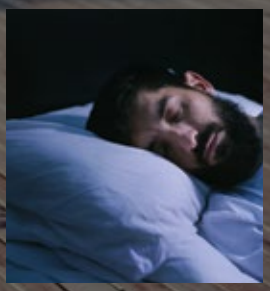
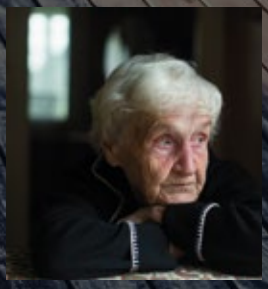
Scottish Pharmacy Review

ISSUE **126** - 2020

INFANT COLIC

HOW TO SUPPORT PARENTS





URINARY TRACT INFECTION

In elderly patients

MYALGIC ENCEPHALOMYELITIS

Scotland's specialist services

LIVER DISEASE

Detection and prevention

SCOTTISH PHARMACY AWARDS

The winners' stories

Daiichi-Sankyo

Lixiana® edoxaban

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

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

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

Recommended by NICE and SMC accepted.

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

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

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

Presentation: 60 mg (yellow) / 30 mg (pink) / 15 mg (orange) edoxaban (as tosilate) film-coated tablets. **Indications:** Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. **Posology and method of administration:** *NVAF:* Recommended dose is 60 mg edoxaban once daily with or without food. Continue therapy long term. *VTE:* Recommended dose is 60 mg edoxaban once daily with or without food following initial use of parenteral anticoagulant for at least 5 days. Duration of therapy (at least 3 months) should be based on risk profile of the patient. For NVAF and VTE the recommended dose is 30 mg edoxaban once daily in patients with one or more of the following: moderate or severe renal impairment (creatinine clearance (CrCL) 15 - 50 mL/min); low body weight ≤ 60 kg; concomitant use of the P-glycoprotein (P-gp) inhibitors, ciclosporin, dronedarone, erythromycin, or ketoconazole. The 15 mg dose of edoxaban is not indicated as monotherapy, and should only be used during a switch from edoxaban to VKA in certain patients (see SmPC for full details). Edoxaban can be initiated or continued in patients who may require cardioversion. For transoesophageal echocardiogram guided cardioversion in patients not previously treated with anticoagulants, edoxaban should be started at least 2 hours before cardioversion to ensure adequate anticoagulation. Cardioversion should be performed no later than 12 hours after the dose of edoxaban on the day of the procedure. Confirm prior to cardioversion that the patient has taken edoxaban as prescribed. If a dose of edoxaban is missed, the dose should be taken immediately and then continued once daily on the following day. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Clinically significant active bleeding. Hepatic disease associated with coagulopathy and clinically relevant bleeding risk. Lesion or condition, if considered to be a significant risk for major bleeding including current or recent gastrointestinal (GI) ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities. Uncontrolled severe hypertension. Concomitant treatment with any other anticoagulants e.g. UFH, low molecular weight heparins, heparin derivatives (fondaparinux, etc.), VKA or DOACs except under specific circumstances of switching oral anticoagulant therapy or when UFH is given at doses necessary to maintain an open central venous or arterial catheter. Pregnancy and breast-feeding. **Special warnings and precautions for use:** *Haemorrhagic risk:* Caution in patients with increased risk of bleeding such as elderly on ASA. Discontinue if severe haemorrhage occurs. The anticoagulant effect of edoxaban cannot be reliably monitored with standard laboratory testing. A specific anticoagulant reversal agent for edoxaban is not available. Haemodialysis does not significantly clear edoxaban. *Renal impairment:* CrCl should be monitored at the initiation of edoxaban and afterwards when clinically indicated. Not recommended in patients with end stage renal disease or on dialysis. *Renal function and NVAF:* A trend towards decreasing efficacy with increasing CrCl was observed for edoxaban compared to well-managed warfarin. Edoxaban should only be used in patients with NVAF and high CrCl after a careful benefit risk evaluation. *Hepatic impairment:* Not recommended in severe hepatic impairment. Caution in mild or moderate hepatic impairment. Caution in patients with elevated liver enzymes (ALT/AST > 2 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. *Patients with a history of thrombosis diagnosed with antiphospholipid syndrome:* DOACs including edoxaban are not recommended. **Drug interactions:** Concomitant use of the *P-gp inhibitors* ciclosporin, dronedarone, erythromycin, or ketoconazole requires edoxaban dose reduction to 30 mg. Edoxaban should be used with caution with concomitant *P-gp inducers* (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital, St John's Wort). Concomitant high dose ASA (325 mg) or chronic NSAIDs is not recommended. Concomitant ASA at doses > 100 mg and < 325 mg should be under medical supervision only. Very limited experience with dual antiplatelet therapy or fibrinolytics. Possibility of increased bleeding risk with concomitant SSRIs or SNRIs. **Adverse reactions:** *Common:* anaemia, dizziness, headache, epistaxis, abdominal pain, lower GI haemorrhage, upper GI haemorrhage, oral/pharyngeal haemorrhage, nausea, blood bilirubin increased, gamma GT increased, cutaneous soft tissue haemorrhage, rash, pruritus, macroscopic haematuria/urethral haemorrhage, vaginal haemorrhage, puncture site haemorrhage, liver function test abnormal. *Serious uncommon:* 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:** May 2019 EDX/19/0141

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

www.lixiana.co.uk

Date of preparation: March 2020 | EDX/20/0334

SPR
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WELCOME

Sarah Nelson Editor
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EDITOR'S LETTER

Welcome to the latest edition of Scottish Pharmacy Review!

I always enjoy when people try to dive into sports-related discussions with me. It's not for the reason you might suspect – but solely for the efficiency and speed it injects into my housework. You see, as I robotically nod at the individual's transfer window worries and sigh at their substitution stress, I'm actually doing a mental sweep of my cupboards and compiling a shopping list.

Clearly, pursuing and following sports is not my passion, but the concept of 'sportsmanship' is one which I can absolutely throw my support behind. In fact, I see and appreciate how its fundamentals are practiced every day by the members of our pharmacy sector – fairness, ethics, respect, a sense of fellowship, and an aspiration to achieve the best and be the best for a greater cause.

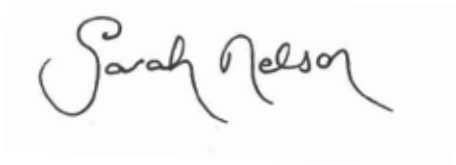
This admirable patient-centred ethos is particularly highlighted as we celebrate the first half of our 2019 Scottish Pharmacy Awards winners – check out their paths to success (beginning on page 23).

Speaking of sports, in this edition of SPR, we invite the Chartered Society of Physiotherapy to take us on a journey from the touchline to the medical room to help advise patients on rugby and football injuries (page 19).

Elsewhere, the British Heart Foundation Scotland cast a light on why a redesign of cardiac rehabilitation is urgently needed (page 11), and Dr Sophie Nelson delves into the causative factors and impact of infant colic – as well as how to help overwhelmed parents (page 16). You can find out, too, about Myalgic Encephalomyelitis – including services in Scotland and how you can support your patients to manage their symptoms (page six).

Before you go, the Medical Defence Union are at hand with resolutions inspiration to get the new decade off to a good start (page 33), and stay sussed on the findings from the 2018 Health Behaviour in School-aged Children study (page 21).

Happy reading!



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PANCREATIC CANCER: TAKING PRIORITY

Towards the end of last year, the United European Gastroenterology (UEG) and Pancreatic Cancer Europe recognised World Pancreatic Cancer Day, a global initiative developed to raise awareness and prompt action against one of the world's deadliest cancers. Professor Matthias Löhr, a member of the UEG Public Affairs Committee, delves into the pressing challenges for clinicians, and why enhanced awareness of pancreatic cancer and increased investment into the field should become an urgent priority.

Over the past 50 years, diagnosis and treatment strategies for cancer patients have evolved rapidly, transforming patient outcomes. Despite the major advancements witnessed in other areas of oncology, improvements in pancreatic cancer patient outcomes have largely stood still. In sharp contrast to the remarkable growth in survival rates observed in other disease areas such as lung, breast or prostate cancer, the overall five-year survival rate for patients diagnosed with pancreatic cancer is just five per cent across the globe, a figure that has not significantly improved since the 1970s. (1)

Compounding the threat of these concerning statistics, the incidence and mortality rates related to pancreatic cancer are on the rise globally. A recent study presented at UEG Week Barcelona 2019 revealed that as well as an increase in pancreatic cancer cases, the number of deaths attributable to the disease has risen from 196,000 in 1990 to 448,000 in 2017. (2) While a proportion of this increase can be explained by a rising population and increased life-expectancy, age-standardised incidence and death rates for pancreatic cancer had still risen by 12 per cent and 10 per cent respectively over the course of the study. (3) Particularly of note, the highest incidence and death rates were recorded in higher-income countries.

While the precise etiology of pancreatic cancer remains unknown, a number of factors have been linked to the development of the disease. Obesity, an epidemic that has a close association with high-income countries, has been shown to increase a patient's risk of pancreatic cancer by almost 47 per cent. (4) The ever-increasing prevalence of obesity and diabetes across the globe, coupled with an ageing population, is set to add weight to the already-heavy burden of pancreatic cancer. Recent forecasts have predicted that both the number of cases and deaths will increase by 40 per cent by 2035 if preventative measures are not taken. (5) With an estimated two-thirds of the risk factors being categorised as potentially modifiable, there is a huge opportunity for both clinicians and the public to promote and partake in lifestyle changes that can significantly reduce the risk of the disease. (6)

However, a number of pressing challenges still face clinicians and the general public in the identification and treatment of pancreatic cancer. In the earliest stages of the disease, symptoms are often silent or general, making pancreatic cancer a notoriously difficult disease to diagnose. Perpetuating this problem further, poor public awareness of pancreatic cancer and the absence of a standard diagnostic tool frequently causes delays in identification, allowing the cancer to remain present in the body for many years prior to detection. (7) For those who are not diagnosed in time for resection, violent tumours can persist, which display extreme resistance to treatment, partially explaining the incredibly low survival rates associated with pancreatic cancer.

Despite these daunting statistics, recent progress has provided renewed hope for the future status of pancreatic cancer. Building upon a wealth of established research, a number of incremental improvements have been seen across the field, including the increased efficacy of a range of treatment options. Traditionally, surgery, chemotherapy and radiation therapy have been the most commonly-used tools in the fight against pancreatic cancer. However, the advent of immunotherapy could signify a new frontier for pancreatic cancer treatment. Recent studies have suggested that combination treatment strategies in conjunction with immunotherapy could potentially yield positive results, improving pancreatic cancer prognosis. (8) In order to provide robust and conclusive evidence of the benefits of immunotherapy, a closer examination of this treatment appears to be a worthwhile future endeavour.

In light of the clear need for further research into pancreatic cancer, the lack of funding provided to this area is particularly unsettling. European funding for the disease lies far behind many other cancers with similar mortality rates, receiving less than two per cent of all cancer research funding in Europe. (9) An increased allocation of funds to pancreatic cancer research will allow for the exploration of a number of different treatment options that could significantly improve patient outcomes.

The Cancer Moonshot programme, a project launched across America with the aim of reducing mortality rates in several major cancers, represents a promising new development in pancreatic cancer research. The resultant Precision PromiseSM, an adaptive randomised clinical trial platform, allows researchers to evaluate multiple novel therapies to develop effective and ground-breaking treatment options for pancreatic cancer. (10) The implementation of similar projects and the wider world should be seen as an essential step in improving pancreatic cancer outcomes.

