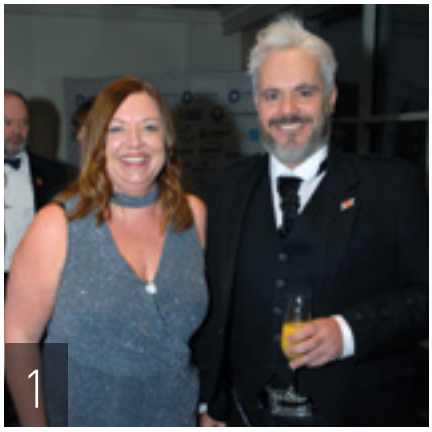
6: SUSANNE AND LAUREN DUNCAN

7: THE RIGHT MEDICINE PHARMACY TEAM

8: THE WIGTOWNSHIRE PHARMACY TEAM

9: ANDREW ROBINSON, BAL SAGOO, LYNNE BADGER, AND CRAIG THOMSON

Check out the rest of the pictures and who took home the remainder of the awards in the next edition of SPR.


1


2


3


4


5


6


7


8


9

HEALTH BOARD RECOGNISED FOR INNOVATIVE APPROACH TO NUTRITION PRESCRIBING

NHS Highland has been shortlisted for a prestigious award for the second time in four years.

Ian Rudd

NHS Highland has been nominated at the Advanced Healthcare Awards in London for innovative work carried out by allied health professionals in improving patient and staff experience.

The health board will be represented by Nutrition and Dietetics Advisor, Evelyn Newman, and Director of Pharmacy, Ian Rudd.

Having produced significant prescribing efficiencies, the work has been selected for presentation at European and Scottish conferences, and many other Scottish boards have requested further details. This proactive approach has also been replicated to transform other areas of clinical practice in the Highlands.

A more proactive Food First approach sees patients being offered more person-centred care plans consisting of conventional food and drinks, rather than prescribed products.

In addition to securing a positive response from patients, GPs, and care home staff, and reducing staff time, product waste, and costs associated with prescribing, the work has dropped annual spending by £300,000, which is an important contribution to the board's overall financial position.

Evelyn Newman explained, 'Care homes across Highland have embraced this change in practice as many residents benefit from great meals, produced by their cooks on-site, to suit their personal preferences. So many prescribed supplements were being wasted as residents were often saying that they didn't like them. Care home managers and owners are happy to support the cost and planning for a Food First approach. Most have said that they haven't noticed a difference to catering costs.

'I would like to pay tribute to the working group which has led this transformation in practice: dietitians, speech therapy, pharmacy, nursing, and general practice. It has been a real team effort, which Ian and I will be privileged to represent.'

Ian Rudd said, 'I can only imagine that sitting down to a plate of fortified food with other residents is a much more socialising experience for the resident, rather than sitting down to drink from a carton. Strong clinical leadership and team engagement have been the key to this very successful project and can be replicated in many other areas of clinical practice. We are actively taking it forward in areas such as tissue viability and continence care.'

The awards ceremony will be held in London on 12th April 2019.

DYSPHAGIA

A HARD ACT TO SWALLOW

We rarely give much thought to the sequence of events that goes on hundreds of times every day as we swallow food, fluids, or just our own saliva. It's one of many complex physiological processes that occur quite subconsciously, until they go wrong – and then the importance of a comfortable and safe swallow can become dramatically evident. Dr Patricia Macnair, Specialty Doctor in Palliative Medicine at Phyllis Tuckwell Hospice Care, and Secretary of the Primary Care Society for Gastroenterology, addresses the subjective sensation of difficulty swallowing, dysphagia.

There are few people who haven't experienced dysphagia at some point in their life, as the most common cause, an acute upper respiratory infection (URTI) with a sore throat, is a fairly universal experience. Most children and adults experience three-to-five viral URTI per year. (1) But a myriad of disorders affecting the top of the GI tract can interfere with swallowing.

THE NORMAL SWALLOW

Swallowing can be considered in three stages; oral, pharyngeal, and oesophageal. Initiating swallow in the oral stage involves the voluntary muscles of the mouth – although often unconscious, we can consciously control it. During this stage a bolus of food or liquid is propelled backwards from the oral cavity into the pharynx by the co-ordinated contractions of several groups of muscles. The next stage – the pharyngeal stage – is involuntary and involves further co-ordinated muscular contractions to move the bolus across the upper oesophageal sphincter and into the top of the oesophagus. In the final, oesophageal phase, smooth muscle in the mid and distal oesophagus generates a peristaltic wave that carries the bolus through the lower oesophageal sphincter and into the stomach.

This series of events requires meticulous neuromuscular co-ordination, especially because the top of the gastrointestinal system shares territory with the respiratory system. To safely swallow, the shared space must reconfigure from a system that moves air for breathing and talking, to one that ceases airflow and protects the airway while food and fluids are taken in. This requires the precise interplay of six cranial nerves (V, VII, IX, X, XI, and XII), as well as higher input from the cerebral cortex.

THE ABNORMAL SWALLOW

The pattern of symptoms usually points towards the cause. Patients may be aware that food is not passing though its normal route smoothly. They may struggle to initiate a swallow and find that food simply moves around the mouth or spills back out, suggesting issues with neuromuscular control. They may have a sense of something partially obstructing the pharynx, or they may find that food seems to get stuck further down. This may be accompanied by pain in the neck or chest, suggesting problems lower in the oesophagus. So a careful history is very important.

RED FLAG SYMPTOMS IN DYSPHAGIA

- Sudden on-set of severe symptoms
- Rapid progression of symptoms
- Weight loss
- Drooling or inability to swallow saliva
- Focal neurological deficit
- History of severe dyspepsia
- Hoarse voice

With so many components that could go wrong, it's not surprising that dysphagia is common, especially as we age. As many as 40 per cent of over-65s experience dysphagia. (2) The risk increases for two reasons. Normal ageing takes its toll on the physiologic and neural mechanisms underpinning swallowing. This progression of change is called presbyphagia, and naturally diminishes functional reserve. Secondly, dysphagia is a co-morbidity of many age-related diseases and / or their treatments.

Oesophageal cancer should always be considered, especially if there are symptoms suggesting obstruction, a history of dyspepsia, or a family history of Barrett's oesophagus. Sudden on-set of dysphagia is common in stroke. In one study, 64-to-90 per cent of acute stroke patients experienced dysphagia (3), and eight per cent went on to develop persistent swallowing difficulties. (4)

In Parkinson's disease, drooling and difficulty swallowing saliva are present in up to 78 per cent of patients, and of those with swallowing problems, 30 per cent show signs of aspiration. (5)

MANAGING DYSPHAGIA

Establishing the cause is the first priority, as well as consideration of reversible factors. Simple causes, such as a viral pharyngitis, have few long-term consequences and can be managed by patients themselves, with help from the pharmacy. In vulnerable patients (such as the frail, elderly, or those on steroids) other oral infections, including Candida, should be considered. Dental or ENT review may be helpful for pre-oesophageal symptoms, while symptoms suggesting oesophageal issues or obstruction need an urgent OGD (oesophagogastroduodenoscopy).

Severe oesophagitis may be successfully treated with drugs, such as proton pump inhibitors or H2 blockers. But other causes require further investigation and even hospital admission. In 2005-to-2006, for example, dysphagia was the primary diagnosis for 24,754 patients admitted to UK hospitals, accounting for 63,204 bed days. (6)

More severe or permanent dysphagia, such as after a stroke, can have major sequalea, including dehydration, malnutrition, and aspiration.

REFERENCES

1. https://emedicine.medscape.com/article/225362-overview#a6 Accessed 8.11.18
2. Ney D, Weiss J, Kind A, Robbins J. Senescent Swallowing: Impact, Strategies and Interventions Nutr Clin Pract. 2009 Jun–Jul; 24(3): 395–413
3. Mann G, Hankey G, Cameron D. Swallowing function after stroke: prognosis and prognostic factors at 6 months. Stroke 1999; 30 (4): 744–748
4. Smithard D, O'Neill P, England R et al. The natural history of dysphagia following a stroke. Dysphagia 1997; 12 (4): 188–193
5. Johnston BT, Li Q, Castell JA, Castell DO. Swallowing and esophageal function in Parkinson's Disease. Am J Gastroenterol. 1995 Oct; 90(10):1741-6
6. HESonline: Hospital Episode Statistics. Primary Diagnosis: 3 Character 2005–06. www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=203 December 2006

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

A PIECE OF ADVICE

Daily prebiotic administration may be a helpful alternative to dietary restrictions for patients with functional gut symptoms.

Diets low in fermentable carbohydrate residues (low-FODMAP diets) are often recommended as a way to reduce symptoms for patients with functional gastrointestinal disorders, such as irritable bowel syndrome. But a new study published in Gastroenterology shows that the prebiotic supplement Bimuno (GOS) may be an effective alternative to reduce symptom scores.

Current dietary advice can include avoidance of prebiotic foods and products due to aerobic fermentation in the colon, causing bloating, wind, and pain. But a randomised, parallel, double-blind study of patients with functional gastrointestinal disorders with flatulence has found that both a low-FODMAP diet and a prebiotic supplement resulted in statistically significant reductions in symptom scores after four weeks.

The study of 40 patients compared the effects of taking dietary supplementation with 2.8g/day Bimuno (containing 1.37g GOS which is a galacto-oligosaccharide) plus a placebo Mediterranean-type diet vs a placebo supplement with a diet low in fermentable oligo-, di-, mono-saccharides and polyols (low-FODMAP group).

The primary outcomes measured were effects on composition of the faecal microbiota (with symptoms of intestinal gas production and digestive sensations as secondary outcomes).

After four weeks, contrasting effects were seen on the microbiota in each group, especially regarding the abundance of Bifidobacteria (these bacteria, linked to gut health, increased in the prebiotic group but decreased in the low-FODMAP group; P=.042), and Bilophila wadsworthia (numbers of these bacteria decreased in the prebiotic group and increased in the low-FODMAP group; P=.050).

After four weeks, both groups had statistically significant reductions in symptom scores. The reduction in symptoms persisted for the two weeks of ongoing assessment after patients discontinued prebiotic supplementation, but reappeared immediately after patients discontinued the low-FODMAP diet. Low-FODMAP diets are not designed to be a long-term solution but a short-term measure to get symptoms under control before they are gradually reintroduced until a level of tolerance can be established. That tailored process may incorporate the use of a prebiotic such as Bimuno.

The full study is published in Gastroenterology in the October 2018 edition.

REFERENCES

• Huaman JW, Mego M, Manichanh C, et al. Effects of prebiotics vs a diet low in FODMAPS in patients with functional gut disorder. Gastroenterology 2018: October

INVESTIGATION INTO MENTAL HEALTH OF SCOTLAND'S FARMERS

A newly-launched research project at Robert Gordon University is set to explore and enhance the mental wellbeing of the nation's farming population.

A team of researchers from Robert Gordon University's (RGU) School of Health Sciences, and NHS Grampian, are seeking to work with the farming community to listen to a range of opinions on mental health and what can be done to improve it.

The project's aim will then be to develop an impactful intervention – hand-in-hand with farmers – to boost and safeguard their wellbeing for the future.

The team of researchers will be led by Professor Kay Cooper, Clinical Professor of Allied Health Professions at both RGU's School of Health Sciences and NHS Grampian, and Professor Liz Hancock, RGU's Vice Principal for Academic Development and Student Experience.