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**Dose delivery study using low, middle and high strength DuoResp Spiromax. Dose consistency was measured over inhaler life. Low dose was included in the study but is not licensed in the UK.[3]
†For 160/4.5mcg strength only.[4]
‡DuoResp Spiromax is licensed for use in adults 18 years of age and older only.[4]

Please refer to the Summary of Product Characteristics (SmPC) for full details of the Prescribing Information. DuoResp® Spiromax® (budesonide/formoterol) 160mcg/4.5mcg inhalation powder and DuoResp® Spiromax® (budesonide/formoterol) 320mcg/9mcg inhalation powder Abbreviated Prescribing Information. **Presentation:** *DuoResp® Spiromax® 160/4.5*: Each delivered dose contains 160mcg of budesonide and 4.5mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 200mcg budesonide and 6mcg of formoterol fumarate dihydrate. *DuoResp® Spiromax® 320/9*: Each delivered dose contains 320mcg of budesonide and 9mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 400mcg budesonide and 12mcg of formoterol fumarate dihydrate. Inhalation powder. **Indications:** Asthma: Treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2-adrenoceptor agonist) is appropriate. COPD: Symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV_1) < 70% predicted normal (post bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. **Dosage and administration:** For use in adults ≥18 years. Not for use in children < 18 years of age. ***Asthma:*** Not intended for the initial management. If an individual patient should require a combination of doses other than those available in the combination inhaler, appropriate doses of β_2-adrenoceptor agonists and/or corticosteroids by individual inhalers should be prescribed. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. When control of symptoms is achieved titrate to the lowest effective dose, which could include once daily dosing. *DuoResp® Spiromax® 160/4.5: maintenance* therapy – regular maintenance treatment with a separate reliever inhaler: *Adults*: 1-2 inhalations twice daily (maximum of 4 inhalations twice daily). *DuoResp® Spiromax®* maintenance and reliever therapy – regular maintenance treatment and as needed in response to symptoms: should be considered for patients with: (i) inadequate asthma control and in frequent need of reliever medication (ii) previous asthma exacerbations requiring medical intervention. *Adults*: The recommended maintenance dose is 2 inhalations per day, given either as one inhalation morning and evening or as 2 inhalations in either the morning or evening. For some patients a maintenance dose of 2 inhalations twice daily may be appropriate. Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. A total daily dose of up to 12 inhalations could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice. *DuoResp® Spiromax® 320/9*: Only to be used as maintenance therapy. *Adults*: 1 inhalation twice daily (maximum of 2 inhalations twice daily). ***COPD:*** *Adults*: 1 inhalation twice daily. *Elderly patients (≥65 years old)*: No special requirements. *Patients with renal or hepatic impairment*: No data available. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** If treatment is ineffective, or exceeds the highest recommended dose, medical attention must be sought. Patients with sudden and progressive deterioration in control of asthma or COPD should undergo urgent medical assessment. Patients should have their rescue inhaler available at all times. The reliever inhalations should be taken in response to symptoms and are not intended for regular prophylactic use e.g. before exercise. For such, a separate rapid-acting bronchodilator should be considered. Patients should not be initiated during an exacerbation. Serious asthma-related adverse events and exacerbations may occur. If asthma symptoms remain uncontrolled or worsen, patients should continue treatment and seek medical advice. If paradoxical bronchospasm occurs, treatment should be discontinued immediately. Paradoxical bronchospasm responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. Visual disturbance may be reported with systemic and topical corticosteroid use. Such patients should be considered for referral to an ophthalmologist for evaluation of possible causes. Systemic effects may occur, particularly at high doses prescribed for long periods. Potential effects on bone density should be considered, particularly in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress. Treatment should not be stopped abruptly. Transfer from oral steroid therapy to a budesonide/formoterol fumarate fixed-dose combination may result in the appearance of allergic or arthritic symptoms which will require treatment. In rare cases, tiredness, headache, nausea and vomiting can occur due to insufficient glucocorticosteroid effect and temporary increase in the dose of oral glucocorticosteroids may be necessary. To minimise risk of oropharyngeal Candida infection patients should rinse mouth with water. Administer with caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, or severe cardiovascular disorders. The need for, and dose of inhaled corticosteroids should be re-evaluated in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections in the airways. Additional blood glucose controls should be considered in diabetic patients. Hypokalaemia may occur at high doses. Particular caution is recommended in unstable or acute severe asthma. Serum potassium levels should be monitored in these patients. As with other lactose containing products the small amounts of milk proteins present may cause allergic reactions. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. **Interactions:** Concomitant treatment with potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration should be as long as possible. Co-treatment with CYP3A inhibitors, including cobicistat-containing products is expected to increase risk of systemic side effects and the use in combination should be avoided. Not recommended with β-adrenergic blockers (including eye drops) unless compelling reasons. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine), and Tricyclic Antidepressants (TCAs) can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance. Concomitant treatment with MAOIs, including agents with similar properties, may precipitate hypertensive reactions. Patients receiving anaesthesia with halogenated hydrocarbons have an elevated risk of arrhythmias. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. **Pregnancy and lactation:** Use only when benefits outweigh potential risks. Budesonide is excreted in breast milk; at therapeutic doses no effects on infants are anticipated. **Effects on ability to drive and use machines:** No or negligible influence. **Adverse reactions:** Since *DuoResp® Spiromax®* contains both budesonide and formoterol, the same pattern of adverse reactions as reported for these substances may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds. *Serious*: Immediate and delayed hypersensitivity reactions, e.g. exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction, Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, hypokalaemia, hyperglycaemia, aggression, psychomotor hyperactivity, anxiety, sleep disorders, depression, behavioural changes, cataract and glaucoma, tachycardia, cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystoles, angina pectoris, prolongation of QTc-interval, variations in blood pressure, bronchospasm, pneumonia in COPD patients and paradoxical bronchospasm. *Common:* Candida infections in the oropharynx, headache, tremor, palpitations, mild irritation in the throat, coughing, pneumonia in COPD patients and hoarseness. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** An overdose of formoterol may lead to: tremor, headache, palpitations. Symptoms reported from isolated cases are tachycardia, hyperglycaemia, hypokalaemia, prolonged QTc-interval, arrhythmia, nausea and vomiting. Supportive and symptomatic treatment may be indicated. **Price per pack:** *DuoResp® Spiromax® 160/4.5* and *DuoResp® Spiromax® 320/9*: £27.97. **Legal Category:** POM. **Marketing Authorisation Numbers:** *DuoResp® Spiromax® 160/4.5*: EU/1/14/920/001. *DuoResp® Spiromax® 320/9*: EU/1/14/920/004. **Marketing Authorisation Holder:** Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, The Netherlands. **Date of Preparation:** September 2018. **Job Code:** UK/MED/18/0194.

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

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Approval Code: UK/DUO/18/0054(1)

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, West Yorkshire WF10 5HX

Date of preparation: August 2019

MYALGIC ENCEPHALOMYELITIS

SUPPORTING YOUR PATIENTS WITH M.E.

The serious neurological condition Myalgic Encephalomyelitis (M.E.) affects at least 250,000 children, young people, and adults in the UK – more than Parkinson's and MS combined. This includes 20,000 people across Scotland, many of whom struggle to access care and support services. UK charity, Action for M.E., shares key information about the condition, and how you can support your patients to manage the symptoms of M.E.

Within the NHS, a diagnosis of chronic fatigue syndrome (C.F.S.) or M.E.-C.F.S. is often given. Experiences of this chronic, fluctuating, neurological condition differ from individual-to-individual, and symptoms and severity can fluctuate and change over time.

People with M.E. experience debilitating pain, fatigue, and a range of other symptoms linked to post-exertional malaise, an increase in symptoms after using even small amounts of physical, cognitive or emotional energy; this may be delayed by hours or even days.

At least one-in-four people are so severely ill they are housebound, and often bedbound, and people with M.E. are 'measurably more disabled' than those with MS; they also work fewer hours and have lower income. (1)

SYMPTOM MANAGEMENT

There has been much scientific debate about the safety and efficacy of the symptom management approaches included in the Scottish Good Practice Statement (SGPS) for M.E.-C.F.S., namely Cognitive Behavioural Therapy (CBT) and Graded Exercise Therapy (GET).

These treatments are based on the theory that the debility of the disease is the result of deconditioning which is the result of a fear of activity, symptom-focusing, and unhelpful cognitions.

While similar NICE guidance for England and Wales is now being reviewed and updated (publication expected December 2020), the Scottish Cabinet Secretary for Health and Sport has announced that a short life working group will convene to review this, and what it means for the SGPS.

According to the SGPS, GET aims to 'redress decline in physical fitness due to inactivity', while CBT can be valuable to patients 'when their symptoms have led to a psychological response that has compounded their problems.' It describes pharmacological and GET and CBT as having the strongest scientific evidence while noting GET has been particularly controversial, and that some patients report a worsening of symptoms.

However, re-analyses of GET research has found insufficient evidence of effectiveness, noting that studies using definitions requiring hallmark criteria, such as post-exertional malaise, were 'blatantly missing'. (2)

In the case of the largest study, the 2011 PACE trial, Wilshire et al (3) found that the original study did not consistently follow protocol procedures, that rates of recovery were consistently low and not significantly different across treatment groups, and that 'the modest treatment effects obtained on self-report measures in the PACE trial do not exceed what could be reasonably accounted for by participant reporting biases.'

Action for M.E.'s 2019 Big Survey of more than 4,000 people with M.E. (4) found that more than a third (38 per cent) said GET worsened symptoms, and less than one-in-10 (six per cent) said that it helps / has helped manage symptoms.

The management approach that most people with M.E. find helpful is pacing – a planned approach to managing activity and rest – with 88 per cent of survey respondents saying they have tried it. It may also be possible to prescribe medication for individual symptoms, including sleep disturbance, pain, nausea and orthostatic intolerance. People with M.E. often have a limited tolerance to drugs, so starting lower doses than usual may be needed.

PACING: BALANCING ACTIVITY AND REST

Pacing is a self-management technique that supports people with M.E. to listen to their body, to balance activity, energy and rest. It should not be seen as a treatment but more as a way of coping with the impact of M.E.

For some, activity may be very minimal (especially for those who are severely affected) yet it still causes considerable impact on energy and symptoms. Some clinicians consider pacing to be about carefully managing activity and other stressors to avoid post-exertional malaise. Others would consider it a way to first stabilise then gradually build up increases in activity, sometimes called pacing up.

This range of views reiterates the importance of the collaborative relationship between the patient and professional, as set out in the SGPS.

Action for M.E.'s 2019 Big Survey of more than 4,000 people with M.E. found that most respondents (88 per cent) had tried pacing in the past five years. Of these, 70 per cent said that they use pacing to do what they feel able to within their manageable limit.

Only one-in-five (20 per cent) said that they used pacing to successfully help gradually increase activity, while one-in-three (30 per cent) said that they tried to do so, but it was unmanageable.

Fully revised for 2020, Action for M.E.'s detailed Pacing for People with M.E. booklet offers a step-by-step pacing guide. (5)

SPECIALIST SERVICES AND OTHER SUPPORT

A number of specialist M.E. clinics exist across the UK, with multidisciplinary teams usually offering diagnostic services and specialist symptom management programmes.

There are three services in Scotland:

- The Centre for Integrated Care in Glasgow offering physiotherapy
- The Ashlie Ainsley Rehabilitation Service in East Lothian
- Keith Anderson, an M.E. specialist nurse in Fife

As the only UK charity supporting both children and adults with M.E., Action for M.E.'s Information and Support Service offers one-to-one support by phone and email on all aspects of living with M.E., and can refer families to its expert Children and Young People's Service in complex cases.

Health, education and social care professionals can find evidence-based information, signposting and resources at www.actionforme.org.uk/medical.

You can also signpost to our national Mentor M.E. project – www.actionforme.org.uk/mentorME – offering adults with M.E. one-to-one support from a trained mentor with lived experience of the condition. Mentor M.E. can also signpost to local support groups and networks campaigning to improve services and reduce the isolation people with M.E. so often experience.

One example is M.E. Highlands and Islands Regional Network, 'a group of individuals who have had to re-address and refocus their lives, careers and family management due to a diagnosis of M.E / C.F.S.', explains founder and steering group member, Ken Macrae.

'As carers, or people living with the illness, they unfortunately found themselves isolated by a lack of knowledge, conflicting and often inconsistent treatment advice, and a lack of support in their local area.

'We want to highlight a lack of provision of patient support in the Highland and Islands, and aim to provide awareness and a voice for the region in the wider debates around M.E. We also hope to assist people with M.E / C.F.S., and carers, in their local areas by linking individuals up, and help with setting up local hubs of support, while offering the benefit of membership of a wider regional patient advocacy group.'