Professor Cooper explained, 'We know that farmers and others working in the agriculture sector regularly experience distress, anxiety, and depression, which in turn are related to greater risk of injury. Levels of depression in the industry are thought to be increasing and, according to the Office for National Statistics, agricultural workers are among the highest suicide rates in the country.

'Aside from the personal impact, poor mental wellbeing has a significant economic cost, with the World Health Organisation recently estimating the global burden at £34.9 billion.'

Professor Cooper continued, 'We have recently completed an initial review of prior interventions for wellbeing and chronic occupational diseases in the farming population, but of the 45 studies we found, only one focussed on mental wellbeing and was not applicable to a Scottish context.'

With the support of the National Farmers Union of Scotland, the team of researchers will be holding interviews with farmers at Thainstone and Orkney marts, before moving on to the in-depth workshop phase.

The National Farmers Union of Scotland President, Andrew McCornick, said, 'Mental health and wellbeing is a hugely important subject which too often is ignored in the farming community. Over the last few years we have been seeing more and more people coming out in our industry and shining a light on the issue of depression and anxiety and how it can be so prevalent in farmers and crofters.

'The National Farmers Union of Scotland is committed to improving the mental health and welfare of farmers and crofters across Scotland and we work closely with organisations, such as RSABI and the Rural Mental Health Forum, which I sit on as a representative, to help tackle mental health stigma in farming.'

AN ACCIDENT WAITING TO HAPPEN

Accidental bowel leakage, also commonly known as faecal incontinence, is the accidental passing of bowel movements, including solid or liquid stools or a mucus discharge from the anus. The condition can be upsetting – with many people too ashamed to discuss this with anyone, including their healthcare professionals. Sparked by the levels of distress imposed on patients, co-authors Ravi Karwa and Anurag Agrawal, Medical Adviser to The IBS Network, from the Department of Gastroenterology, Doncaster and Bassetlaw Teaching Hospitals, depict how open discussion with the doctor is important to diagnose and manage the condition, in addition to the avenues which should be considered for elevating care.

Dr Anurag Agrawal

Ravi Karwa

HOW COMMON IS ACCIDENTAL BOWEL LEAKAGE AND WHAT ARE THE PREDISPOSING CONDITIONS?

It is a common condition, with approximately 500,000 people in the UK affected. The prevalence rises significantly in older individuals, with nearly one-in-40 sufferers above the age of 65. Adults who are in nursing homes are especially vulnerable, with over 50 per cent prevalence.

Patients with faecal incontinence may also have other health problems, including diarrhoea, chronic conditions, such as irritable bowel syndrome (IBS), diabetes, a history of gall bladder surgery, damage or weakness of the muscles or nerves of pelvic floor, anus or rectum, or inflammatory bowel diseases (IBD), such as proctitis.

A difficult childbirth with a history of instrumentation during labour can also predispose to this condition, along with local conditions such as haemorrhoids or prolapsed bowel.

Factors which are particularly liable to cause accidental bowel leakage include constipation wherein passage of large hard stools over a period of time can stretch and weaken the muscles in the rectum and anal canal. This leads to a build-up of watery stools that accumulates behind the solid stools.

Nerve damage due to brain or spinal cord injury or neurological conditions, such as dementia, Parkinson's disease, stroke, and Multiple Sclerosis can all affect the nerves supplying the pelvic floor, leading to incontinence.

ACCIDENTAL BOWEL LEAKAGE

SYMPTOMS OF FAECAL INCONTINENCE AND WHEN TO SEEK MEDICAL ADVICE

Faecal incontinence can be associated with the urge to open the bowels, but there is a loss of control with leakage occurring before getting to the toilet. Alternatively, accidental bowel leakage can be passive wherein stool or mucus can be passed without the individual being aware.

The decision to seek advice from a GP is personal and is dependent at least in part on the severity of symptoms, as well as the individual's ability to cope with these distressing symptoms. It is common for individuals to seek medical help due to the emotional and social distress that associates with this problem.

CLINICAL ASSESSMENT AND INVESTIGATIONS

A detailed history, including the on-set and severity of symptoms, active or passive leakage, obstetric history, and associated symptoms of diarrhoea or constipation, should be taken. In addition, any other medical conditions, such as IBS or IBD, neurological and neurosurgical conditions, the impact of the condition on quality of life, and any red flag symptoms.

Examination should include a rectal exam to assess for associated conditions such as faecal impaction and any other structural problems such as haemorrhoids or a prolapsed bowel. In selected patients a bimanual examination for assessment of pelvic conditions such as rectocele is also undertaken.

Investigations should be tailored to the individual and include blood tests and stool tests, as well as an endoscopic or radiological evaluation to rule out inflammatory and any other structural cause of the symptoms. Physiological tests such as anorectal manometry, defaecography or electromyography may be necessary in some instances to assess the function of distal bowel as well as the pelvic musculature. Endo-anal ultrasound for assessment of the internal and external anal sphincter, as well as magnetic resonance imaging, may also be required in selected individuals.

MANAGEMENT OF ACCIDENTAL BOWEL LEAKAGE

There are several management approaches; these include medical, dietary, an alternative therapeutic approach, or surgery. The success rate is variable, although up to 60 per cent of individuals will respond to medical or dietary treatment and therefore this remains the first line of approach.

The anal discomfort with irritation, itching, or pain that accompanies accidental bowel leakage can be managed by keeping the area dry and clean after a bowel movement, changing soiled underwear, using moisture barrier cream, and wearing absorbent pads.

Depending on the cause, if accidental bowel leakage associates with diarrhoea, over-the-counter medicines, such as loperamide, can help relieve, not just diarrhoea, but also incontinence, as they have some added beneficial effect on improving the anal sphincter tone.

If constipation is the cause, laxatives or stool softeners, such as docusate, can be tried. Laxative combinations, such as a stimulant and a stool softener, can be considered for resistant symptoms and where the constipation is due to a pelvic floor disorder, a suppository, such as Bisacodyl or Glycerine, may be considered. Management of associated conditions, such as IBS or IBD, may be necessary in some patients before considering anti-diarrhoeals or laxatives.

Bowel training by encouraging patients to try to open their bowels, e.g. after meals, and daily pelvic floor exercises; tightening and relaxing bowel muscles several times, help strengthen muscles and are a positive therapeutic approach. Biofeedback is augmented muscle strengthening of the pelvic muscles with the assistance of devices.

During biofeedback a balloon is placed in the rectum, and is progressively distended until there is a sensation of rectal filling. Successively smaller volume re-inflations of the balloon aim to help the person detect rectal distension at a lower threshold, giving more time to contract the external anal sphincter and prevent incontinence. On the other hand, in those with urge incontinence / rectal hypersensitivity, training is aimed at teaching the person to tolerate progressively larger volumes.

Surgery can be considered if symptoms are severely debilitating, and medical, dietary, and alternative approaches have not been helpful. This is needed only in a handful of patients and the principles include surgical management of associated conditions such as prolapse or haemarrhoidal banding or ligation. Very occasionally sphincter repair procedures, sacral nerve stimulation, or in extreme cases, a colostomy may have to be considered.

ABOUT THE IBS NETWORK CHARITY

The IBS Network is the national charity that helps people with IBS and has provided support to those with the condition and to healthcare professionals for over 26 years. Funding for the charity is received from a number of sources, including annual memberships, an online shop for purchasing the Can't Wait card, radar keys, and other useful aids. The charity receives no funding from the government or NHS and relies wholly on donations.

Members of the charity's community can gain access to a whole range of services from just £2 / month, including the IBS Self-Care Programme, a specialist IBS nurse helpline, individual advice from healthcare professionals, a growing network of support groups, an online forum, plus factsheets, research, and updates via the charity's magazines, email newsletters, and other supporting material.

ABOUT IBS

At any one time, IBS affects between 10-to-20 per cent of people living in the UK, which equates to approximately 12 million people. IBS is a chronic, long-standing illness consisting of frequent abdominal discomfort and bowel symptoms that can't be explained by any other disease. Symptoms can be complex and conflicting and may include one or a combination of constipation, diarrhoea, abdominal cramps, and pain, bloating, changes in bowel movement, and frustrated defaecation. It can lead to feelings of isolation and cause major problems in people's working and personal lives.

For more information, or to become a member, get in touch via the following contact details:
Email: info@theibsnetwork.org
Tel: 0114 272 3253
Website: www.theibsnetwork.org
Twitter: www.twitter.com/IBSnetwork
Facebook: www.facebook.com/TheIBSNetwork
Linkedin: www.linkedin.com/company-beta/4601772
Address: The IBS Network, Unit 1.16 SOAR Works, 14 Knutton Road, Sheffield, S5 9NU

ACCIDENTAL BOWEL LEAKAGE

BREAKING BARRIERS AND ENSURING DIGNITY

Debbie Gordon is a Chartered Physiotherapist with a specialist interest in bowel dysfunction. Debbie has worked in the NHS, private practice, and industry – resulting in her deep understanding of the issues faced by patients trying to manage their symptoms. Debbie is passionate about raising awareness and ensuring that the right levels of care are accessed at the right time.

Debbie Gordon

Faecal incontinence, commonly referred to as accidental bowel leakage, is a debilitating symptom that significantly impacts both quality of life and general health.

NICE guidance CG 49: Faecal Incontinence in Adults – Management confirms that the current epidemiological information shows that between one per cent and 10 per cent of adults are affected with faecal incontinence, depending on the definition and frequency of faecal incontinence used.

It is likely that 0.5-to-one per cent of adults experience regular faecal incontinence that affects their quality of life.

Understandably, faecal incontinence remains a largely hidden problem, with many patients hiding their symptoms from close family and friends.

Faecal incontinence is a socially stigmatising condition, and so healthcare professionals are encouraged to actively yet sensitively enquire about symptoms in high risk groups.

For some, conservative management will provide resolution of symptoms, while others will develop a long-term management plan or progress to surgery.

HIGH RISK GROUPS

- Frail older people
- People with loose stools or diarrhoea from any cause
- Women following childbirth (especially following third- and fourth-degree obstetric injury)
- People with neurological or spinal disease / injury (for example, spina bifida, stroke, Multiple Sclerosis, spinal cord injury)
- People with severe cognitive impairment
- People with urinary incontinence
- People with pelvic organ prolapse and / or rectal prolapse
- People who have had colonic resection or anal surgery
- People who have undergone pelvic radiotherapy
- People with perianal soreness, itching, or pain
- People with learning disabilities

GOOD PRACTICE IN MANAGING FAECAL INCONTINENCE

People who report, or are reported to have, faecal incontinence should be directed to healthcare professionals who have the relevant skills, training, and experience, and who work within an integrated continence service.