This network is reducing the isolation of people living with M.E. in the area by organising coffee meet-ups in The Oxygen Works in Inverness, formerly a centre for people with MS, that now work with people with other neurological conditions. It also co-hosts twice-yearly information and advice drop-ins, for those living with or caring for people with M.E.

HOPES FOR FUTURE RESEARCH

A historic lack of investment in biomedical research means that the cause or causes of M.E. remain unknown. Nevertheless, an American National Academy of Medicine report (2015) showed substantial evidence of physical abnormalities in the microbiome and cardiovascular, autonomic nervous, neuroendocrine, metabolic and immune systems. Much of this has come from small pilot studies, and there is an urgent need to invest resources to accelerate biomedical M.E. research.

A new alliance of people with M.E., researchers and charity advocates, the M.E. / C.F.S. Biomedical Partnership, is planning a genome-wide association study (GWAS) for M.E. Led by Professor Chris Ponting, University of Edinburgh, and making a funding application in early 2020, this aims to identify new avenues for further research.

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

The GWAS was catalysed by the UK C.F.S. / M.E. Research Collaborative which, since its inception in 2013, has successfully brought together significant numbers of researchers, clinicians, patients, charities, and mainstream funders. Its sixth annual conference, open to clinicians, researchers and people with M.E., takes place in Bristol, on Tuesday 10th and Wednesday 11th March.

For more information, visit www.actionforme.org.uk/CMRC.

CASE STUDY: KAREN

Karen from Glasgow shared her story in Action for M.E.'s 2019 Big Survey.

'I am slowly recovering and feel positive of avoiding severe relapses now as I have learned to accept and adapt, and my symptoms are now mild. I know pacing works but I struggled to find the baseline of activity and regularly did more than I was capable of. It took four years for me to get the hang of it and my health has improved in the last year, and especially the last three months.

'I was off work for nine months. I was then on reduced hours for a further nine months before relapsing again. I am now back at work with adjustments and have had to buy extra leave to allow more rest time.

'I have had to give up being on the board of a charity, my football season tickets, some hobbies, reduced my social and lost touch with some friends. I see less of my family than I would like, but they live too far away for me to travel.

'I have hired a cleaner and my partner does a lot to help. He has been amazing and his kids are great when they stay. I am starting to do more with them and they understand when I can't do anything which makes it easier.'

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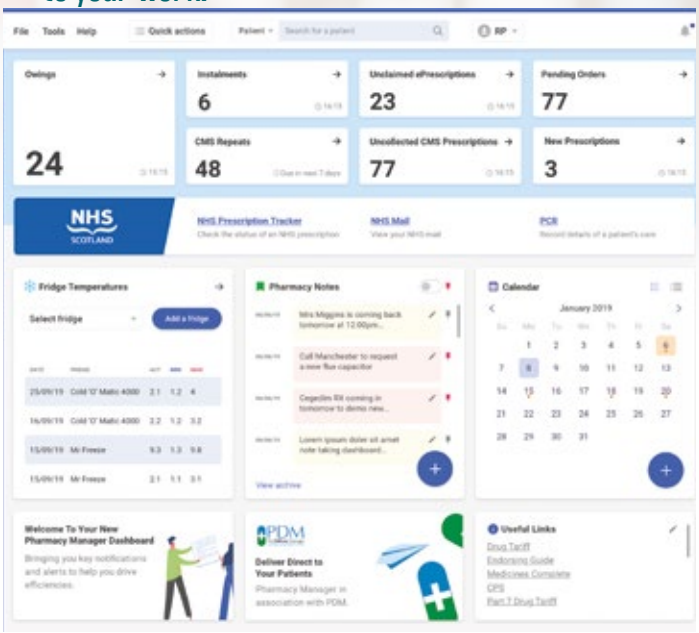
action for m·e

PROMOTION

WORK SMARTER – NOT HARDER

Against a backdrop of ever-changing pharmacy needs, the Cegedim team remain committed to serving the sector and fulfilling your needs where possible. As a result, they have taken their popular Pharmacy Manager product on an evolutionary journey – with it now delivering new regional insights, and even greater efficiency, to your work.



Cegedim have listened to YOU. They have taken the industry-leading product that you know and trust and made it work harder for you.

Pharmacy Manager now includes a modernised intuitive, interface for easy navigation, and has introduced an intelligent dashboard tailored for each region with dynamic tiles which help improve the user experience. This is an evolution of the industry-leading pharmacy solution that has led the way for over 20 years since its accreditation in the market.

Tracey Robertson, Pharmacy Product Director, explained, 'We have made Pharmacy Manager work harder. The first step was listening to you; the second step was acting on what we heard. We are on a continuous improvement journey where we listen, act, and improve Pharmacy Manager for YOU!'

A NEW REGIONAL FOCUS

Since devolution in the late 1990s, the NHS in England, Scotland and Wales has been organised and funded by the devolved governments. Pharmacies already know that there are differences across the UK depending on where their store is located and that they need to adapt the way they work depending on their region. That's why Cegedim have tailored their new dashboards within Pharmacy Manager to be region-specific – this way users see only what's relevant to them in the country they operate.

Tracey said, 'To ensure we continue to delight our customers across all regions, over the last few months my team have been busy walking in their shoes across the UK, in order to understand their needs and key challenges. Having gained insights into regional variations they have been busy designing and validating prototypes before starting development of our phase one solution for both Scotland and Wales. Our successful beta phase was completed at the end of last year and we have already begun rolling out version 11 to all our Scottish customers to ensure that pharmacies in all regions can benefit from these fantastic new features.'

FEATURES DESIGNED FOR YOU

As a result of the team's innovative steps, you now have access to a vast array of exciting and useful features. For example, to address the needs of Scotland the team have included a one-click journey from the new intelligent dashboard to manage CMS prescriptions that are due to be dispensed over the next seven days. Whereas for Wales, the team have included real-time notifications of ETC claims submitted that month, which help to achieve the monthly thresholds and IM&T allowance.

The key improvements and advancements to date include:

- A modernised intuitive interface for easy navigation
- An intelligent dashboard with dynamic tiles to help improve the user experience
- A notes feature enabling the electronic capture of notes in the pharmacy
- A calendar to enable the electronic capture of key events and appointments to aid the smooth running of the pharmacy
- Fridge temperature recording
- Real-time notifications and alerts of prescriptions that need to be claimed so that the pharmacy never loses money

Many more efficiency-saving features delivered as part of this release are also set to follow.

BUILDING FOR THE FUTURE

Pharmacy Manager version 11 is now rolling out to customers and has already garnered fantastic feedback regarding the simplification of the user journey, as well as the key pharmacy insights delivered through the introduction of the new intelligent dashboard.

This is only the start of Cegedim's evolutionary journey – in which various exciting plans are already in store for this year and beyond.

Tracey said, 'This is a key milestone for Cegedim, it means we start 2020 with the foundations in place for all regions, allowing us to build out new value add features across the wider PMR.

'This will bring efficiencies and key intelligence across all fundamental areas such as dispensing, stock and order management, patient management and automation. We are very much looking forward to the journey ahead of us, working collaboratively in partnership with our customers to change pharmacy for the better.'

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NEWS

CHAS and NHS Forth Valley Launch Pioneering Partnership

Children with life-shortening conditions are to benefit from a unique service.

Children's Hospices Across Scotland – better known as CHAS – and NHS Forth Valley have officially launched CHAS Community Pharmacy Network, the first of its kind for children in the UK.

This unique community network is being piloted from January 2020 until December 2020. The network aims to support babies, children and young people (aged 0 to 21 years) with life-shortening conditions, and their families by providing timely access to specialist medicines and paediatric palliative care advice in their local community.

Encompassing 14 community pharmacies in Forth Valley, all of which are part of the existing adult palliative care network, this pilot will be regularly evaluated, helping shape the further development of community pharmacy-led services responsive to the needs of children with life-shortening conditions, and their families.

Kate McCusker, Lead Pharmacist at CHAS, said, 'Working alongside colleagues at NHS Forth Valley, we identified the important role that community pharmacy can play in delivering paediatric care services, improving the safe use of medicines for those children. As a consequence, an exciting new service has been developed with community pharmacists taking a leading role.

'The service will capitalise on the clinical expertise of community pharmacists, their unique accessible position within local communities and their reach across Forth Valley to improve access to specialist medicines and palliative care advice for healthcare professionals and parents who care for children with life-shortening conditions.'

A ground-breaking report published in 2018, Children in Scotland Requiring Palliative Care (CHiSP2), identified that in Forth Valley alone there were 857 children with a life-shortening condition with only 36 per cent of those having a stay within hospital or CHAS services.

Anne Wilson, Specialist Palliative Care Pharmacist at NHS Forth Valley, said, 'Inspiration for the CHAS Community Pharmacy Network came from two existing adult services that operate across Scotland, namely the NHS Forth Valley Palliative Care Community Pharmacy Network and the Scottish Palliative Care Pharmacists Association.

'Children should have timely access to palliative care medicine and the 14 community pharmacists who are participating in the network are spread geographically across Forth Valley. They will hold key medication for palliative paediatric patients and help with any questions parents might have. The impact a community pharmacist can have on these patients in Forth Valley is extremely significant.'

Rose-Marie Parr, Chief Pharmaceutical Officer at the Scottish government, said, 'This is a great example of person-centred care which we know from evidence can have a positive impact on health outcomes. Through this pilot, pharmacists will be trained in the delivery of pharmaceutical paediatric palliative care and can pro-actively support parents to safely manage their children's changing medication requirements. This is tailored to the individual needs of the parent and child and addresses any emerging health literacy issues head-on.'

Once the Community Pharmacy Network has been established within Forth Valley, CHAS aims to spread this network across Scotland and explore how community and primary care-based pharmacists can provide a direct patient-facing medicines review and symptom control service for children with life-shortening conditions.

CHAS is the only charity in Scotland that provides hospice services for babies, children and young people with life-shortening conditions. The national charity offers palliative care and respite for the whole family via its two hospices, Rachel House in Kinross and Robin House in Balloch, and via its CHAS at Home service; supporting families in their own homes. CHAS also supports in clinical settings across the whole of Scotland through their Diana Children's Nurses and in December 2019, CHAS launched a new Supportive and Palliative Care Team in the Royal Hospital for Children in Glasgow.

BRITISH HEART FOUNDATION

CARDIAC EVENTS: ABOUT THE AFTER

Every 50 minutes in Scotland, someone is admitted to hospital due to a heart attack. Following discharge, research shows that taking part in cardiac rehabilitation reduces the risk of dying from further cardiac events and leads to improved quality of life. Richard Forsyth, Health Services Engagement Lead, British Heart Foundation Scotland, tells us more – and depicts the value of transitioning to a more person-centred approach of care.

In the 1960s, when the British Heart Foundation (BHF) was established, more than seven-in-10 heart attacks in the UK were fatal. Today, thanks to huge advances in diagnosis, treatment and care – many of them made possible by research funded by the BHF – at least seven-out-of-10 people survive.

However, being discharged from hospital is not the end of the journey, and this is where cardiac rehabilitation can make a huge difference to both physical and mental wellbeing. Usually offered after a cardiac event, such as a heart attack, heart surgery or after diagnosis of some other heart conditions, cardiac rehab, as it's known, provides the information, support and practical help and advice that people often need to make positive changes to their lifestyle and get their confidence back.

As our understanding of heart disease has improved, so, too, has our view of what cardiac rehab should offer. A traditional 'one-size-fits-all' model of a time-limited programme based primarily around exercise just doesn't fit the needs of today's patients.

Now, more people with heart problems also have other health conditions. They're often looking to get back to work as soon as they can, or they may have other responsibilities, like caring for a family member. It's simply not possible to design a single programme that can meet the needs of, for example, a 45-year-old marathon runner with a full-time job, and a 78-year-old woman with diabetes who's caring for her husband.

THE FULL PICTURE

That's why BHF Scotland is working with the NHS, community partners and the Scottish government to help redesign cardiac rehab. We want each patient who is eligible for cardiac rehab to have a holistic needs assessment that focuses on what matters to them in terms of mental, physical and emotional help and support, empowering them to design and undertake their own personalised programme. There are a number of key factors that need to be in place to achieve this, including the appropriate assessment protocol, personalised care planning, and stronger links with community, leisure and social services.