CONSERVATIVE MANAGEMENT SHOULD INCLUDE THE FOLLOWING:

- Disposable body-worn pads in a choice of styles and designs, and disposable bed pads if needed
- Pads in quantities sufficient for the individual's continence needs – it's inappropriate to limit the number of pads given
- Anal inserts / plugs – single-use medical devices that prevent leakage
- Skincare advice that covers both cleansing and barrier products
- Advice on odour control and laundry needs
- Disposable gloves

EMPOWERING PATIENTS

Pharmacists are ideally placed to support and educate and, in line with NICE CG49, should offer people with faecal incontinence advice on coping strategies, including:

- The use of continence products and information about product choice, supply sources, and use
- Where to get emotional and psychological support, including counselling or psychological therapy, where appropriate, to foster acceptance and positive attitudes
- Links to charities and groups that can provide support and strategies, such as planning routes for travel, to facilitate access to public conveniences, carrying a toilet access card or RADAR key to allow access to 'disabled' toilets

PROFESSIONAL SUPPORT CAN BE OBTAINED FROM THE FOLLOWING GROUPS:

- Pelvic Obstetric & Gynaecological Physiotherapists (POGP) – www.pogp.csp.org.uk
- Association of Continence Advisors (ACA) – www.aca.uk.com

REFERENCE

NICE guidance CG 49: Faecal Incontinence in Adults – Management

"I USED TO *DREAD* GOING AWAY...

NOW I HAVEN'T GOT A CARE IN THE WORLD!"

When Nicola, 72, started suffering from Accidental Bowel Leakage, she feared she'd never enjoy an active life again. Then she discovered Renew Inserts...

It's been eighteen years since Nicola, a mother of three, first experienced symptoms of Accidental Bowel Leakage (ABL) – a form of bowel incontinence that affects thousands of men and women of all ages in the UK.

'It was slight to start,' she says. 'I first noticed if I ate anything acidic, or if I was abroad and it was very hot. Then it gradually got worse as the years went on.'

Like many people who suffer from ABL, Nicola was embarrassed about the problem and initially found her own ways to manage – always leaving home with a bag full of panty-liners and spare underwear as a 'just in case'.

'At times it was very, very difficult,' she says. 'I used to dread going away, eating different foods. You just didn't know when it was going to happen. I wore dark underwear, dark trousers. I daren't go out in white trousers or white shorts.'

When she eventually sought medical help, Nicola was diagnosed with a weak anal sphincter. Though she was offered a form of treatment, getting to the hospital proved difficult – especially as she was also coping with the recent loss of her husband. 'I had so much to contend with,' she says. 'It was just a nightmare.'

Everything changed three years ago when Nicola came across a small advert for Renew Inserts in her newspaper. 'It was by pure chance,' she laughs, 'because I never look at adverts.' After phoning the Freephone number and speaking to a Renew advisor, she decided to order a free sample: 'I thought, what have I got to lose?'

Renew Inserts are clinically-tested product that helps to prevent involuntary bowel leakage. Made from soft, supple silicone that adapts to your body for a comfortable fit, the inserts are safe to wear day and night, and come with a hygienic fingertip applicator.

For Nicola, the transformation was immediate. Without the fear of an 'embarrassing accident' she was finally able to return to the things she loves. 'I do ballroom dancing, I do dance aerobics, I swim, I walk, I can do anything,' she beams. 'Even wearing white trousers and white shorts, which is something I haven't been able to do for donkey's years!'

Though she doesn't require one every day, Nicola makes sure she's always got a Renew Insert in her handbag – she laughs at how it's a lot more discreet than the panty-liners and spare underwear she used to carry.

I believe that Renew Inserts have done for ABL what tampons did for periods. 'They set you free,' she says. 'You can wear what you like, eat what you like and do what you like, whenever you like. I look forward to things again.'

Do you suffer from Accidental Bowel Leakage (ABL)?

- You have episodes of soiling yourself, sometimes without even realising you needed the toilet
- You experience these episodes frequently or from time to time (not just a one-off)
- The fear of an embarrassing episode prevents you from enjoying a normal, active life

Visit:
www.renew-medical.uk

Or call:
0800 542 0814

GETTING BACK ON TRACK

Research published in The Lancet, the world-leading UK medical journal, found that worldwide disability due to back pain has risen by more than 50 per cent since 1990 (1), standing as the leading cause of global disability. In more tangible terms, it is estimated that around 540 million people are experiencing low back pain at any one time (2), with this figure set to rise further in the coming years. In response to this startling – and clearly problematic – prevalence, Catherine Quinn, President of the British Chiropractic Association, discusses some of the latest research around treatment for back pain.

Catherine Quinn

Recent research from the British Chiropractic Association (BCA) found that people in Scotland experience back or neck pain the most frequently in the UK, with a third experiencing back or neck pain on a daily basis. (3)

BEARING WITH BACK PAIN

Back pain is an issue that will affect most adults at some point in their lives, so it is surprising that there remains a scarcity of research into its prevention and common misconceptions concerning its treatment. (4) In light of the latest research, the BCA is now joining other back pain management specialists across the world to raise awareness of the importance of protecting our spinal health and educating both patients and other healthcare professionals of the most effective treatment options available.

When leading a busy life, it is often easy to overlook the early warning signs of back problems. Recent research by the BCA revealed that women are more prone to neglecting their back health, taking twice as long as men to seek professional help for their pain. (5) Yet patients failing to pay enough attention to their back could increase the potential of experiencing persistent spinal pain. Although back pain can't be attributed to a single cause, there is strong evidence linking the condition with sedentary lifestyles, a problem that is becoming particularly pertinent amid the growing trend to spend long hours working behind a desk. Other lifestyle factors associated with poor health, such as smoking and obesity, have also been referenced as potential contributors to back pain (6), pointing to the changes we can make to prevent the condition.

WHAT IS CHIROPRACTIC?

Chiropractic is a regulated primary healthcare profession which encompasses the effective treatment strategies as outlined in The Lancet series. Chiropractors take a holistic approach to care, specialising in the examination, diagnosis, treatment, and management of conditions of the spine and other musculoskeletal conditions. Various evidence-based techniques are used by chiropractors to reduce pain, improve function, and increase mobility as part of a full package of care for managing low back pain which includes education and advice to stay active, spinal manipulation, massage, and exercise therapy as recommended by NICE. (7)

PREVENTION

As is the case with many ailments, prevention of back pain is always better than cure. Our bodies are not designed for inactivity, so it is crucial to keep moving on a regular basis to avoid musculoskeletal pain such as back or neck pain. My general advice for patients is therefore to incorporate more movement into their daily lives, reducing the amount of time spent sitting in one position and taking time to stretch regularly. In clinic, I find that patients are often surprised at the difference they feel just by making some simple changes to their daily routines, such as taking regular breaks from their desks to stretch and move or incorporating more exercise into their lifestyle.

The BCA provides practical advice to assist the one-in-10 Brits that continue to suffer in silence. (8) Straighten Up UK, a simple, three-minute stretching programme designed to improve posture and help prevent back pain by promoting balance, strength, and flexibility in the spine, is available for free on the BCA's website (www.chiropractic-uk.co.uk/straighten-up-uk).

RELIEF

Prevention is only one part of the wider story concerning back pain's prevalence in the UK and across the globe. While such steps are crucial in diminishing the likelihood of musculoskeletal pain, for those already in the throes of back pain it may be necessary to consider alternative methods. Nevertheless, such options must be approached with caution given the misconceptions that surround the treatment of the condition.

The recent review in The Lancet collates evidence for treatments for low back pain from multiple examples of high-level research, attesting to the benefits of gentle exercise and continuing daily activities. Additionally, the report makes a valuable contribution to the discussions dispelling ungrounded beliefs in best practice among healthcare professionals for the alleviation of back pain.

Billions of dollars continue to be spent on spinal fusion surgery in America, despite high rates of failure and limited evidence supporting its use. Furthermore, the referral of patients for imaging greatly increases their likelihood of receiving unnecessary care and surgery. (9) The 68 per cent of sufferers stating that they are still in pain for more than 12 hours per day despite treatment (10), strengthens the researchers' calls for the reduction of invasive spinal procedures and the crucial need for global strategies for managing the condition which are both cost-effective and personalised to the patient.

THE ROLE OF CHIROPRACTIC

At a time when alternatives to medication and surgery are required for treatment of back pain, the recent The Nordic Maintenance Care Program report (11) stands as a pivotal testament to the efficacy of chiropractic maintenance care in lieu of symptom-guided treatment. The report details a clinical trial, in which a group of patients with persistent or recurrent lower back pain were all initially given standard chiropractic care. Following this, these patients were randomised into one of two groups.

For the first group, the frequency of their visits over the following year were driven by the patients having recurring pain. For the second, a programme of Maintenance Care (MC) was implemented where the chiropractor themselves scheduled regular visits, aiming to see the patient before any reoccurrence or flare up of lower back pain occurred. The result for the group with MC was a marked and significant reduction of an average of between 10-to-15 days less with bothersome pain over a 52-week period. (12)

The authors conclude that visiting a chiropractor before low back pain reoccurred was more effective at reducing symptoms than seeking treatment only when the pain reoccurred. For those experiencing persistent back pain, paying a visit to a chiropractor could reward you with an extra two weeks per year of precious pain-free days.

The BCA strives to open up the conversation concerning treatment options for back pain in order to rectify the one-third of patients claiming that they have been poorly informed about new options to manage their pain. (13) Through increasing education on back pain and its treatment, preventative measures and chiropractic visits can entrench themselves as viable alternatives to painful, costly, and often ineffective, treatments.

ABOUT THE BRITISH CHIROPRACTIC ASSOCIATION

The British Chiropractic Association (www.chriopractic-uk.co.uk) is the largest and longest established association for chiropractors in the UK, representing over 50 per cent of all registered chiropractors across England, Scotland, Wales, and Northern Ireland. The British Chiropractic Association members are regulated by the General Chiropractic Council and required to maintain high standards of conduct, practice, education and training.

REFERENCES

1. The Lancet series on low back pain, The Lancet, Vol. 391, No. 10137
2. The Lancet series on low back pain, The Lancet, Vol. 391, No. 10137
3. Consumer research carried out between 28/02/2018 and 07/03/2018 on a sample of 2,066 UK adults aged 16+ on behalf of the British Chiropractic Association
4. The Lancet series on low back pain, The Lancet, Vol. 391, No. 10137
5. Consumer research carried out between 28/02/2018 and 07/03/2018 on a sample of 2,066 UK adults aged 16+ on behalf of the British Chiropractic Association
6. Musculoskeletal (MSK) conditions and back pain in Europe and the role of chiropractors; https://www.chiropractic-ecu.org/musculoskeletal-msk-conditions-and-back-pain-in-europe-and-the-role-of-chiropractors
7. NICE guideline NG59, November 2016
8. Consumer research carried out between 28/02/2018 and 07/03/2018 on a sample of 2,066 UK adults aged 16+ on behalf of the British Chiropractic Association
9. Musculoskeletal (MSK) conditions and back pain in Europe and the role of chiropractors; https://www.chiropractic-ecu.org/musculoskeletal-msk-conditions-and-back-pain-in-europe-and-the-role-of-chiropractors
10. The Lancet series on low back pain, The Lancet, Vol. 391, No. 10137
11. Eklund A, Jensen I, Lohela-Karlsson M, Hagberg J, Leboeuf-Yde C, Kongsted A, Bodin L, Axen I. The Nordic Maintenance Care program: Effectiveness of chiropractic maintenance care versus symptom-guided treatment for recurrent and persistent low back pain—A pragmatic randomized controlled trial. PLoS ONE 2018; 13(9): e0203029
12. Eklund A, Jensen I, Lohela-Karlsson M, Hagberg J, Leboeuf-Yde C, Kongsted A, Bodin L, Axen I. The Nordic Maintenance Care program: Effectiveness of chiropractic maintenance care versus symptom-guided treatment for recurrent and persistent low back pain – A pragmatic randomized controlled trial. PLoS ONE 2018; 13(9): e0203029
13. The Lancet series on low back pain, The Lancet, Vol. 391, No. 10137

PROMOTION

PHARMAPOD DELIVERS THE WORLD'S FIRST GLOBAL LEARNING SYSTEM FOR REDUCING MEDICATION ERRORS

According to the European Medicines Agency, medication errors account for roughly two million deaths per year worldwide. The global price tag of medication errors has been estimated at $42 billion annually – however healthcare professionals only report 14 per cent of them. Kyle Malone, Locum Pharmacist, MPharms MPSI, PhD Researcher, School of Pharmacy, University College Cork, tackles this data and shares how a platform for improvement to patient outcomes has emerged via the concept of a Learning Healthcare System.