We also need to embrace and embed digital technology where appropriate, with more online and smartphone options to meet individual needs.

To help achieve this transition to a more person-centred approach, BHF Scotland is working with all 14 health boards across the country. A successful pilot is currently running in NHS Lothian, and we've held a series of workshops with NHS partners to make the cardiac rehab system even more effective and accessible.

Of course, we're all very aware that there are huge demands on our NHS and resources are limited, but evidence shows that cardiac rehab is extremely cost-effective, reducing the risk of complications or further unplanned hospital admissions.

ENHANCING ACCESS TO SUPPORT

To get the most out of cardiac rehab, it's important that people are informed about how the programme can benefit them, and that they know how and where to ask for support. That means that clinicians need to inform patients so that they understand their heart condition, why it's happened and what positive changes they can make. Health professionals should also be enthusiastic advocates for this vital part of the recovery process, encouraging more people to participate, wherever they are in their journey.

That's why cardiac rehab isn't a time-limited or linear process – we need to make sure it's person-centred, based on a menu of options and can flex with life's challenges. Although an individual's contact with clinicians and staff might be for a fixed period of time, the positive lifestyle choices they make should last a lifetime, and there need to be safety nets in place to help people who either aren't ready to engage straight away, or fall away for a while but want to start again.

Successful cardiac rehab is about helping people who've had a cardiac event or diagnosis to achieve their individual goals and providing them with access to the support they need to get on with living their lives as fully as possible, whatever that means for them.

CASE STUDY

Margaret Davis, from Lanark, had a heart attack in May 2018 while on holiday and later underwent cardiac rehabilitation.

Margaret explained, 'I couldn't believe it. I was fit, healthy, happy. I was in total shock. I felt lost, scared and alone. 'However, the cardiac rehab team at my local hospital were fantastic. They not only offered to work with me but went to exceptional lengths to explain how cardiac rehab could help me. The team rightly identified that I was living in fear and was terrified to move – mental rehab is as important as physical. They knew I loved to dance and gently restored my confidence. I had to learn to live again – the easiest thing would have been to wrap myself up in cotton wool and stop doing everything I had done before. I had to force myself back out there but I'm glad I did. The doctors saved my life but the cardiac rehab team gave me my life back.'

LIVER DISEASE

TIME FOR CHANGE

Liver disease is chronically overlooked and underfunded due to a lack of awareness of its seriousness and prevalence, together with the stigma that often surrounds it. Help cultivate change for your patients and beyond by improving early detection and prevention courtesy of The British Liver Trust's advice.

Liver disease is a major public health crisis and is currently the biggest cause of death of those aged between 35 to 49 years old in the UK. Since 1970, liver disease mortality rates have increased by 400 per cent. This is in stark contrast to other major killer diseases, such as heart disease and cancer, in which the number of deaths have either remained stable or decreased.

In many cases, liver disease is linked to social deprivation. People who live in more deprived areas are up to six-times more likely to die of liver disease than those who live in wealthier areas. There is much to be done.

The British Liver Trust want to make liver disease prevention, detection and treatment a central part of routine healthcare in primary care.

Three-quarters of people are diagnosed with liver disease at a late stage, by which time the opportunity for treatment and intervention is often limited and sometimes too late. This is because there are very few symptoms in the early stages, and if there are, they are vague and often go unnoticed. When symptoms do start to appear, such as jaundice, damage to the liver has reached an advanced stage.

PREVENTION IS BETTER THAN CURE

More than 90 per cent of liver disease is preventable. The three major causes of liver disease in adults are alcohol-related liver disease, obesity, and viral hepatitis.

The British Liver Trust's Love Your Liver campaign focuses on three simple steps to improve liver health:

- Drink within recommended limits and have three consecutive days off alcohol every week
- Cut down on sugar, carbohydrates and fat, and get more exercise
- Know the risk factors for viral hepatitis and get tested or vaccinated if at risk

Health professionals are well-placed to reduce the public's risk of developing liver disease by screening them for the risk factors and signposting them to the relevant support services.

RESOURCES FOR HEALTHCARE PROFESSIONALS

The British Liver Trust are supporting GPs and primary care professionals to deliver care to patients with a range of resources, materials and best practice guidelines.

INTERPRETING LIVER BLOOD TESTS

Most people learn that they have a liver problem from their GP, often as a result of routine blood tests.

Guidelines on the management of abnormal liver blood tests have been commissioned by the Clinical Services and Standards Committee of the British Society of Gastroenterology (BSG) under the auspices of the liver section of the BSG with input from a wide number of groups, including the Royal College of General Practitioners and The British Liver Trust.

They deal specifically with the management of abnormal liver blood tests in adults in both primary and secondary care under the following sub-headings:

- What constitutes an abnormal liver blood test?
- What constitutes a standard liver blood test panel?
- When should liver blood tests be checked?
- Does the extent and duration of abnormal liver blood tests determine subsequent investigation?

THE ROYAL COLLEGE OF GENERAL PRACTITIONERS TOOLKIT

The Royal College of General Practitioners made liver disease a clinical priority area in April 2016 for three years. The liver champion's mandate was to support primary care to work towards better identification of patients at risk of, or in the early stages of, liver disease. The goal of the programme was for GPs to intervene before liver disease becomes established. This included the development of a toolkit with a range of resources for all primary care professionals.

NHS HEALTH CHECK

The new NHS Health Check, Best Practice Guidance 2019, published in October 2019, now includes liver disease for the first time, which will contribute to earlier diagnosis of liver disease in a variety of settings, including general practices, pharmacies, and community settings.

The check will focus on finding ways to lower this risk and to ensure that people with the early stages of liver disease are diagnosed earlier. They can then make lifestyle changes to improve their liver function and prevent it from becoming a serious health problem.

The British Liver Trust continue to campaign for change, working tirelessly to raise awareness, improve early diagnosis and detection, and support clinicians to give the best possible care.

For more information and resources, visit www.britishlivertrust.org.uk/gpresources.

AN AGE-OLD PROBLEM

With an ageing population, the burden of urinary tract infection in older adults is likely to grow, making the need for improved diagnosis and appropriate management essential to managing the health of older adults. (4) Ased Ali B.Sc.(Hons), MB.ChB, PhD, FRCS(Urol), Consultant Urological Surgeon at Mid Yorkshire Hospitals, explains further – providing a comprehensive overview of lower urinary tract infection in the elderly.

Urinary tract infection (UTI) is broadly defined as an infection of the urinary system involving the lower urinary tract and may include involvement of the upper urinary tracts. (1) The definition of a symptomatic UTI generally requires the presence of urinary tract-specific symptoms in the setting of significant bacteriuria with a quantitative count of ≥10 (5) colony forming units of bacteria per millilitre (CFU/ml) in one urine specimen. (2) Asymptomatic bacteriuria (ABU) is defined as the presence of bacteria in the urine, without clinical signs or symptoms suggestive of a UTI. (2)

INCIDENCE

UTI is one of the most commonly-diagnosed infections in the elderly. It is the most frequently-diagnosed infection in long-term care residents, accounting for over a third of all nursing home-associated infections. (3)

The incidence of UTI is higher in women compared with men across all age groups. In post-menopausal women, the incidence of UTI is estimated at 0.07 per person-year and 0.12 per person-year in older women with diabetes. (5) For men aged 65-to-74 years, the incidence of UTI is estimated to be 0.05 per person-year. (6) Over 10 per cent of women over the age of 65 years report having a UTI within the previous 12 months (7) which increases to almost a third of women over the age of 85 years. (8) Consequently, in both men and women over the age of 85 years, the incidence of UTI increases substantially. A cohort study looking at this older age group found the incidence of UTI in women to be 0.13 per person-year and 0.08 per person-year in men. (9)

ABU is also more common with increasing age in both men and women. In younger women, the estimated prevalence of ABU is one-to-five per cent, increasing to an estimated six-to-16 per cent in women over the age of 65 years. (10) The use of urinary catheters predisposes both men and women to ABU. The risk in catheterised older adults ranges from three to 10 per cent per day of catheterisation, eventually reaching 100 per cent in adults with chronic indwelling catheters. (11)

RISK FACTORS

Women, both young and elderly, are at greater risk of UTI than men, however, the most consistent and strongest predictor across women of all age groups is having a history of previous UTI. (12) In one study, post-menopausal women with a prior UTI were over four-times more likely to develop a subsequent infection compared with women without a previous diagnosis. (12)

Urinary retention and high postvoid residual (PVR) urine has been postulated to be a risk factor for UTI in older adults. In men, high PVR and urinary stasis as a result of chronic obstruction due to prostatic hypertrophy are thought to be important factors for developing UTI and ABU; however, studies evaluating the association in this population are limited. A study of post-menopausal women in 2011 found that a PVR greater than 200 ml was associated with more frequent urinary symptoms. (13)

Older adults in residential or nursing care are more likely to have functional and cognitive impairments plus more medical comorbidities compared to older adults living in the community. All of these characteristics predispose this population to higher rates of ABU and UTI. (14) The most significant risk factors associated with UTI in long-term care facilities is the presence of a urinary catheter and, similar to community-based older adults, history of prior UTI. (9) Comorbidities, such as stroke and dementia, which may predispose individuals to bowel and bladder incontinence, are also associated with symptomatic UTI and persistent ABU in this population.

Continued onto next page

URINARY TRACT INFECTION

DIAGNOSIS

UTI in healthy older women without a urinary catheter or abnormalities of the genitourinary tract is generally regarded as uncomplicated. (1) Diagnosis is usually based on common urinary symptoms suggestive of cystitis including urgency, frequency, dysuria and supra-pubic tenderness.

However, post-menopausal women may also present with non-specific generalised symptoms, such as lower abdominal pain, back pain, chills and constipation. (15) Traditionally, a diagnosis of UTI has required the presence of urinary tract-specific symptoms together with significant bacteriuria denoted by a quantitative count of ≥10 (5)16 CFU/ml in one urine specimen. However, a diagnosis can often be made based on symptoms and signs – a culture is not routinely required. (16)

ABU in women is defined as the presence of two consecutive urine specimens positive for the same bacterial strain in quantities ≥10 (5) CFU/ml, in the absence of any signs or symptoms of a genitourinary tract infection. For men, ABU is defined as a single voided specimen with one bacterial isolate in quantities ≥10 (5) CFU/ml, in the absence of symptoms. (2) For adults with an indwelling urethral, suprapubic or intermittent catheter, ABU is defined as a positive urinary culture for one bacterial isolate in quantities ≥10 (2) CFU/ml, in the absence of symptoms. (19)

In nursing home residents, the diagnosis of symptomatic UTI can be particularly challenging, often due to impaired ability to communicate as a result of cognitive deficits, and chronic genitourinary symptoms (e.g., incontinence, urgency and frequency). Furthermore, when suffering a UTI, long-term care residents are more likely to present with non-specific symptoms, such as loss of appetite, confusion and general decline in function. (17) In the setting of atypical symptoms, clinicians are often faced with the challenge of differentiating a symptomatic UTI from other infections or medical conditions.

To address this issue, a cohort study in nursing home residents attempted to identify clinical features that were predictive of 'culture-confirmed' UTI. The most commonly-reported clinical features for suspected UTI in this cohort were change in mental status (39 per cent), change in behaviour (19 per cent), change in character of the urine (i.e., gross haematuria and change in the colour or odour of urine; 15.5 per cent), fever or chills (12.8 per cent) and change in gait or a fall (8.8 per cent). (17) In a multivariable analysis, change in mental status, dysuria and change in character of the urine were significantly associated with culture-confirmed UTI.

The diagnosis of UTI remains a significant diagnostic dilemma for clinicians caring for older adults – fever and localised urinary symptoms should still be the initial trigger for UTI evaluation. The Scottish Antimicrobial Prescribing Group (SAPG) produced a decision aid tool in 2018 to help identify those patients likely to require treatment. (18)

TREATMENT

The most common organism responsible for causing UTI in both community and healthcare settings is Escherichia coli, followed by other Enterobacteraciae, such as Proteus mirabilis, Klebsiella and Providentia species (found more commonly in catheter-associated UTI). Gram-positive organisms, such as methicillinresistant Staphylococcus aureus (MRSA) and Enterococcus, are also found but less commonly overall, although frequency is increasing in healthcare settings and in adults in long-term care. (19)

With increased emphasis on antibiotic stewardship, careful prescribing of antibiotics has become paramount. The risk of Clostridium difficile diarrhoea and other healthcare-associated infections can be reduced by greater use of targeted, narrow spectrum antibiotics. However, this also increases the necessity for accurate diagnosis and organism identification where possible. Local guidelines based on local resistance patterns and available agents are therefore essential.

The management of uncomplicated symptomatic UTI in women has been the subject of several randomised controlled trials but most exclude the very elderly and focus on younger adults. Current British National Formulary (BNF) and SAPG guidance advocate that Nitrofurantoin and Trimethoprim may be used as the first-line antibiotic in uncomplicated symptomatic UTI in females. (10, 20) Nitrofurantoin is not to be used in those with renal impairment due to the inability to achieve necessary concentrations in the urine and possibility of toxic levels in the plasma. (10) Trimethoprim should only be used if there is low risk of resistance. Second-line treatments are listed as Nitrofurantoin, Fosfomycin and Pivmecillinam. The European Association of Urology (EAU) guidelines no longer include Trimethoprim as first-line treatment and advise usage only in areas where resistance rates for E. coli are less than 20 per cent. (21)

A three-day course of Nitrofurantoin is recommended for women and a seven-day course for men. A Cochrane Review of 15 randomised controlled studies examined evidence for duration of antibiotic therapy for uncomplicated, symptomatic lower UTIs in older women (1,644 elderly females) were reviewed and the authors concluded that short course antibiotics of three-to-six days could be adequate for treating uncomplicated UTI in older women. (22) However, for persistent, chronic and recurrent infections, longer courses and or prophylactic courses may be required to remove bacterial persistence. (1, 21, 23)

In catheterised patients with symptoms of UTI, a seven-day course of antibiotics, following local antibiotic guidelines, is recommended in both men and women. (11) The catheter should be removed then replaced if necessary.

For more information, visit Bladder Health UK at www.bladderhealthuk.org or call 0121 702 0820.

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Treat uUTIs with just one sachet!

Profile

Monuril®
Fosfomycin trometamol

- Included in NICE guidance as second choice or as an alternative empirical treatment, if first choice options are unsuitable[1]
  - For non-pregnant women aged 16 years and over[1]
- Indicated for the treatment of uUTIs in women >12 years[2]
  - Contra-indicated in patients with severe renal insufficiency < CrCl 10 mls/min
- One sachet - stat dose[2]
  - Due to mean urinary concentration above the MIC for *E.coli* for up to 72 hours[3]
- Very low *E.coli* resistance, showing minimal increase over time[4]
- Active against common urinary pathogens including multidrug resistant strains[5,6]

How to take Monuril

Monuril should be dissolved into a glass of water and taken immediately after its preparation. It should be taken on an empty stomach, preferably before bedtime and after emptying the bladder[2]

Monuril PIP code: 4028635

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Prescribing Information. Monuril 3g granules for oral solution. Consult Summary of Product Characteristics before prescribing. Legal Category: POM **Marketing Authorisation number and basic NHS cost:** PL 31654/0006, £4.86 per sachet. Presentation: One sachet contains 5.631 g of fosfomycin trometamol equivalent to 3.0 g fosfomycin. Uses: Monuril is indicated in the treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females. Monuril is also indicated for prophylaxis in diagnostic and surgical transurethral procedures. Consideration should be given to official guidance on the appropriate use of antibacterial agents. **Dosage and administration:** Acute lower uncomplicated urinary tract infections: Adults and adolescent females (>12 years of age): 1 sachet (3 g) once. Prophylaxis of urinary tract infections for surgery and diagnostic procedure involving the lower urinary tract: Adults: One Monuril 3 g sachet 3 hours before surgery. A second dose of 3 g may be given 24 hours after surgery. Method of administration Monuril is for oral administration, it should be dissolved into a glass of water and taken immediately after its preparation. It should be taken on an empty stomach, preferably before bedtime and after emptying the bladder. **Special populations:** The safety and efficacy of Monuril 3 g in children below 12 years of age have not been established. It is not recommended for children under the age of 12. At the present time, single-dose antibacterial treatments are not suitable to treat urinary tract infections in pregnant women. Only moderate amount of safety data on pregnant women is available and does not indicate any malformative or foetal/neonatal toxicity of fosfomycin. The use of Monuril may be considered during pregnancy, if necessary. Fosfomycin is excreted into human milk at low level after a single injection. Therefore fosfomycin can be used during breastfeeding, after a single oral dose. **Warnings and Precautions:** Hypersensitivity reactions including anaphylaxis and anaphylactic shock may occur. Antibiotic associated diarrhoea has been reported with fosfomycin and nearly all antibacterial agents. It may be symptomatic of Clostridium Difficile. Monuril contains sucrose; its use is not recommended in patients with hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Patients with severe renal insufficiency (Creatinine clearance <10 ml/min). Patients undergoing haemodialysis. **Interactions:** Concomitant administration of metoclopramide has been shown to lower serum and urinary concentrations of fosfomycin and should be avoided. Other drugs that increase gastrointestinal motility may produce similar effects. Food may delay the absorption of the active ingredient of Monuril, with consequent slight decrease in peak plasma levels and urinary concentrations, see above. **Side Effects:** The most common adverse reactions following the single-dose administration of fosfomycin trometamol involve the gastrointestinal tract, mainly diarrhoea. Other common undesirable effects are vulvovaginitis, headache, dizziness and nausea. Anaphylaxis and angioedema have been reported with an unknown frequency. Further information is available from Profile Pharma Ltd, Bicentennial Building, Southern Gate, Chichester, West Sussex. P019 8EZ United Kingdom. General Information: E-mail: info.profilepharma@ZambonGroup.com Tel: +44(0)1243859000 Medical Information: Tel: +44 (0) 800 0288 942 **Prescribing Information drawn up: March 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 Profile Pharma Ltd. at Profile.Drugsafety@ZambonGroup.com or telephone: +44(0)800 0288 942

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GB_MON_103 September 2019

A CRY FOR HELP

IT'S ESTIMATED THAT UP TO ONE-IN-FIVE BABIES IN THE UK SUFFER FROM INFANT COLIC, GENERATING FEAR AND CONFUSION IN THEIR EXHAUSTED CARERS. GP AND ENDOSCOPIST, DR SOPHIE NELSON, SURVEYS THE SIGNS, CAUSATIVE FACTORS AND IMPACT, AND HOW WE CAN SUPPORT THE PARENTS OF BABIES WITH COLIC.

Dr Sophie Nelson

When a newborn baby has been crying for more than three hours a day, for more than three days a week, for at least three weeks, it could be a sign of infant colic. Colic is an emotional condition that leaves parents exhausted and often desperate for reassurance. The conditions for infant colic's diagnosis remain vague and its treatment options are debated still. How, then, can healthcare professionals help in such a fraught arena? What can they advise, and how can parents of a colicky baby be reassured?

Commonly observed in babies aged under six months – when infants will cry more than at any other time in their lives – colic is defined as perceived excessive crying in babies who otherwise appear to be healthy. Unsurprisingly, few parents agree on how much crying is considered 'excessive'; statistics have shown that the average time spent crying for a baby under three months is a little over two hours per day. After three months this total halves.

The aforementioned 'rule of three' diagnosis can sometimes be helpful, but there are other symptoms to consider. If crying is worse in the evening, if they clench their fists, if they go red in the face, draw their knees to their chest, arch their back, or have an excess of wind, all while experiencing no failure to thrive in any other capacity, then these are signs that a baby could be suffering from colic. After six months, infant colic usually disappears as mysteriously as it arrived.

CAUSES AND TREATMENT CONSIDERATIONS

The causes of colic are unknown, but it has been suggested that trapped wind, indigestion, or food allergy could all play a role. In addition to digestive problems, more controversially, behavioural issues such as family tension, parental anxiety, or inadequate parent-infant interaction have also been explored as causative factors for infantile colic.

Almost always diagnosed by the parents and treated at home, it is difficult for research into colic to be standardised. Furthermore, research pools are rarely large enough to provide conclusive evidence, thereby adding to the inconclusive nature of diagnoses and treatment of the condition.

Results of testing are gathered from parental perception in a chaotic home life environment and as a result are anecdotal and problematic. In a real-world evidence study, 4,004 parents of children with colic were asked about their experiences of the condition; over 75 per cent had either diagnosed colic in their child themselves, or a friend or relative had done so; only 24.3 per cent of the cases had been diagnosed by a healthcare professional of some description.

INFANT COLIC

As far as treatment is concerned, the NHS website states that parents of children with colic do not need to see a doctor and does not endorse medicines, focussing more on physical and environmental options, including how to hold or rock the baby and the use of soothing background noise.

NICE guidelines recommend that parents be given advice, reassurance and support and suggests that medical options be considered only if parents feel unable to cope.

However, there are a variety of over-the-counter treatments formulated to improve the symptoms of colic that are widely bought and used, and which parents often report have a positive impact on their babies. Simethicone (an anti-foaming agent), gripe water, lactase drops (to aid the breakdown of lactose in formula and breastmilk) and probiotic drops are all available from pharmacies and bought in vast numbers each year.

Despite NICE advice, of the 4,004 parents involved in the aforementioned real-world evidence study, more than two-thirds (69.7 per cent) of respondents, who had made use of a simethicone suspension, either on its own or alongside another treatment, reported improvements in the signs of infant colic within one day. Almost all (93.2 per cent) considered that its use was associated with either complete resolution of the condition or had some effect on its symptoms.

Advising anyone on how to manage crying babies remains a touchy subject to navigate. By the time parents come to their pharmacist or GP for advice, they can be sensitive, exhausted, and verging on desperate. These anti-colic products, found in most pharmacies, can provide reassurance to parents that they are doing something to help, which can in turn lessen the stress they may be transmitting to their newborn. The support of friends and family is also a massive comfort to new parents. When this kind of relief isn't available, charities like Cry-sis can step in. Founded with the aim to provide assistance to parents of inconsolable babies, Cry-sis began life in 1981 as a support group. It is now a helpline open to parents seven days a week.

AWARENESS AND REASSURANCE

As part of Colic Awareness Month last September, Cry-sis have engaged in a number of projects to raise awareness of colic among parents and healthcare professionals, including producing a new patient leaflet, due to be printed and distributed among 3,000 GP practices, offering advice on how to manage crying babies. The leaflet includes information on colic, advice about how to tell if your baby is unwell, and tips on how to soothe a crying baby. It is their hope that spreading awareness on the subject of infant colic will reassure parents that they are not alone, at a time that can feel very lonely.

Though the diagnosis of colic is difficult, the distress experienced by parents is very real and it is important not to dismiss. The new patient leaflet closes on advice to parents about how to handle feeling overwhelmed, including putting the baby down and leaving the room for a little while. The early months of a newborn's life can be frightening, particularly if it is the parents' first child and healthcare professionals can often be a port in the storm when it comes to reassurance.

ABOUT THE AUTHOR

Dr Sophie Nelson is a salaried GP in Wilmslow, Cheshire. She also works as a GPwSI at Manchester Royal Infirmary, both in outpatients clinics and the endoscopy suite. She graduated from the University of Manchester in 2006 and is a member of The Royal College of General Practitioners and The Royal College of Surgeons of Edinburgh, and has a Masters degree in Surgical Sciences from Edinburgh University.

IBS: AN EDUCATION

How can healthcare professionals help patients and raise irritable bowel syndrome (IBS) awareness? Patient education, peer support and health coaching are all valuable tools, shares Dr Simon Smale, Gastroenterologist and Medical Adviser to The IBS Network.

Dr Simon Smale

Up to 12 million people in the UK are thought to suffer from IBS. This is a long-term condition that has a significant impact on the quality of life and wellbeing of people with the condition and affects their working and social lives.