Internationally, the study of healthcare systems has become increasingly common. Annually, the World Health Organisation alone compiles data on dozens of healthcare metrics – from life-expectancy, to financial fairness, to overall health expenditure.

At a glance, cross-country comparisons between nearly 200 nations can be made.

Nevertheless, lost among the decimal points and the soccer-style league tables are the answers to the most fundamental questions:

- Why do we collect healthcare system data?
- What, if anything, can we do with the results?
- Are there improvements being made and better patient outcomes as a result?

Despite the many differences in the provision of healthcare globally, overall some stark realities can't be escaped. In 2018, the worldwide demand for healthcare services continued to rise. At current growth rates, experts predict that by 2050 many countries will spend more than 20 per cent of gross domestic product in this sector.

When we speak of such increased demands on healthcare systems, what we really mean is an increased call for scarce resources. Rarely do the demands on healthcare systems shift from short-term, transactional goals (greater investment, faster access to new therapies) to more long-term issues of structure (quality, innovation, efficiency). The bottleneck, of course, is that the primary function of all healthcare systems – from single organisations to entire nations – is to meet the day-to-day needs of patients. These needs are increasing but the resources to meet the needs are decreasing in many cases. If, at the same time, a healthcare system wishes to root out inefficiencies and operate according to best practice, it needs to doggedly comb its past in search of lessons for its future. In short, a healthcare system needs to learn.

The concept of a Learning Healthcare System, or more broadly, a Learning Health System (LHS), is itself not new. First advanced in academic circles by the US Institute of Medicine in 2007, LHSs have since gained global traction. Unsurprisingly, the rapid evolution of the LHS concept has occurred against the backdrop of a decade where we've witnessed an explosion in health-related data. After all, information (be it biomedical or otherwise), is a central tenet in the LHS philosophy. Through a series of loops (commonly termed 'learning cycles'), information gathered on a health-related issue can be transformed into improvements on current practice.

By definition, LHSs have been described as 'sociotechnical systems for continuous improvement and innovation' that result in 'higher quality, safer, and more efficient care'. In essence though, any health system (at any scale) could become a LHS, so long as it made a commitment to routinely study and improve itself through the model described. That said, several key properties distinguish LHSs from their more conventional counterparts:

1. The characteristics and experience of every participant are available to learn from (D2K)
2. Best practice knowledge is immediately available to support decisions (K2P)
3. Improvement of the system is continuous through ongoing study
4. Infrastructure enables improvement to happen routinely and with economy of scale
5. All the above is part of the culture

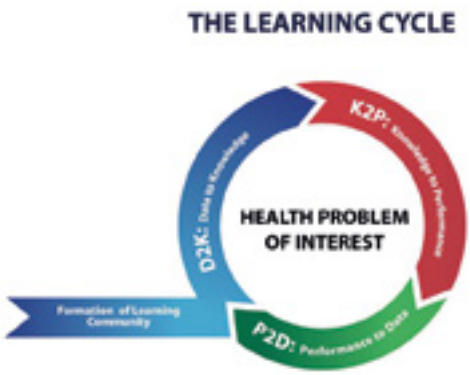


Figure 1

A key cornerstone of the LHS philosophy is the availability of a common infrastructure. Without one, each learning cycle requires its own technology, policies, staffing, and analytics. In a LHS, however, these building block services are instead shared across learning cycles. As a result, a LHS can function at a fraction of the overall cost, while still addressing a variety of unique health problems. The multitude of other benefits LHSs offer only become apparent when we consider one of these issues in more detail.

THE SCIENCE OF HEALTH LEARNING

The world's first medical school academic department dedicated to the Learning Health Sciences department was created at the University of Michigan in America.

Professor Charles Friedman, the Chair of the Department of Learning Health Sciences, and Editor-in-Chief of the Learning Health Systems Journal, believes that the principles of the LHS approach can be applied to accelerate reduction of health problems such as medication errors.

'If we continue to rely on journal articles as the means of dissemination, there will continue to be a 10, 15, 17-year latency before learning makes its way into practice. We need to find a way to interpret findings and codify knowledge. Automated systems could codify knowledge with machine executable guidelines and representations of information. These are potential methods that could be used to translate knowledge back into the efferent aspect of the cycle.' (1)

According to the European Medicines Agency, medication errors (preventable events that may lead to inappropriate medication use or patient harm) account for roughly two million deaths per year worldwide. Similarly, in the paper, 'Medication Errors: Technical Series on Safer Primary Care', published by the World Health Organisation in 2016, it states that in the UK it is estimated that, '38 per cent of all primary care patients over 75 may be affected by a medication error'.

REDUCING MEDICATION ERRORS VIA A LEARNING HEALTH SYSTEM

Evidently, the issue of medication errors could benefit from the LHS approach. Despite the staggering statistics noted however, healthcare professionals only report a paltry 14 per cent of medication errors, citing time required as the main barrier.

This vastly reduces the amount of data entering the learning cycle. Where data is gathered, limited analysis occurs, often because the information is only available in paper form. For the small amounts of data that do reach the interpretation stage, their final destination will almost certainly be the pages of a medical journal. Yet, in America alone, more than 800,000 medical studies are published each year. As a result, information which should be immediately applied in practice becomes lost in a sea of ever-growing biomedical knowledge. On average, it will take the same information 17 years to swim the path between publication and practice.

For a LHS to successfully tackle the issue of medication errors, a fully-integrated infrastructure is required. In terms of policy, several leaps forward have already been made, most notably the World Health Organisation's commitment to halve medication-related errors by 2020. Now, the stage is set for the introduction of technological solutions on a global scale.

THE PHARMAPOD GLOBAL LEARNING HEALTH SYSTEM FOR MEDICATION ERRORS

Pharmapod is creating a Global Learning Health System of the future. With over 10,000 pharmacies using its cloud-based platform internationally, it is providing the necessary infrastructure to enable improvement to happen routinely and with economies of scale – a key requirement of a true LHS.

Rather than gathering data to satisfy regulatory requirements alone, healthcare professionals can now engage in the LHS approach. Information about medication errors and near-misses – from single pharmacies to multiple sites – can be regularly collated. From there, the platform can carry out an effective root-cause analysis and offer pharmacists a mechanism to track their preventative measures and imporvements to their own practice.

When actions are taken, the platform can evaluate the impact on practice, thus completing the learning cycle. The Pharmapod platform can get the right information to the right person(s) at the right time, locally in each pharmacy as well as on an aggregate basis through each of Pharmapod's National 'Response Teams' made up of local academics and medication safety experts.

Pharmapod's founder and CEO, Leonora O'Brien, is a pharmacist. This is key to its success. One of the reasons IT systems in healthcare have limited benefit is because when they are developed commercially, they are very rarely developed by healthcare professionals.

IMPORTANCE OF A JUST CULTURE

Melissa Sheldrick, a mother who tragically lost her eight-year-old son Andrew through a medication error in 2016, has been involved in the Pharmapod training in Ontario, Canada. Here, she explains how the right culture must be present to enable a LHS to flourish.

Andrew Sheldrick

Analysing and collaborating on how to prevent incidents from occuring or reocurring is an essential piece of a pharmacy team's work. The objective must be to adopt a 'systems approach' and not a 'person approach' when dealing with incidents. A 'person approach' focusses on what the person did wrong and blames them, whereas a 'systems approach' concentrates on examining the conditions the person works under, the training that is in place, and the supports they have.

This system aims to build preventative measures into the healthcare organisation's processes so that the same errors do not recur. When there is a culture at work that does not apportion blame but instead strives to support your development as a professional, that is when the learning occurs. This is the reason Pharmapod also now offers a platform to objectively measure an organistion's Patient Safety Culture and provides training to help embed a just, non-punitive culture of safety and learning.

REFERENCE

1. The Learning Healthcare Project: Professor Charles Friedman Interview. Available online: http://www.learninghealthcareproject.org/section/evidence/25/50/professor-charles-friedman-interview

GUT MICROBIOTA

A GUT FEELING

Did you know that the human body has over 100,000 billion bacteria in the gut alone, located mainly in the colon? With the past decade having marked a growing interest in the importance of gut microbiota to health, Professor Glenn Gibson, Department of Food and Nutritional Sciences, University of Reading, strengthens our awareness of human gut microbiota and prebiotics, and summaries some of the segments of research relating to this area.

Although information about the microbial composition of this ecosystem in health and disease remains incomplete, it is known that the GI tract contains five-to-six phyla, 50-to-60 different genera, and over 1,000 different species of bacteria. Together these make the gut the most metabolically active organ in the body. About 70 per cent of our immune system also lies within the gut and the microbiota has a complex interaction with it, helping to protect us from infection and disease.

Professor Glenn Gibson

Many diseases have been linked in some way to the microbiota, including ulcerative colitis, irritable bowel syndrome (IBS), peptic ulcers, and bowel cancer. Some bacteria are well-known as pathogens – species of enterobacteria or clostridia, for example, may cause infections, diarrhoea, liver damage, or produce carcinogens. Fortunately others, especially lactobacilli and bifidobacterial, inhibit the growth of harmful bacteria, aid the digestion and absorption of food, synthesise vitamins, reduce inflammation, and stimulate immune function.

There is now a heavy focus on therapeutic modulation of the microbiota as a way to optimise health and prevent disease. Tactics range from interventions during pregnancy and delivery of a newborn (when we are seeded with microbes from our mother and family), to lifestyle and dietary modifications throughout development and adult life. More specific interventions, such as faecal transplants, are also under study.

Taking the view that the gut is an ecosystem, one of the simplest ways to improve the health of that ecosystem is to manipulate the diet, because this is the main driver for the composition and activity of the gut microbiome.

AT LEAST TWO APPROACHES CAN BE USED

Firstly, live microbes, known as probiotics, can be added to the diet. Nearly 20,000 research articles have now been published on probiotics. Although the use of probiotics in diarrhoeal disease has been most extensively studied to date, a growing number of studies have explored the use of probiotics for use in conditions such as inflammatory bowel disease (IBD) (with particularly promising data in pouchitis); constipation; lactose intolerance; and for use as adjunctive therapy in H. pylori eradication.

Bifidobacteria and lactobacilli are the commonest types of bacteria used probiotics in order to fortify the intestinal microbiota. Currently there is something of a dichotomy between what the science is telling us and the (absence of) health claims that are allowed to be made to consumers. As a result, throughout Europe advertising for probiotics remains rather nebulous. There is a need to demonstrate more clearly which products have been shown in good studies to help in which conditions and therefore eligible for transparent claims.

Alternatively, by including basic foods or supplements in the diet that will act as growth substrates, it's possible to selectively promote an individual's existing 'healthy microbiota'. Put simply, this means feeding your own bacteria with what they need to flourish.