Many people with IBS often struggle to receive a positive diagnosis based upon current NICE guidance (www.nice.org.uk/guidance/cg61). It's important that patients receive a positive diagnosis based on a typical history and examination, exclusion of red flags, and appropriate tests based upon exclusion of coeliac disease and inflammatory pathology within the gut. They can then move forward in identifying their triggers and managing the lifestyle factors which exacerbate their condition.

SELF-MANAGEMENT

Self-management underpins the treatment of IBS, and people with the condition are significant users of healthcare resources. However, they spend relatively little of their time in consultation with healthcare professionals. Most of their time is spent at home, at work, or with friends and families. While many patients manage their condition themselves and become 'experts through experience'; most can benefit from additional support and education from professionals.

Most patients recognise the importance of self-management for their condition but there is variable ability to do this successfully. There are a number of strategies professionals can use to support patients in managing their condition. Patient education, peer support and health coaching can all enable patients to better address the lifestyle factors that may exacerbate their condition.

EMPOWERING THROUGH EDUCATION

Education is key to improving understanding and empowering patients, both to ask pertinent questions and to make appropriate changes to their lifestyle based upon their own knowledge and personal experience and awareness of their lifestyle. This may be undertaken on a face-to-face basis or by directing them to appropriate online resources.

The IBS Network (www.theibsnetwork.org) is an excellent resource for people with the condition, providing support, advice and information for those identifying their triggers and learning how to live well with IBS. The charity provides members with access to an ongoing support network and range of educational materials that help them to make better decisions and choices for themselves.

IBS self-help groups provide peer support, and while not available in every location, enable patients to access mutual support. Many of the self-help groups address issues which are common to all patients, giving people the chance to learn more about their condition and ways to manage better.

A SHOW OF SUPPORT

Diet and psychological stressors are common triggers for many, so the mutual support and mentorship from people who are living well with IBS is helpful and inspiring to those recently diagnosed or struggling to manage their IBS. This support is invaluable. The IBS Network has a growing network of support groups throughout the UK.

Health coaching can support behavioural change. Evidence suggests that few patients undergo 'Damascus' conversion and radically change their behaviour overnight, regardless of how forceful the message to change their lifestyle might be. Indeed, forceful and patronising lectures make most people less likely to change their behaviour.

Much more likely to affect change is an approach, with support, which helps patients identify the opportunities for themselves and explores how they might make small incremental changes in the right direction. An example would be the reduction of a beverage such as caffeinated coffee that can both exacerbate symptoms in IBS and is habit-forming. Patients might struggle to give up caffeine overnight, but reduction can help, so it is worth exploring whether it is possible to alternate caffeinated with decaffeinated coffee.

In terms of psychological support, both face-to-face and online psychological therapies have evidence for efficacy. Patients may find apps, such as Zemedy, a useful aid to addressing some of the psychological factors which exacerbate IBS. Similarly, Food Maestro is a well-evidenced diet-focussed app from the team at King's College Hospital designed to support patients to make the necessary changes involved in undertaking the low FODMAP diet, with the support of an appropriately-trained health professional.

Patients often need help to select from the plethora of apps – some of which are less well-evidence-based.

Many professionals are concerned that investing time in educating patients about their condition, coaching them and exploring how they might change their lives and advising them about the apps, groups and resources available to support them takes too long. However, evidence suggests that time invested in supporting meaningful lifestyle change and self-management, including signposting them to the support of The IBS Network, pays dividends in reducing the demand for ongoing support and repeated attendance.

For more information, visit The IBS Network at www.theibsnetwork.org.

KNOWING THE SCORE

FROM BROKEN METATARSALS TO MUSCLE STRAINS, PHYSIOTHERAPY HELPS WITH A HOST OF SPORTS INJURIES. PHYSIOS ARE PRESENT ON THE TOUCHLINE AND IN THE MEDICAL ROOM – THEY ARE PART OF A PLAYER'S JOURNEY, ASSESSING THE INJURY, REHABILITATION AND RETURN TO PLAY. HERE, THE CHARTERED SOCIETY OF PHYSIOTHERAPY OFFER AN EXPERT VIEW ON RUGBY AND FOOTBALL INJURIES, PARTICULARLY HOW THEY HAPPEN AND HOW TO TREAT THEM.

Physios incorporate sports-specific skills into a player's rehabilitation and are best placed to understand the functional demands of the sport and to analyse individuals for potential areas of risk. They assess posture and biomechanics, as well as movement mechanics, to look at how all the joints work together in unison, and perform tests to assess individual joints, muscles, tendons, ligaments and the functionality of the nervous system. For safety and to reduce the risk of re-injury, players should complete rehabilitation under the guidance of a chartered physiotherapist.

COMMON FOOTBALL INJURIES

HAMSTRING STRAIN

The hamstrings are a group of four muscles found at the back of the thigh that bend the knee. When they are overstretched the muscle fibres can tear, leading to a strain. This happens during explosive or rapid movements such as sprinting. Immediate physiotherapy will involve the 'PRICE' protocol to reduce bleeding, swelling and pain. Rehabilitation will include gentle stretching, soft tissue work and muscle strengthening. The player will move onto football-specific drills, including jumping, running and sprinting.

A grade one hamstring strain involves around five-to-10 per cent of the muscle fibres and requires one-to-two weeks' rest before a player can return. A grade two strain is more extensive, including a greater number of muscle fibres, and players will tend to be out for three-to-six weeks. A grade three muscle strain is a severe tear involving most or all (rupture) of the muscle fibres. Players may require surgery and could be out for three-to-four months.

SPRAINED ANKLE

This is where there is soft tissue damage to the ligaments in the ankle joint. Around 70-to-85 per cent of ankle sprains are 'inversion' sprains. This occurs when you roll the ankle outward and the sole of the foot faces in and up. This can happen during a tackle, by running on uneven ground or landing awkwardly.

Initial treatment will involve the 'PRICE' protocol. As the ligaments start to heal, the player will be encouraged to put more weight through the ankle joint. The physio will then work with the player on their balance, co-ordination and muscle strength.

Grade one ankle sprains are a mild sprain of the ligaments. Grade two is a partial tear of the ligament(s) and may result in some 'looseness' at the joint. Grade three is a complete tear of the ligament which results in gross instability at the ankle joint and may require surgery. Dependent on the grade, a player may be out for three-to-six months.

ANTERIOR CRUCIATE LIGAMENT (ACL) INJURY

This is the supporting ligament in the knee joint that enables twisting and turning movements. It can tear or completely rupture during an awkward landing or fall, or under the impact of a tackle.

This injury is more common in women. Rehabilitation is an intensive and staged process to work on fitness and strength, and to ensure that the repair (graft) does not fail from early stressors. Initial treatment could include electrical muscle stimulation, hydrotherapy, anti-gravity treadmill work and exercises for flexibility.

Football-specific drills will be introduced later, starting with straight line running. Pivoting and quick turns will be introduced towards the latter stages of rehab, as these put the newly-repaired ligament under the most stress.

MEDIAL COLLATERAL LIGAMENT (MCL) SPRAIN

This is the ligament that joins the thigh bone and the shin bone and is found on the inner side of the knee joint. As with the ACL, it can be torn through twisting or impact. Immediate treatment will involve the 'PRICE' protocol.

As the ligaments start to heal, the player will be encouraged to put more weight through the ankle joint. The physio will then work with the player on their balance, co-ordination and muscle strength to get them back to match fitness. They may use bracing techniques to support the joint during rehabilitation.

MCL sprains can be categorised into three types. A grade one sprain is a mild sprain of the ligaments. Grade two is a partial tear and may result in some 'looseness' at the joint. Grade three is a complete tear of the ligament which results in gross instability and may require surgery.

Continued onto next page

THIGH (QUADRICEPS) AND CALF STRAINS

A tear can occur in the quadriceps group of muscles found on the front of the thigh that are responsible for straightening the leg, i.e. when kicking a ball. The calf is at the back of the lower leg and is made up of two key muscles which enable players to push off and run. Like other muscles, the calf can be torn and strained when stretched beyond its limits.

Immediate physiotherapy treatment will involve the 'PRICE' protocol to reduce the bleeding, swelling and pain. Rehabilitation will include gentle stretching, soft tissue work and muscle strengthening before the player can start football-specific drills, including jumping, running and sprinting.

Muscle strains are categorised into three grades – grade one will involve around five-to-10 per cent of the muscle fibres. A grade two strain involves a greater number of muscle fibres. A grade three muscle strain is a severe tear or rupture involving most or all of the muscle fibres.

HOW TO MINIMISE THE RISK OF RUGBY INJURIES

JAMES MOORE, A FORMER SARACENS PHYSIOTHERAPIST, OUTLINES THE WAYS IN WHICH PLAYERS AT ALL LEVELS CAN MINIMISE THEIR RISKS OF BEING INJURED.

KNEES

Knee injuries have been shown to result in the largest amount of time lost from sport. It can take up to nine months to return after an ACL injury, for example. The hamstrings have been shown to be the region most frequently injured by the outside backs (full backs and wings) and the most common injury to occur away from contact.

The hamstring works effectively well with the knee in that it supports the ACL by controlling the shin. But while the hamstring can support the knee well the knee also needs to be able to produce huge forces and in particular large amounts of deceleration forces, especially when changing direction. Hamstring injuries predominantly occur during high-speed running, which is why the back three are most vulnerable.

Effective eccentric exercise training (slow and controlled) will help with deceleration movements and effective high-speed training will help to minimise hamstring injuries. Examples include any form of pressing movements such as leg presses, squats and deadlifts but done under control and tension through the lowering phase (i.e. lowering slowly).

Train your hamstrings with both complex movements (split squats and lunges) as well as isolated movements (hamstring curls). Strength training in the gym alone will not protect your knees – the hamstrings need to be trained at speed, so effective drills and running sessions will help to condition your hamstrings. Practicing cutting movements and decelerations can condition your knees.

ANKLES AND CALVES

Calf injuries have been shown to be the most frequent injury experienced by the front row. While simple ankle sprains and minor calf strains do not result in a large amount of time lost per injury, they can occur regularly, so through a season their cumulative effect of time lost is significant.

The surface that rugby is played on can vary and this means that your feet and ankles need to adapt constantly and at the same time produce force.

Running alone doesn't condition the ankles, feet and calves well enough to deal with the demands of the surfaces and the sport. Effective strategies include strength training through calf raises, calf and ankle mobility through range by working uphill, and by maintaining good ankle and calf flexibility (through regular stretching), and working on reactivity through proprioceptive exercises such as single leg balance work.

SPINE

Spinal injuries – ranging from simple sprains to catastrophic injuries involving spinal fractures – are becoming more common in rugby. There is an increased use of the head and neck being used as a lever arm to help with 'clearing out'. Training your neck muscles by maintaining neck flexibility drills and by building the muscles around the neck can help. Exercises that can help include simple shrugs. There are much more complex exercises, but we would advise specialist input being sought before commencing them as the neck is a very sensitive and vulnerable area.

The low back can also be very vulnerable. When you go back to basics the spine is really a large spring that is designed to transfer force around the body. It is not designed to be the primary force producer. This primary force production should come from the shoulders and hips, so effective mobility and flexibility for both your hips and shoulders, coupled with good strength through your available range of motion, can take a lot of pressure off your spine and therefore protect it.

RECOVERY

The most important part of training is recovery to allow your muscles to adapt and recover effectively. Rugby is a high velocity collision sport that traumatises the muscles and joints with impact. This needs effective recovery to allow the body to be ready for the next session.

Monitoring your nutrition, sleep and the amount of work you have done is key to achieving the right physiological state so that you are ready to play at the weekend. If you turn up to a game fatigued and not completely recovered, your risk of injury goes up significantly.

Schedule in regular breaks where you reduce your rugby training, and reduce your running and weight training. This does not need to be done at the same time in the same week but cycling the reduction can be key to making sure that you are not over-cooking it for the weekend.

For more information, visit www.csp.org.uk/public-patient/sports-injuries.

MALE BREAST CANCER IN SCOTLAND AT RECORD 25-YEAR HIGH

The number of men living in Scotland who have received a breast cancer diagnosis has risen continuously for the last 25 years and in 2017 reached 1.3 cases per 100,000 men.

According to new research from the University of Aberdeen, the incidence of male breast cancer in Scotland has almost doubled from 0.8 cases per 100,000 men in 1992 to 1.3 cases per 100,000 men in 2017. This rising trend was most pronounced in the North of Scotland, although the trend was also generally stronger in rural areas.

The study, published in The European Journal of Surgical Oncology, found that male breast cancer accounted for 0.36 per cent of all breast cancers diagnosed in 1992, rising to 0.65 per cent of all breast cancers in 2017.

The study, led by Professor Valerie Speirs, used publicly-available data from the Information Services Division Scotland to monitor trends in the number of men living in Scotland receiving a breast cancer diagnosis.

Professor Speirs explained, 'With this type of data, it's hard to say if this is a real rise or just that men are becoming more aware and presenting with symptoms. Maybe 25 years ago, they would have just ignored it then either died with the disease without even knowing they had it or before it became a bigger problem. Plus, we are living longer, and cancer is associated with ageing, so the rise may reflect this.

'Importantly, our findings emphasise the need for a better understanding of male breast cancer. We need to determine the risk factors of the disease so that improved prevention policies can be applied. Going forward there may also be a call to design bespoke treatment for men so we can target molecules expressed by male breast cancer.'

Professor Valerie Speirs

NATIONAL STUDY REVEALS INSIGHTS INTO CHILD MENTAL HEALTH

A national report – carried out every four years – has provided insights into child mental health in Scotland.

The 2018 Health Behaviour in School-aged Children study in Scotland (HBSC), led by researchers at the MRC / CSO Social and Public Health Sciences Unit, University of Glasgow, and funded by NHS Health Scotland, provides data on the health and wellbeing of the nation's young people.

Key findings include that the majority (85 per cent) of young people reported high life satisfaction in 2018, while almost one-in-five adolescents rated their health as excellent. However, the report also revealed the lowest levels of adolescent confidence seen in 24 years, with only 51 per cent of adolescents in Scotland reporting often or always feeling confident in themselves.

Beyond mental health and wellbeing, the HBSC study covers areas such as sleep habits, time spent online, physical activity, in addition to school and home life. The report presents data collected from surveys with a representable sample of 11, 13 and 15-year-olds in Scotland in 2018. The surveys were conducted in schools, with all of the pupils in the selected classes being asked to fill in the confidential questionnaire anonymously.

Dr Rory Mitchell, Public Health Intelligence Principal, NHS Health Scotland, commented, 'This report highlights some positive trends as well as ongoing challenges. The data shows that children from wealthier families tend to report better health and wellbeing than those from poorer families. This highlights the need for a continued focus on tackling health inequalities in Scotland.

'The information provided by this long-running study has enormous value in helping to improve health and wellbeing. Using such information to make a real difference requires a collaborative effort that co-ordinates local and national action. The formation of Public Health Scotland in April this year will contribute to this.'

EPILEPSY

A WORK-IN-PROGRESS

Around 220,000 people of working age in the UK identify epilepsy as their 'main' health condition, making it one of the most common serious neurological conditions in the world. Yet despite its encompassing nature – spanning any age and background – a glaring employment gap shockingly persists. SPR takes a look at this demoralising deterrent for patients, and how fairer access to, and treatment, in the workplace have therefore been prompted.

87 people are diagnosed with epilepsy every day, but the fluctuating and invisible condition impacts the lives of individuals differently. While some people are unable to work at all, depending on how epilepsy affects their daily life, many can work with minimal adjustments. Despite this, patients commonly encounter hurdles when applying for jobs or within the workplace – reporting that disclosing their epilepsy at the interview stage can have a negative impact on their application, and at times, they also experience discrimination from their employer or colleagues.

ON THE DOWN LOW

According to recent government findings highlighted by national charity Epilepsy Action, statistics have demonstrated that as high a proportion of 66 per cent of working-age people with epilepsy are not in work. The employment rate for people with epilepsy is far lower than for those with most other disabilities, according to data from the Office for National Statistics. The employment rate for people with epilepsy as their main condition is only 34 per cent compared to 53 per cent for people with disabilities generally, and 81 per cent for those without a disability.

People with epilepsy are also more likely to be economically inactive than people with any other disability and are more than twice as likely as those without the condition to be unemployed. Furthermore, research by the Trade Union Congress has highlighted that people with epilepsy in work are paid on average 11.8 per cent less than non-disabled workers. This means that not only are people with epilepsy less likely to have a paid job, but when they do, they earn less than their non-disabled peers.

Further depicting the difficulties for those with epilepsy seeking to work, and the extent as to which their enthusiasm can simultaneously be impeded, Philip Lee, Chief Executive at Epilepsy Action, said, 'These figures are very worrying, yet they only skim the surface. Despite its prevalence, epilepsy is still a stigmatised condition in the workplace. From the initial application and job interview process to the day-to-day experience of working, many people with epilepsy encounter clear barriers and discrimination. This treatment can lead to fear of dismissal and even cause some people to hide their condition.'

NEIL'S STORY

Neil, 57, from Oxfordshire, has been looking for work for the last two years and describes it as a demoralising experience. He went for a kitchen porter vacancy last year and said that the interview was going well until he mentioned that he had epilepsy – something the Job Centre had advised him to do. He has sleep seizures, which may require him to rest for a few hours in the morning. Neil explained that the atmosphere immediately changed and the interviewer told him, 'No, I want someone 100 per cent and normal' and wouldn't let him explain any further.

Neil added, 'Some employers are really great, some less so. I think when employers do first-aid courses, they should also learn about how to help someone having a seizure. It's so horrible just sitting at home – I want to work but it's so hard getting past the interviews when they find out I have epilepsy. All I want to do is work and wish someone would give me a chance.'

ADDRESSING THE ISSUES

Why are – in so many cases – the career aspirations of those with epilepsy being curbed?

In a recent Institute for Employment Studies report, commissioned by Epilepsy Action, employers admitted that they were reluctant to hire people with epilepsy, largely due to concerns over safety. This is backed up by data that reveals that more than three-quarters (76 per cent) of people have not been offered any training on how to support a colleague when they have a seizure at work. This is despite current UK regulations requiring employers to provide staff with the required health and safety information and training.

SMASHING THE STIGMA

It's time for change – to come together and make a start on closing this inequality gap which has lingered for far too long already.

Speaking on how we can turn frustration into transformation, Philip explained, 'Increased knowledge and a change in attitudes are the only ways we can start to close this inequality gap. We are calling on employers to take simple steps to help support people with epilepsy. They should encourage transparency from the outset and make it their business to learn more about epilepsy. It's only then that they can improve workplace culture and create a level, more inclusive, playing field to help people with epilepsy pursue the career they want.'

MAKING A DIFFERENCE

Epilepsy Action is currently developing a toolkit to help businesses support their staff with epilepsy and delivers bespoke training sessions to employers.

For more information, visit www.epilepsy.org.uk/awarenesstraining or call the Epilepsy Action freephone helpline on 0808 800 800 5050.

REACHING FOR THE STARS

The sector's achievements were driven to the frontlines as the Scottish Pharmacy Awards honoured its 2019 title-holders.

The pinnacle of the sector's talent and success dazzled during the presentation of the Scottish Pharmacy Awards.

The 2019 ceremony – steered by host, Shereen Nanjiani – attracted an audience of 300-plus pharmacy representatives to the Crowne Plaza in Glasgow.

As a benchmark of industry brilliance, the annual event invites entries from across the wide spectrum of pharmacy, with the categories ranging from Student Leadership, and Hospital Pharmacy Team of the Year, to Management of Substance Dependency in the Community, and Community Pharmacy Practice of the Year. The applicants were whittled down by an esteemed panel of judges, and the victors were revealed on the night.

Rounding off the celebrations, which also encompassed dining and networking opportunities galore, was the declaration of the prestigious Lifetime Achievement Award. The 2019 title was granted to a recently-retired Evelyn McPhail in acknowledgement of her inspirational commitment to the field as Director of Pharmacy at NHS Fife.

Throughout the evening, donations were kindly contributed by guests to the 2019 nominated charity – the Scottish Association for Mental Health (SAMH).

The categories which the winners triumphed in were:

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

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!

HOSPITAL PHARMACY TEAM OF THE YEAR AWARD WINNER, THE LAURISTON AND CHALMERS PHARMACY TEAM (NHS LOTHIAN), WITH PAUL CONCANNON, ETHYPHARM UK, AND ALISON WILSON, DIRECTOR OF PHARMACY (NHS BORDERS)

WINNER

HOSPITAL PHARMACY TEAM OF THE YEAR

THE LAURISTON AND CHALMERS PHARMACY TEAM NHS LOTHIAN

Sponsored by Ethypharm UK

The team's day-to-day contribution to the sector is exemplary, providing a high quality, patient-centred service – in line with best practice – for individuals under their care, within a multidisciplinary working environment.

Consisting of permanent core staff – including a lead pharmacist, specialist pharmacist, senior pharmacy technician and pharmacy support worker – the specialist pharmacy outpatient team deliver clinical pharmacy and dispensing services to patients across two specialities, namely HIV and dermatology, in a city centre location at Chalmers Centre and Lauriston Building.

As well as the expected dispensing of medicines in a proficient manner, the team go above and beyond in demonstrating person-focussed care in partnership with their multidisciplinary colleagues. Their vast range of responsibilities include routinely providing medication review, patient counselling and education on high-risk medicines, such as antiretrovirals, biologics, oral retinoids, DMARDs and cytotoxics. The pharmacists teach patients how to inject biologic and cytotoxic medicines and work in partnership with these patient groups to achieve concordance with therapies where non-compliance could have potentially drastic consequences.

The pharmacy team's role in ensuring the safety and effectiveness of medicines in this setting is pivotal as they are able to establish a link with all new patients starting high-risk medicines in both HIV and dermatology, and therefore able to immediately address pharmaceutical care issues as they arise, with timely access to the multidisciplinary team when required.

Due to the complexities of HIV and dermatology patient care, and the fact that these services both transcend the primary and secondary interphase, the team interact with a wide assortment of healthcare professionals on a daily basis. For example, they support three HIV clinics a week and attend a weekly multidisciplinary team meeting to discuss various aspects of patient care. During HIV clinics, after a consultation has taken place, clinicians will discuss each patient with pharmacy to ensure that the patient receives the most appropriate pharmaceutical care from pharmacists. Additionally, the pharmacy team facilitate HIV patient care by managing the homecare service for patients, ensuring that prescriptions are processed correctly and in a timely manner.

Further expanding the team's role – and showcasing their determination to put the patient at the very centre of all that they do – the members are currently in the process of agreeing dermatology shared care agreements for methotrexate, azathioprine and ciclosporin with their primary and secondary care colleagues working in rheumatology and gastrointestinal medicine. The crossover of medicines being used for autoimmune conditions means that there is a potential to standardise their protocols and monitoring arrangements.

Notably, the team recently undertook a very successful short-term project which involved switching all dermatology patients on Humira to the biosimilar version, Amgevita, which was more cost-effective. This switch was managed and conducted by the specialist pharmacist working in dermatology and was supported by the dermatology multidisciplinary team and service managers. The pharmacist conducting the switch programme ensured that each patient was counselled over the telephone prior to the switch and that patients were given the opportunity to attend for device training if required.

> 'We are very excited and honoured to win this award. The whole team have worked really hard and the other finalists are amazing too. It's the people who make up the teams and this is a testament to them.'
>
> The Lauriston and Chalmers Pharmacy Team (NHS Lothian)

> 'Ethypharm UK is delighted to be sponsoring this award. The winner deserves the recognition they have received – a lot of hard work goes on. Well done!'
>
> Paul Concannon
> Ethypharm UK

COMMUNITY PHARMACY PRACTICE OF THE YEAR AWARD WINNER, BERNADETTE COLFORD AND TEAM, CADHAM PHARMACY HEALTH CENTRE, GLENROTHES, WITH RACHEL WRIGHT, KENT PHARMA, IAN MCWILLIAMS, KENT PHARMA, AND DR JOHN MCANAW, HEAD OF PHARMACY, NHS 24

WINNER

COMMUNITY PHARMACY PRACTICE OF THE YEAR

BERNADETTE COLFORD AND TEAM
CADHAM PHARMACY HEALTH CENTRE, GLENROTHES

Sponsored by Kent Pharma

The pharmacy's consistent demonstration of high standards of healthcare delivery is testament to the team behind it – sharing a vision and supporting one another through challenging times of change in the sector.