These foods are known as prebiotics, and they can be defined as 'a substrate that is selectively utilised by host microorganisms conferring a health benefit'. It can be compared to using a fertiliser to help the growth of the positive components of gut microbiota. It is possible to target, in a specific way, particular microbes indigenous to the gut microbiota that carry positive health benefits.

This happens during breast-feeding, for example, where bifidobacteria become very dominant in the gut as a result of high levels of oligosaccharides found in breast milk.

Sources of prebiotics include several natural foods such as asparagus, onion, artichoke, bananas, leeks, and chicory. But manufactured forms are now being developed as dietary supplements or processed food ingredients. Most interest in the development of prebiotics has been aimed at non-digestible oligosaccharides, such as inulin-type fructo-oligosaccharides and galacto-oligosaccharides. Both have been shown to be prebiotics, through numerous reproducible volunteer trials, as evidenced by their ability to positively change the gut microbiota composition after a short feeding period. They have been tested in IBS, IBD, obesity, Travellers' Diarrhoea, atopic issues, infants, and elderly people. Trials that include a functional, as well as compositional, assessment of microbiota changes following prebiotic may be a useful way forward, as are further studies into clinical outcome.

EXAMPLES OF SOME PREBIOTIC STUDIES

A trial of prebiotics in infants using a GOS/FOS (9:1) prebiotic at 8g/L for two months showed that when prebiotics were added to a formula feed, this could generate similar levels of faecal bifidobacteria and lactobacilli to those seen in breast-fed babies, and significantly more ($p<0.05$) than in babies fed with

standard formula milk.
Ref: Ivakhnenko and Nyankovskyy (2013) Pediatr. Polska 88: 398-404

In atopic dermatitis, a prebiotic infant formula was shown to be beneficial in reducing the disease burden. In one study, infants at risk of atopic disease were given prebiotic formula (0.8 per cent GOS/FOS 9:1) or control (0.8 per cent maltodextrin) for six months. At follow-up at 18-to-24 months, dermatitis was reduced in those given the prebiotic. It's thought that this inflammatory dampening effect is due to cell wall structures of bifidobacteria, which were selectively enhanced with the prebiotic.
Ref: Moro et al. Arch Dis Child 2006; 91: 814-819

In a five-year follow-up of infants given a prebiotic formula or placebo for the first six months of life, significant benefits were shown across allergic disease in general ($p = 0.01$) and, more specifically, atopic dermatitis ($p = 0.05$) rhino-conjunctivitis ($p = 0.08$) and allergic urticarial ($p = 0.08$). This suggests that early programming of the microbiota is critical in producing lasting effects on health.
Ref: Arslanoglu et al. (2012) J Biological Regulators and Homeostatic Agents. 26: 49-59

A double blind placebo-controlled study in health volunteers showed that a GOS prebiotic developed at the University of Reading had a striking bifidogenic effect at a daily intake of 1.37g of active ingredient (at 3.6g/d and 7g/d dose of GOS). The bifidogenicity and prebiotic effect of GOS followed a dose response relationship, and led to levels of bifidobacteria similar to those seen in the gut flora of breast-fed infants. The prebiotic value of GOS was attributed solely to bifidogenicity.
Ref: Depeint et al. (2008) American Journal of Clinical Nutrition 87: 785-791

As we age, levels of bifidobacteria and other health-promoting genera decrease while, concomitantly, gut inflammation increases. A further trial of GOS in older people demonstrated significant increases in bifidobacteria numbers after five weeks, followed by a further significant increase after another five weeks of treatment. At the end of the 10-week treatment, the bifidobacterial profile of the elderly subjects was similar to that of healthy adults. In the same study, beneficial effects on immune function markers were shown with this GOS prebiotic compared to placebo, with a favourable shift in cytokine ratios towards a less inflammatory picture. Results included effects on IL-6 ($P<0.001$) IL-10 and TNF-a ($P<0.01$) and IL-1b ($P<0.05$) as well as enhanced phagocytic activity against E. coli. Significant improvements were also shown in NK and T cell activities compared to placebo.
Ref: Vulevic et al. (2008) American Journal of Clinical Nutrition 88, 1438-1446
Ref: Vulevic et al. (2015) British Journal of Nutrition 28, 1-10

Human studies have looked at the prebiotic GOS in IBS. This is said to affect about 20 per cent of the population of Western countries, including the UK. Levels of bifidobacteria may be reduced in IBS. In a single blinded randomised placebo-controlled study, patients with diarrhoea, constipation, and alternating types of IBS were given four weeks of prebiotic. The study demonstrated increases in faecal counts of bifidobacteria and lactobacilli. When symptoms were assessed, significant improvements were seen in stool consistency, flatulence, bloating, subjective global assessment, composite score of symptoms, and anxiety.
Ref: Silk et al. (2009) Alimentary Pharmacology and Therapy 29, 508-518

About eight years ago, there was a flurry of interest in reports suggesting that people with obesity and at risk of metabolic syndrome and type 2 diabetes had a different gut microbiota to those who are lean, with links to appetite, satiety, and inflammation in the gut. The potential benefits of GOS were demonstrated in a 12-week placebo-controlled cross over study in overweight people with risk factors for metabolic syndrome. The study showed a very specific effect on levels of faecal bifidobacteria as well as a reduction in bacteroides. By week 12, markers of inflammation had fallen (plasma C-reactive protein $p<0.0012$ and faecal calprotectin $p<0.0001$). There was also a significant fall in plasma triglycerides and cholesterol:HDL-cholesterol ratio in men but not women taking GOS. However, no changes were seen in terms of weight or blood pressure. Longer treatment regimens may be needed to achieve this.
Ref: Vulevic et al. (2013) Journal of Nutrition 143, 324-331

Studies have also shown benefits from prebiotic supplements when used by people travelling abroad. One such trial looked at people travelling to low or high-risk countries who had been randomised to either maltodextrin (a placebo) or GOS. They were monitored for frequency of bowel motions (number per day), nature of motions (semi-solid, watery, bloody), impact of symptoms of Travellers' Diarrhoea (none, mild, moderate, or severe), and the presence or absence of abdominal pain and vomiting. The results showed a significant reduction in the incidence and duration of diarrhea among people travelling abroad for at least two weeks. There was also a non-significant reduction in abdominal pain. While microbiological tests could not be done on the group, bifidobacteria are known to be powerful inhibitors of pathogens including enteropathic E.coli, Campylobacter and other common causes of acute diarrhoea.
Ref: Drakoularakou et al. (2010) European Journal of Clinical Nutrition 64: 146-152

A further benefit of increasing bifdobacteria levels is that this genus has an inability to manufacture gas as part of its metabolism and so increasing levels using GOS may help to reduce bloating and flatulence. Trials using GOS reflect this, with low levels of bloating and flatulence reported.

Further clinical studies with GOS and other prebiotics are underway and to firmly consolidate the safe role of prebiotics in maintaining health.

STRIKING BACK

The on-set of a new year is the ideal time to take stock of the opportunities which line our way. And when it comes to society's frayed understanding of strokes – and lack of recognition of the risks – that means considering the potential power of innovation. SPR overviews the new insights into the causes and impact of strokes, which we can equip ourselves with when dealing with this life-threatening medical condition.

NO SMOKE WITHOUT FIRE

A flurry of new studies are helping to reroute our thinking regarding the contributory factors of a stroke's occurrence. Of key concern – particularly due to the habit's prevalence – is the suggestion that using e-cigarettes increases the odds of having a stroke, as well as suffering from a heart attack, and coronary heart disease.

In the largest study to date examining e-cigarettes and stroke, researchers tapped a database of 400,000 respondents; finding that compared with non-users, e-cigarette users had:

- 71 per cent higher risk of stroke
- 59 per cent higher risk of heart attack or angina
- 40 per cent higher risk of coronary heart disease
- 4.2 per cent of e-cigarette users reported having suffered a stroke

ONE THING AFTER ANOTHER

When forging our treatment plans for stroke sufferers, it's important to encourage a new era of awareness concerning their progress, and the potential risks posed by the aftermath journey.

To help keep track of the patient's post-stroke status, a new computer programme has been developed by scientists at the Universities of Edinburgh and Glasgow to assess whole brain deterioration, and to help predict cognitive function after the stroke up to 10-times more accurately than current methods.

The new approach – published in the International Journal of Stroke – can quantify visible brain injury from cerebral small vessel disease and brain atrophy by translating the million-plus bits of information stored in brain scans into a single measure: the 'brain health index'.

This innovation may also provide early warning of the risk of future cognitive decline in individuals before they notice any symptoms – sculpting how immediate patient care can be provided.

Dr David Alexander Dickie, from the University of Glasgow's Institute of Cardiovascular and Medical Sciences, explained, 'We recognised a need for a more inclusive approach to assessing common brain disorders of ageing. Our new method allows us to use every piece of information from a brain scan, rather than just individual features of the brain that can only tell us so much about a person's risk for cognitive problems.'

A MENTAL NOTE

Integral post-stroke territory which mustn't be neglected by healthcare providers is the impact of the condition on the patient's mental health – as despite the fact that the severity and symptoms are wide-ranging, about one-third of all survivors experience depression following their stroke: approximately 400,000 people in the UK today. There's been a worrying female focus at recent, too, with data indicating that women are twice as likely to suffer from severe depression following a stroke than men.

Directing us to this cause for concern, the team of researchers from King's College London followed the progress of symptoms over five years after stroke on-set in 2,313 people (1,275 men and 1,038 women) – finding that 20 per cent of women suffered from severe depression compared to 10 per cent of men. They also detected varying patterns of symptom progression; that long-term increased symptoms of depression are associated with higher mortality rates; and that initially moderate symptoms in men tend to become worse over time.

Lead author, Dr Salma Ayis, from the School of Population Health & Environmental Sciences at King's College London, said, 'While we cannot pinpoint exactly why depression is more common among women, it could be that women draw more of their sense of self and self-worth from their social relationships and so are more sensitive to challenges in maintaining these. Also, as women live longer, they are more exposed to loneliness, poor physical health, and loss of support, all of which could lead to depression.

'What is common to both sexes is the dramatic decrease in the likelihood of survival as depression symptoms increase. We believe, therefore, that by monitoring symptoms of depression in stroke survivors and acting accordingly, clinicians may be able to provide better long-term care.'

STROKE STATISTICS

- An estimated one-in-six people worldwide will have a stroke in their lifetime
- According to Different Strokes, 25 per cent of strokes happen in people under the age of 65
- There are more than 100,000 strokes in the UK every year
- There are 1.2 million stroke survivors in the UK
- Stroke doesn't just affect adults, as every year around 400 children in the UK will have a stroke, according to the Stroke Association

For your eligible patients with NVAF:

ONCE-DAILY LIXIANA®▼ (edoxaban)

- **Superior reduction in major bleeding** vs. well-managed warfarin[1]
- **Proven stroke/SEE prevention** comparable to well-managed warfarin[1]
- **Simple & convenient** once daily dosing, with or without food[2]

Indicated for:[2]

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

In NVAF patients with high CrCl, there is a trend towards decreasing efficacy with increasing CrCl for edoxaban vs well-managed warfarin, therefore careful evaluation of thromboembolic and bleeding risk is necessary before initiation.

RECOMMENDED BY NICE AND SMC ACCEPTED[3,4]

The primary safety endpoint was the incidence of adjudicated major bleeding as defined by the International Society on Thrombosis and Haemostasis (ISTH)[1,5]

once-daily Lixiana® edoxaban

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

See Lixiana Summary of Product Characteristics (SmPC) prior to prescribing for full list of adverse events

Presentation: 60 mg (yellow) / 30 mg (pink) / 15mg (orange) edoxaban (as tosilate) film-coated tablets.

Indications: 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. **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 x ULN) or total bilirubin ≥ 1.5 x 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. **Drug interactions:** Concomitant use of the *P-gp inhibitors* ciclosporin, dronedarone, erythromycin, or ketoconazole requires edoxaban dose reduction to 30mg. 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:* thrombocytopaenia, 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: August 2018. EDX/18/0379

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

References: 1. Giugliano RP *et al. N Eng J Med* 2013;369(22):2093–2104. **2.** LIXIANA® Summary of Product Characteristics. **3.** NICE Technology appraisal guidance [TA355]. September 2015. **4.** Scottish Medicines Consortium advice. SMC No. (1095/15). October 2015. **5.** Schulman S *et al. J Thromb Haemost* 2005;3(4):692–694.

www.lixiana.co.uk

Daiichi-Sankyo

FEELING THE PRESSURE

As male mental health is catapulted further into the spotlight, so, too, must be the roots of their unwarranted sense of insecurity – one of which is erectile dysfunction. With cases of the condition being attributed to both psychological and physical triggers, SPR confronts a number of the unexpected causes.

Entrapped in a minefield of work worries, daily duties, and the pressure of fulfilling society's stereotype of masculinity, the mental health of men calls for careful attention. Erectile problems can be a key aggravator of anxiety – and vice versa, with it being estimated that half of all men between the ages of 40 and 70 will have them to some degree.

As a result, it's crucial that we get to the crux of the problem as soon as possible; exploring the potential causes, while simultaneously advocating the importance of open discussion, and the availability of confidential, professional advice.

The inability to obtain and maintain an erection sufficient for sexual activity is a common and costly condition of men of primarily middle and older ages. It's also one that can elicit much confusion due to the fact that homing in on the key source of influence means assessing the many possible contributors, such as neurological, hormonal, and vascular factors.

Treatment for erectile dysfunction has significantly improved during the last 10 years, but with new research surrounding these possible triggers emerging, we must continue to hone our awareness.

IN THE GENES?

A recent discovery has advanced our understanding of the genetics underlying erectile dysfunction – outlined in the study, 'Genetic Variation in the SIM1 Locus is Associated with Erectile Dysfunction,' which is published in the journal, Proceedings of the National Academy of Sciences.

The study pinpointed that variations in a specific place in the genome – called a genetic locus – near the SIM1 gene are significantly associated with an increased risk of erectile dysfunction. Also demonstrated was a biological role for the genetic location in regulating sexual function, strongly suggesting that these variations can cause erectile dysfunction.

'Identifying this SIM1 locus as a risk factor for erectile dysfunction is a big deal because it provides the long sought-after proof that there is a genetic component to the disease,' commented the study's lead author, Eric Jorgenson, PhD, a Research Scientist at Kaiser Permanente Northern California's Division of Research.

THE DIABETES LINK

Echoing the findings that erectile dysfunction has a genetic cause, and going further by opening the possibility that living a healthier lifestyle may help reduce risk, is a study led by the University of Exeter and the University of Oxford, which looked at data on more than 220,000 men across three cohort; 6,000 of whom experienced erectile dysfunction.

Utilising genetic analysis, the team were able to delve into the complex correlations between diabetes and aspects including body weight. They subsequently found that having a genetic predisposition to type 2 diabetes was linked with erectile dysfunction, providing evidence that diabetes can be a cause of erectile issues.

Professor Michael Holmes, of the Nuffield Department of Population Health at the University of Oxford, one of the study's lead authors, explained, 'Our finding is important as diabetes is preventable and indeed one can now achieve 'remission' from diabetes with weight loss, as illustrated in recent clinical trials. This goes beyond finding a genetic link to erectile dysfunction to a message that is of widespread relevance to the general public, especially considering the burgeoning prevalence of diabetes.'

RESTING THE CASE

While nocturia and poor sleep quality have been linked to such daytime problems as difficulty concentrating, a general lack of energy and irritability, or impulsive behaviours, three insights presented at the 113th Annual Scientific Meeting of the American Urological Association highlighted the association between poor sleep quality, nocturia, low testosterone, erectile function, elevated body mass index, and even death.

Researchers assessed the relationship between sleep and erectile function while controlling for age, BMI, burden of comorbidity, testosterone, and PDE5 inhibitor use. Caffeine, melatonin, and other sleep medication use, CPAP use, shift work, smoking, depression status, and antidepressant use were also examined.

'These studies point to some very alarming consequences for men with impaired sleep habits,' said Dr Tobias S Köhler, MD, MPH, FACS, Men's Health Specialist and Urologist with the Mayo Clinic in Rochester, MN.

'Men should be aware that a commitment to improving one's sleep habits could lead to improved erectile function along with a host of many other established health benefits that accompany a good night's sleep.'

VITAROS®
URETHRAL ALPROSTADIL CREAM

VITAROS® IS THE ONLY URETHRAL ALPROSTADIL IN A CREAM[1-3]

Find out more about the **efficacy and safety** of VITAROS® and why it is a first choice alprostadil for patients with erectile dysfunction (ED) at **www.vitaros.co.uk**

- **VITAROS®** works when the cream is applied directly into the urethra[3–5]
- **VITAROS®** works when stored in a refrigerator between 2-8°C[4] immediately after purchase
- **VITAROS®** works with prolonged use and may be applied up to 3 times per week[4,5]*
  - Use of **VITAROS®** 8 times a month provides noticeable results, with continued use associated with increased efficacy vs baseline[5]

If clinicians believe more than one treatment a week is appropriate to treat ED in their patient, this can be prescribed on the NHS[6,7]

VITAROS® works when stored and applied correctly at the recommended frequency. Find out why **VITAROS® is a first choice alprostadil** at **www.vitaros.co.uk**

*Only once per 24 hour period

References: 1. Moncada I and Cuzin B. *Urologia* 2015;82(2):84–92. **2.** Cuzin B. *Ther Adv Urol* 2016;8(4):249–256. **3.** Padma-Nathan H and Yeager JL. *Urology* 2006;68:386–391. **4.** VITAROS® Summary of Product Characteristics 2016. Available at: https://www.medicines.org.uk/emc/medicine/28866. Date accessed: July 2018. **5.** Rooney M, *et al. J Sex Med* 2009;6:520–534. **6.** NHS Executive. Health Service Circular. 1999. Available at: http://webarchive.nationalarchives.gov.uk/20121012055159/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012086.pdf. Date accessed: July 2018. **7.** National Institute for Health and Care Excellence. Clinical Knowledge Summaries. Erectile dysfunction. December 2017. Available at: https://cks.nice.org.uk/erectile-dysfunction#!uptodate. Date accessed: July 2018.

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

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 Ferring Pharmaceuticals Ltd. Tel: 0800 111 4126. Email: medical.uk@ferring.com

FERRING
PHARMACEUTICALS

ASTHMA

A TEST OF TIME

Expert tips and resources; devices and case studies – over time they've all been subscribed to by healthcare professionals and patients alike as mainstays of asthma diagnosis. However, with new variables generating increasing interest, SPR takes a look at how the process may be more complicated than we thought.

With the relaxed ease of recalling our own phone number or relaying a well-rehearsed fact, the majority of us can conjure up the name of at least one person in our life who has been diagnosed with asthma. Rather than a reflection of our incessant research – this is simply a sign of how common the chronic inflammatory airway disease is in our present day.

In fact, as reported by the British Lung Foundation, eight million people – over 12 per cent of the population – have been diagnosed with asthma. This means that more people have had an asthma diagnosis than have been diagnosed with all other lung diseases combined.

In order to meet its prominence, healthcare professionals have expanded their knowledge base – particularly when it comes to diagnosis, and the variability of individual patients and their needs. However, we must be careful not to submit to the perception that we have all the information required.

For example, the asthma-related statistics don't necessarily portray reality; demonstrating just how complex matters of diagnosis are. Children diagnosed with asthma can grow out of it, with Asthma UK stating that around 5.4 million people receive treatment for the disease. As such, there's ongoing concern that asthma may be considerably over-diagnosed.

AS CLEAR AS DAY?

It's also important to bear in mind that influential factors for diagnosis may be beyond the realms of the patient's current wellbeing or medical background.

Research has hurtled towards the possibility that the human body clock significantly impacts on sample results used to diagnose and treat asthma when taken at different times of the day – therefore having implications as to how the respiratory condition is diagnosed and treated in the future.

Dr Hannah Durrington, Senior Clinical Lecturer at The University of Manchester, who led the research, funded by Asthma UK, explained that the test results from an asthma patient taken in the morning differ from those taken from the same patient in the afternoon. The process entailed analysing blood, in addition to the mucus coughed up from the lungs, and the breath of 10 moderately severe asthmatics, and 10 healthy volunteers at different times of the day.

Indicative of how change can be activated, the asthmatic volunteers displayed greater narrowing of their airways in the early hours of the morning than in the afternoon, and this corresponded with a change in inflammatory cells – or eosinophils, measured in their sputum. Sputum eosinophil levels can be used to guide treatment in severe asthma patients.

The research also revealed that sputum eosinophil levels can vary considerably between the morning and afternoon; they were higher in the morning, and lower in the afternoon.

Dr Samantha Walker, Director of Research and Policy at Asthma UK, commented on the new consideration for asthma diagnosis, saying, 'People's body clocks are incredibly powerful. This research, which we are proud to help fund, shows that for the 5.4 million people in the UK who have asthma, the results of an asthma test could differ depending on the time of day the test took place. While this research is at a very early stage, it could have a significant impact on when people with asthma are tested at some stage in the future. We look forward to seeing the results of the next stage of the team's research in this area.'

AGAINST THE CLOCK

The complicated relationship between asthma and time can be wielded for the welfare of patients – in that if the body clock controls the inflammatory response, we may be able to target the conditions at certain times of the day to have the most benefit. New findings – led by researchers at Dr Annie Curtis' Lab at the Royal College of Surgeons in Ireland in partnership with Professor Luke O'Neill's Lab at Trinity College Dublin – may also shed light on why individuals who experience body clock disruption, such as shift workers, are more susceptible to inflammatory conditions.

Dr Jamie Early, first author on the study, explained, 'We have made a number of discoveries into the impact of the body clock in macrophages on inflammatory diseases, such as asthma and Multiple Sclerosis. However, the underlying molecular mechanisms by which the body clock precisely controls the inflammatory response were still unclear. Our study shows that the central clock protein, BMAL1, regulates levels of the antioxidant response protein NRF2 to control a key inflammatory molecule called IL-1β from macrophages.'

Intelligently designed.
Simple to use.[1,2]

The first and only ICS/LABA fixed-dose combination (FDC) delivered in a breath-actuated aerosol inhaler.[3]

References:

1. Mundipharma International Limited. flutiform k-haler. Summary of Product Characteristics. Available from: www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1533874768129.pdf Last accessed September 2018.
2. Bell D et al. J Aerosol Med Pulm Drug Deliv 2017; 30:425–34.
3. MIMS. Available from: www.mims.co.uk/search/drugs?keywords=Beta 2 agonists,long-acting/corticosteroids. Last accessed July 2018.

***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.

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

ALCOHOL

SETTING THE BAR

If you're a social media stalwart, you may have been privy to the onslaught of posts revolving around New Year's resolutions over the last few months, with unrealistic promises at times taking precedence. But this year, why not help your patients make a lifestyle transformation which has benefits which far surpass merely the 12 months of 2019? While many people enjoy social drinking, we definitely have a serious drinking problem in that every year far too many are harmed or even killed by alcohol, often cheap alcohol, either by getting serious illnesses or by being involved in accidents, fights, or as victims of domestic abuse fuelled by it. Fiona Sim, Chief Medical Advisor to Drinkaware UK, shares her know-how for cutting down, or stopping, excessive drinking.

Fiona Sim

It does not have to be in our culture to drink to excess, but certainly many popular activities – sporting, celebratory, social – are almost by tradition linked with drinking too much alcohol. However, in the UK, younger people are drinking less than previous generations and that trend is likely to continue. But by contrast, among men and women aged 45-to-64, we are seeing increasing numbers drinking substantially more than the upper limits in the Chief Medical Officers' (CMOs) low risk guidelines (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/545937/UK_CMOs__report.pdf).

It's common for people who drink regularly at potentially harmful levels not to acknowledge it for quite some time. It's problematic for most people to answer honestly if they find it difficult to enjoy themselves or relax without having a drink: but if they do, it's possible they have become dependent on alcohol. Although statistically one-in-five UK adults drinks more than the CMOs' low risk guidance of not more than 14 units a week for both men and women, three-quarters of people surveyed nationwide in 2018 claimed that they didn't drink too much.

14 units equates to (just) six standard 175ml glasses of wine (13 per cent alcohol by volume) or six pints of beer (four per cent alcohol by volume).

KNOWLEDGE IS POWER

Health professionals need to know what problems alcohol can cause in order to answer their patients' questions or to raise the subject with them sensitively. Drinking alcohol increases the risk of getting a whole range of serious long-term medical problems, from heart and liver disease, to several types of cancer and mental health problems.

As well as causing diseases, alcoholic drinks contain a lot more calories than most of us realise, and so drinking less can be an effective incentive for those needing to lose weight.

Last but not least, people who have drunk alcohol are far more likely to be involved in any sorts of accidents and in domestic violence.

Health professionals might be asked about the health benefits of alcohol. Although there is some evidence to suggest that a small amount of alcohol might be associated with less chance of getting certain types of heart disease in people over 55 years of age, this one possible benefit is greatly outweighed by the risks of all the other medical problems if you drink alcohol regularly.

Most experts now say that there is no completely safe level of drinking, so it is important that we understand the risks when we offer advice about drinking.

STAYING ON-TRACK

People can count and keep track of the number of the units they drink week-by-week, by using one of the free apps that are available for smartphones – for instance, the Drinkaware app (www.drinkaware.co.uk/tools/app). That can help someone to see how much they are drinking and also to monitor their efforts to cut down. They can also keep track of drink-free days, using the Drink-Free Days website (www.drinkfreedays.co.uk).

For health professionals, it's important to know that there is evidence that identification and brief intervention (IBA) can be effective, and it takes only a very few minutes to administer. Visit www.e-lfh.org.uk/programmes/alcohol to access free self-guided online training on IBA, tailored for primary care, pharmacy, dentistry, and hospital settings.

BENEFITS OF CUTTING DOWN SUBSTANTIALLY OR STOPPING COMPLETELY

APPEARANCE

Firstly, a lot of people don't realise that alcohol causes dehydration, and one place that really shows is their skin. Dry skin, often with a flushed complexion, isn't a look most of us would choose. Secondly, the calories in alcohol often go unrecognised and contribute to being overweight and obese. A great way to lose weight is to cut down on alcohol.

MIGRAINE

In some people, migraine seems to be triggered by alcohol. This can be any alcoholic drinks or a specific one, so it's worth patients keeping a diary of what they eat and drink to identify what their triggers are. If they have alcohol-related migraines, the individual might need to stop drinking completely to prevent them.

CANCER RISK

Alcohol has been proven to be linked with seven types of cancer, including breast cancer, bowel, and some other common cancers. Not drinking or drinking within low risk guidelines reduces the risk of these cancers.

For more information, visit www.drinkaware.co.uk.

SWEET TALK

Good child health is the key to a healthier, more prosperous society – but as we move forward into 2019 and beyond, we need action from the government, at local level, and from parents themselves. With this joined-up approach, we will be well on our way to winning the race against childhood obesity, explains Dr Max Davie, Officer for Health Promotion at the Royal College of Paediatrics and Child Health.

Dr Max Davie

Knowing how much sugar you are consuming is like trying to win a 100m sprint while wading through treacle. It's exhausting for parents to know how much their child can safely have, and if they do happen to find out, the information presented on product packaging can be misleading or hard to interpret.

How much sugar can my child eat? The government recommends that free or added sugars shouldn't make up more than five per cent of the energy (calories) you get from food and drink each day. Children aged between four and six should have no more than five sugar cubes (19g); those aged between seven and 10 should have no more than six sugar cubes (24g); and children over the age of 11 should have no more than 11 cubes (30g). When a can of coke contains the equivalent of nine cubes of sugar, you can begin to see how easy it is for a child to reach and exceed their daily limit very quickly.

The main sources of sugar in children's diets are sugary soft drinks which have more sugar than ice cream and puddings combined. Other main sources of sugar include coke, buns, pastries and cakes, biscuits, and sugary breakfast cereal and confectionary. These can be easy go-to items, but unfortunately the impact of enjoying too many of these items too often isn't so enjoyable.

Too much sugar can lead to tooth decay, with carbonated drinks, both sugar-free and those containing sugar, leading to enamel erosion. Research has also linked the high acidity of these drinks to incidence of dental carries. Nearly half of 15-year-olds have some form of tooth decay and the painful condition remains the number one reason why children aged five-to-nine are admitted to hospital, costing millions of pounds a year to treat, and putting them through the unnecessary stresses of surgery. Excess sugar also leads to obesity, and with a third of children overweight or obese by the time they leave primary school, helping families cut down on sugar needs to be a top priority. Failure to do so makes these children more likely to become overweight or obese adults, have children who are overweight themselves, and go on to develop serious preventable health conditions, including type 2 diabetes, heart disease, and some cancers.

The food industry has already been challenged to cut 20 per cent of sugar from a range of products by 2020, and reduce sugar levels by at least five per cent in the first year. Businesses are encouraged to focus their efforts on their top selling products within 10 categories by reducing sugar levels, reducing the portion size, or encouraging consumers to purchase lower or no sugar alternatives. But the latest figures show that of the top 20 brands, only a third achieved any sugar content reduction – and worryingly 12 per cent increased the amount of sugar in their products. The five per cent reduction target for the first year has only been met by three food groups – breakfast cereals, sweet spreads and sauces, and yoghurts and fromage frais – so meeting the 20 per cent target by 2020 doesn't seem achievable.

In June 2018, Public Health England warned that children in England had already consumed more than a year's worth of sugar in just six months. They revealed that children aged between four and 10 were consuming on average 13 cubes of sugar a day, putting them on-track to consume around 4,800 cubes of sugar by the end of the year – that's more than double the maximum recommendation.

SO HOW DO WE PREVENT THIS FROM HAPPENING AGAIN IN 2019?

Families can:

- Try swapping sugary snacks like cakes, biscuits, chocolate, and sweets for fruit, plain rice cakes, and toast, using lower fat spread
- Fruit juice and smoothies should be limited to a combined total of 150ml per day – but try swapping fizzy drinks for water, sugar-free, or no added sugar options where you can
- Brush their child's teeth twice daily for two minutes at a time with fluoride toothpaste
- Ensure that their child visits the dentist by their first birthday

STANDING TOGETHER

Nationally, the government has taken bold steps via the launch of its Childhood Obesity Strategy, and providing these policies are introduced, I am sure it will be easier for families to reduce the amount of sugar they consume.

Policies such as clear front of pack labelling and age restrictions on the sale of energy drinks will be vital. At a local level, Oral Health Community Champions should be adopted by all local authorities to help raise awareness of good oral health in the community.

We know that families living in deprived areas are more likely to fall victim to weight management issues and tooth decay. That's why, as a college, we are asking that in areas where there are significant oral health problems, children's oral health should be prioritised in their health and wellbeing strategies.

ANTIBIOTIC RESISTANCE: DISPENSE SOME HELP

Resistance to current antibiotics is rapidly becoming one of the world's biggest healthcare threats. What steps can be taken to help curtail this crisis? Professor Colin Garner, founder and Chief Executive of Antibiotic Research UK, highlights the importance of the sector taking ownership of an issue that will directly affect not just our generation, but those to come too.

Professor Colin Garner

A Public Health England-led study recently revealed that up to one-in-five antibiotics were prescribed inappropriately in the UK – with coughs, sore throats, and ear infections chief among the conditions wrongly treated. That could point to prescribers either not caring about antibiotic resistance, or at best being ignorant of a problem that already costs 700,000 lives per year globally.

Antibiotic Research UK's (ANTRUK) close relationship with GPs and other prescribers, however, has revealed often disturbing feedback around patients' insistence on receiving antibiotics. This has resulted in threats of reporting family doctors to the General Medical Council, a dire online review of the practice, and even physical violence, if patients are denied the drugs.

We deplore this behaviour but recognise it is a direct consequence of a cultural relationship with antibiotics that insists that they are a cure-all. And when people are refused that silver bullet, this is construed as bad practice, or even a lack of compassion.

THE ANTIBIOTIC AGE

ANTRUK has recently been working with Sarah Whitlow, the granddaughter of Sir Alexander Fleming, whose discovery of penicillin began the antibiotic age. A practice nurse, Sarah believes that over the course of her long career, people have begun to simply not countenance being ill any more (and are pressured back to work by unscrupulous bosses), and therefore want an effective panacea, there and then – even if that antibiotic won't cure their viral infection and may prove dangerous to their health going forward.

Sir Alexander Fleming actually predicted as early as 1945 that we faced returning to a pre-antibiotic age unless we developed new medications to build upon his discovery. Apocalyptic warnings that routine hospital operations could be cancelled for fear of infection and that we could return to an age where human beings could die of something as simple as a scratch, seem to have done little or nothing to inspire governments to incentivise and generally take the situation more seriously.

A FIGHTING CHANCE

Set against this background, ANTRUK is the small but growing charity fighting the world's biggest health problem. And it needs the assistance of clinicians and pharmacists to not only improve prescribing habits, but to be flag-wavers in a bid to change behaviours in the public and put pressure on decision-makers.

Health workers are our natural allies in this battle. Every day they display a vested interest in what is best for their patient Unlike other medications, antibiotics are dispensed in short-term courses, and yet the profitable drugs that big pharma do develop to treat everything from heart disease to cancer (sometimes through charitable donations) would be rendered useless to the patient if they then picked up a hospital-acquired superbug such as MRSA.

ANTRUK needs you to stand shoulder-to-shoulder with us to persuade drugs companies to invest not just in headline-grabbing innovative solutions, but the development process that will put effective antibiotic treatments into the pharmacy. Big pharma cries out that it needs incentives to make that transition. Again health workers have a massively strong voice; and were every one of you to write to or lobby your MP on this matter, politicians would surely sit up and take note. More investment might also be put into training around antibiotic prescribing and support for prescribers under pressure from the public.

OTHER PIECES OF THE PUZZLE

The farming industry, and indeed those practicing animal healthcare, can also play a pivotal part. Livestock is still being fed antibiotics, not only to cure illness, but to protect them from infections in intensive production facilities. While some way behind countries such as Sweden, British farming has taken a more responsible attitude towards antibiotic usage; but that isn't the case in other countries we trade with (and more meat could be imported from less regulated countries such as America following Brexit). Antibiotics are therefore in our food chain and their residue is increasingly being discovered in our water courses.

Britain, seen a few years ago under the David Cameron government as a leader in combating antibiotic resistance, doesn't even have a record of how many patients die or are treated for superbugs. Together we must make such a register a reality. We can't tackle the problem unless we know how big it is!

Education is vital and awareness can begin in what is still a hub of the community; the pharmacy and the surgery. Materials from Public Health England's Keep Antibiotics Working campaign have been distributed to NHS outlets throughout the country and in many cases are displayed prominently for patients to see. But in an online age where antibiotics can be ordered as simply as a takeaway pizza, the dangers of misuse and abuse of antibiotics needs to be hammered home (a recent American survey of parents showed that around half were giving their children their own leftover antibiotics – is this also happening here?).

BUILDING KNOWLEDGE THROUGH EDUCATION

Education can be done during the course of appointments, but also via local events and health education sessions. For example, NHS out-of-hours service BARDOC (covering Bolton, Bury and Rochdale) organised a Great British Tea Party fundraising event for ANTRUK at Bury's premiere health centre. They raised over £500 for our charity, but also put the organisation in even better touch with its community and allowed BARDOC to share messages around antibiotic resistance.

ANTRUK has just appointed its first patient support officer. While organisations such as Macmillan issue tremendous support to those living with conditions such as cancer, where is the information and arm around the shoulder when a patient contracts C. diff or MRSA? Your input into this new post and its proposed network is vital.

At the heart of last year's winter crisis, ANTRUK ran a campaign on ensuring hospital cleanliness, which illustrates perfectly how we can work together effectively with health professionals. We have been genuinely impressed by the efforts of infection control teams in improving cleanliness in wards and departments and results have been tangible since the dark days of the early 2000s and outbreaks of MRSA. But over-occupancy and the close proximity of patients – plus scant resources, especially in staffing – made us call on the public to become vigilant visitors and report shoddy cleanliness to hospital authorities. We were so encouraged that staff in primary and acute care, plus pharmacies, responded to this campaign positively, recognising it not as an attack, but as a concerted effort to protect health and beat the superbugs.

STEPS IN THE RIGHT DIRECTION

As with the environment, individuals can feel remote from being able to solve the problem of antibiotic resistance. For some, it seems like miles away from the every day. But their small changes allied to seriousness around the problem from the pharmaceutical industry, health charities, and food producers might just tip the balance. That united front would be even more successful if the glue that kept it together was healthcare professionals and pharmacists, championing the cause at local and national level and leading by example by prescribing wisely.

The problem of antibiotic resistance is terrifyingly real, but as Sir Alexander Fleming famously said, 'There's never been a better time for humanity, despite the hydrogen bomb.'

And, with healthcarers in the fold, I am optimistic and firmly believe that we can beat the superbugs and preserve health for future generations.

ABOUT THE AUTHOR

Professor Colin Garner is the founder and Chief Executive of ANTRUK, the world's first charity to fight bacterial antibiotic-resistant infections. ANTRUK aims to raise sufficient funds over the next few years to bring at least one new antibiotic therapy to market by the early 2020s, as well as expand its patient support and education activities.

For more information about ANTRUK's work, and to donate to the charity's cause, visit www.antibioticresearch.org.uk.

COMPETITION IS A TWO-SIDED COIN

It was only a few years ago that the UK was struggling to keep pace when it came to the adoption of biosimilar medicines. A lack of awareness and understanding was a significant factor in lower comparative uptake to other European countries. However, in a relatively short space of time the UK has gone from lagging to leading – and collaboration has been a key aspect in the turnaround. But it's now more important than ever to keep complacency at bay, warns Warwick Smith, Director General of the British Biosimilars Association.

Warwick Smith

The past 12 months have been another significant period of achievement from a UK biosimilar perspective. We have just experienced the patent expiry of Adalimumab, the world's top selling prescription medicine, which is expected to make the single biggest contribution to the NHS objective of saving in the order of £200 million to £300 million per year by 2021 through biosimilar uptake, according to NHS Chief Executive, Simon Stevens.

In addition, following collaboration between a wide range of stakeholders, including industry, regulators, and clinicians, an updated second version of NHS England's What is a Biosimilar? guide will be published. This will help further enhance understanding and embed the benefits across the NHS of these important medicines.

So there is a lot to be positive about in terms of further establishing and growing the biosimilars market in the UK. However, complacency can't be allowed to creep in as challenges remain in 2019 and beyond.

From a regulatory and Brexit perspective, there is still uncertainty which needs to be removed. Today, the one and only licensing route for biosimilar medicines in Europe is the Centralised Procedure, operated by the European Medicines Agency (EMA). If under a 'no deal' Brexit scenario the UK is separated from the EMA and the EU regulatory network, then it has not been clear yet how the UK licensing authority, the Medicines and Healthcare products Regulatory Agency (MHRA), would operate.

It's hoped that the MHRA would review in parallel to the EMA for the assessment of biosimilar medicines, taking account of the EMA opinions, and not duplicate or diverge on scientific issues. It's vital that the same scientific dossier can be submitted at the same time to the EMA and the MHRA, followed by the same assessment and approval timetable. Some reassurance came from the technical notices published by the UK government last year. These indicated that the MHRA will continue to reference opinions and decisions coming out of the EMA procedure when a company applies to the EU27 and UK in parallel.

However, no mention is made of national control laboratory testing (National Institute for Biological Standards & Control – NIBSC – in the UK) which is an important pillar of the regulatory control of biological medicines. It is important that even if the UK and EU regulatory systems start off in parallel, they do not gradually diverge over time.

Elsewhere, within the UK, we also need to address the significant variability in uptake in different parts of the country, as well as in respect of different molecules. At a headline level, the UK has done very well in using competition to reduce price and thus increase patient access to biological medicines, but there are outliers.

For example, we have seen some biosimilar medicines taking 90 per cent of the market, leading to price reductions of approximately 80 per cent due to the competition introduced by having a multi-source system. However, in other examples the take-up has been less than 10 per cent, leading to a similarly small reduction in price. Competition is available but uptake hasn't occurred to the same extent. This needs to be examined to see how improvements in take-up can be made.

From the industry's perspective, companies can provide competition on the supply side but it needs to be accompanied by interest on the demand side if the true extent of savings and increases in access are to be realised.

From a geographic perspective, there are also examples of take-up variability on a hospital trust level. Some are showing high percentages of uptake while others have much lower figures. NHS England is already looking at this via its Regional Medicines Optimisation Committees where sharing best practice across a range of issues are being discussed. Biosimilars have been a priority topic in the first year of these boards but they must stay high on the agenda in 2019.

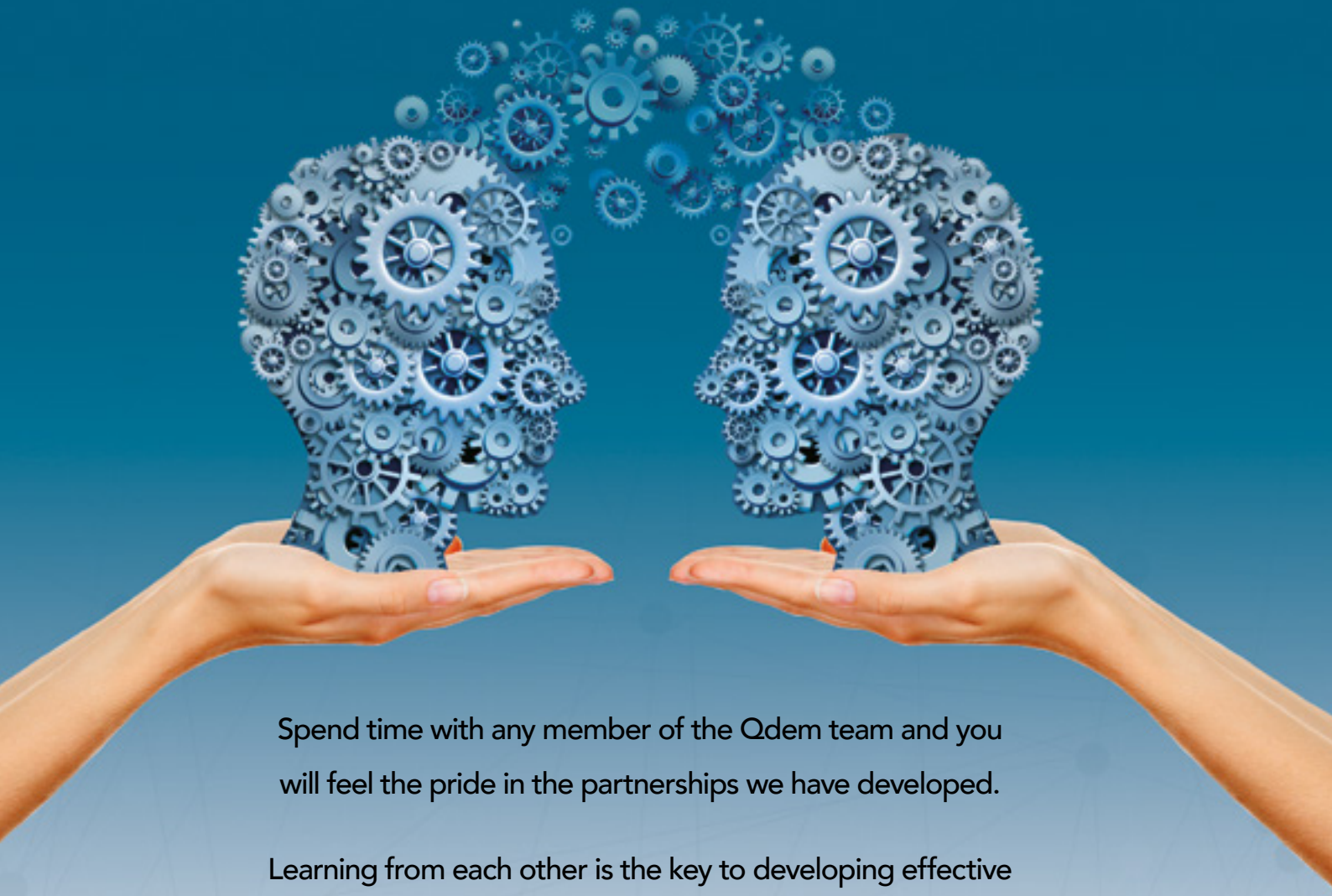
So while a considerable amount has already been achieved in establishing the UK as a market leader for biosimilars, there remains work to be done. A key focus ahead is to build on the collaboration to date and introduce greater consistency of uptake across the board.

THE REGION'S ONLY INDEPENDENT PHARMACY PUBLICATION

www.scothealthcare.com
02890 999 441
info@nimedical.info

Qdem pharmaceuticals

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'.

www.qdem.co.uk

BRAND QUALITY. GENERIC PRICES

Date of preparation: January 2019