The team includes three accuracy checkers and three technicians who – as a result of their committed and forward-thinking nature – have welcomed the opportunity to learn new machines, adapt to the introduction of huge screens, and develop private travel and aesthetics services, in addition to new innovative NHS services, which meant going back to university.

As well as nurturing the current business, the pharmacy team have embraced this new digital era. Through her attendance at numerous conferences, Bernadette was introduced to the idea of having an NHS-approved app which was launched last year after a three-month training and planning phase. The feedback thus far has been positive – helping the pharmacy further in their journey to meeting the ever-changing expectations of the consumer and offering additional accessibility. Continuing this path, Bernadette is aiming to establish an online shop and offer a 24 / 7 click and collect service.

In 2017 Bernadette was approached by a pharmacist who thought that she might be interested in a 24 / 7 collection robot; two machines were subsequently installed due to how popular this service has been for the community. The innovation injects functionality into the pharmacy; however, the biggest saving is staff time collecting repeat packages already assembled and ready to collect. The interface with the Patient Medication Records adds safety to the collection process and ease and convenience 24 / 7, 365 days a year.

The biggest driver for the creation of the pharmacy's asthma clinic was the knowledge that a lot of asthma deaths were preventable; strongly believing that they could make a difference to the lives of the people they serve, working as a partner in their lives and in the NHS. The team therefore took action to add in enhanced triage to the patient's journey of care in acute and long-term disease management, providing enhanced assessments and having access to a pharmacist practitioner to prescribe in community pharmacy.

In line with the pharmacy's objectives, Bernadette, as an IP pharmacist, embarked on many routes to upskill, including core and advanced consultation skills courses; core and advanced respiratory courses, such as sounding chests with NES; a common clinical conditions course (NES); and she attended various pharma events and shadowed the local GP clinics and out-of-hours services to gain experience in the more hands-on practical skills.

The provision of services continued to be boosted through the employment of a nurse with no additional funding due to the skills she could bring to the clinic, supporting the pharmacist's journey to provide the acute care side of the clinic and patient experience. This was an invaluable experience for all of the pharmacists, and the pre-registration pharmacist, Zia, who became hugely involved in running the clinics and benefited from inter-professional sharing of expertise.

> 'I'm so proud of the whole team – I can't thank them enough. I hope that our work inspires other pharmacists and shows them that it's possible. If we can support anyone else, or help in any way, we absolutely will. The people we serve are the reason we do what we do.'
>
> Bernadette Colford
> Cadham Pharmacy Health Centre
> Glenrothes

> 'Kent Pharma is incredibly proud to sponsor such an important award that showcases the inspirational work – and the leaders at the helm of it – in community pharmacy in Scotland. Congratulations to the winning team and the fantastic finalists.'
>
> Rachel Wright and Ian McWilliams
> Kent Pharma

RESPIRATORY PROJECT OF THE YEAR AWARD WINNER, LIBBY KENNEDY, NEWCASTLETON MEDICAL PRACTICE (NHS BORDERS), WITH JAMES DALE, TEVA UK RESPIRATORY, AND ROISIN KAVANAGH, DIRECTOR OF PHARMACY (NHS AYRSHIRE & ARRAN)

WINNER
RESPIRATORY PROJECT OF THE YEAR
LIBBY KENNEDY
NEWCASTLETON MEDICAL PRACTICE, NHS BORDERS

Sponsored by Teva UK Respiratory

Positive, motivated, enthusiastic and knowledgeable, Libby is an integral asset to respiratory care – helping to ensure the best outcomes for all patients.

As a result of the recent shortage of GPs, Libby has increased her clinical role, particularly with regards to respiratory patients who are referred to her for follow-up after acute episodes. If a patient has been admitted to hospital, Libby will also contact them promptly after discharge.

Peak flow diaries are used as part of the initial asthma diagnosis and this resource has proved useful to patients, GPs and secondary care. As different inhalers are tested, and dose changed, patients are able to monitor the outcome subjectively. A high percentage of the consultation time is spent on inhaler technique, which is reviewed at every visit, while the In Check device is a practical tool for demonstrating the ideal technique.

Spreading awareness of accurate asthmatic care is a key priority for Libby; she therefore visits the local primary school, educating teachers on MDI / pacer use, and providing Asthma UK 'school cards' which the staff have found very effective in helping to monitor children and quantify SABA use. Libby also places great significance on the education of carers centring on the supervision and administering of inhalers, and carries out home visits to house-bound patients which prove valuable.

Living in the village, Libby has a lot of background knowledge on her patients and this can prove very helpful in encouraging people to attend for respiratory review. It also means that patients often ask her for advice outside of working hours in which she is always happy to be available to help them have optimal treatment.

Sparked by an acknowledgement of the busy schedules of patients, and aiming to incorporate ease of access within their care, the asthma clinics are operated with flexible hours, so that individuals can be seen before or after work or school. Phone consultations are also carried out as necessary at any time during the working week. Ensuring consistency of care is crucial too, with patients being reviewed at suitable intervals, and newly-diagnosed patients being seen regularly until they have symptomatic control.

Collaborative working and good communication underscore Libby's work, as she ensures that information is passed quickly and accurately to the appropriate person or place. She spends time with the locum GPs – updating them on current prescribing guidance and training them on how to use inhalers and educating patients – and works closely with the respiratory pharmacist in the Borders Prescribing Support Team and the respiratory specialist nurses, often seeking advice from them.

To further equip individuals with all the necessary skills and information, Libby and the team utilise all the excellent patient education material provided by Asthma UK, the British Lung Foundation and various pharmaceutical companies. Meanwhile, the recycling of all inhalers is actively promoted, and stock control is carried out efficiently – they keep a minimal range of inhalers according to current formulary guidance.

> 'I just feel so passionate about the difference that we can make to patients, and I can tell you many stories about individuals who have had their lives changed by using their inhalers properly. I love the work that I do. Thank you.'
>
> Libby Kennedy
> Newcastleton Medical Practice
> (NHS Borders)

> 'It's so encouraging to hear how passionate Libby is and to learn of the brilliant work she does. Congratulations!'
>
> James Dale
> Teva UK Respiratory

COMMUNITY PHARMACIST OF THE YEAR (INDEPENDENT) AWARD WINNER, ALISON HAIR, PARKHEAD HEALTH CENTRE PHARMACY (NHS GREATER GLASGOW & CLYDE), WITH NATHAN WILTSHIRE, CAMBRIAN ALLIANCE GROUP, AND DAVID THOMSON, LEAD PHARMACIST, COMMUNITY PHARMACY DEVELOPMENT AND GOVERNANCE (NHS GREATER GLASGOW & CLYDE)

WINNER

COMMUNITY PHARMACIST OF THE YEAR (INDEPENDENT)

ALISON HAIR

PARKHEAD HEALTH CENTRE PHARMACY, NHS GREATER GLASGOW & CLYDE

Sponsored by Cambrian Alliance Group

From the outset, Alison and her team have helped drive primary care teamwork, through initiatives such as pharmacist-led clinics, real-time contact allowing safe and cost-effective prescribing, and generating an environment where sharing ideas and working together creates a rewarding place of work.

The infrastructure and processes which the team have in place allow pharmacists to be released from the dispensing and checking benches to deliver clinical care. The pharmacists work in an environment where the embedded culture is one of continuous learning and development in which they all have the opportunity, and are motivated, to utilise their professional experience and knowledge to deliver effective paths of care, such as the chronic medication service. This has been renamed as Medicines, Care and Review, and through this service the team are able to support patients to make informed decisions about their care. Everyone in the team considers themselves equal partners in the delivery of care and the positive effect this has on morale and motivation simultaneously has a positive impact on patients and the broader NHS.

Reflective of Alison and the team's motivation to facilitate care for different corners of the population, they have implemented a clinic for homeless patients who are registered with their homeless GP practice. Alison works in collaboration with the clinicians and other healthcare workers affiliated to the homelessness practice, in which the aims are to minimise the negative health impact of homelessness by helping patients access healthcare and support attendance at other relevant services, not only healthcare.

Alison and the pharmacy have worked on innovative ways to engage with patients and support adherence to, and storage of, their medicines. They prescribe for these patients and refer on, across all clinical conditions common in this population, including infections, infestations, injury, malnutrition and addictions, along with the long-term conditions prevalent in the general population.

Within the pharmacy setting the team are also participating in a project to increase public awareness of alcohol consumption and the recommended low risk guidance by way of offering advice, support and onward referral. They are collaborating with staff from the Glasgow Council on Alcohol to facilitate alcohol brief interventions.

The presence of four IP clinics within the pharmacy has also hugely contributed towards the cultivation of improved patient care and team morale. In particular, the polypharmacy clinic is an opportunity to optimise medicines use by stopping unnecessary or ineffective medication, initiating medication where indicated, and making dosage adjustments to manage the patients' long-term or acute conditions optimally. This involves a collaborative approach, with the patient at the centre of all decisions, supporting them to make informed choices about their care. Alison and the team work closely with their GP and nurse colleagues in delivering this care, only referring to secondary care where necessary.

Mindful of the future of the profession and how they can help its continued fruition through learning, Alison and the pharmacy work in collaboration with their GP undergraduate training practice, delivering educational sessions for their medical students.

> 'I'm shell-shocked. This is for the patients who give us the great honour and privilege of sharing our knowledge of medicines to help them live their lives. Thank you so much.'
>
> Alison Hair
> Parkhead Health Centre Pharmacy
> (NHS Greater Glasgow & Clyde)

> 'From a Cambrian Alliance perspective, we're particularly pleased to sponsor this award which is so important. We're delighted for Alison.'
>
> Nathan Wiltshire
> Cambrian Alliance Group

INNOVATIONS IN CLINICAL DEVELOPMENT IN CARDIOLOGY PHARMACY AWARD WINNER, ANTHONY MCDAVITT AND TEAM, GILBERT BAIN HOSPITAL (NHS SHETLAND), WITH JOANNE JERVIS, DAIICHI-SANKYO, AND IAIN SPEIRITS, WEST GLASGOW ACH CARDIOLOGY PHARMACIST

WINNER

INNOVATIONS IN CLINICAL DEVELOPMENT IN CARDIOLOGY PHARMACY

ANTHONY MCDAVITT AND TEAM
GILBERT BAIN HOSPITAL, NHS SHETLAND

Sponsored by Daiichi-Sankyo

Within an island-based rural general hospital, a small team of pre-operative assessment nursing staff work with patients and the wider multidisciplinary team to safely take patients through their procedure.

The team pre-assess a wide variety of procedures and interventions delivered by a broad range of consultant general and specialist surgical staff, with a strongly heterogenous case mix. Oral anticoagulants and the planning required are a significant, complex clinical area for the team to manage effectively – POA nurses have to ensure that the patient has the right plan for them based on their risk of bleeding and VTE by considering clinical status and frailty; comorbidities; previous interventions; planned procedure (and referral reason); other medications; and their location in Shetland.

Complexity is increased further for staff who are often liaising with locum or visiting consultant surgeons, anaesthetists or other specialists who are not familiar with local processes and expectations – with staff also pre-assessing patients for procedures in other units i.e. the Golden Jubilee National Hospital.

The team's initiative entailed identifying – via general practice clinics – issues around anticoagulants and perioperative plans; and – via hospital pharmacy – issues around on-the-day procedure cancellations due to anticoagulants. Working with colleagues from anaesthetics, surgery, preassessment and day surgery, they utilised Significant Event Analysis (SEA) to review previous issues OACs presented POAC staff with. This interdisciplinary team were brought together to review the current process' weaknesses, and develop a new approach to reduce variation, support staff, foster responsibility in teams, and provide clear information for patients and community professionals to safely manage oral anticoagulation during the entire perioperative period.

The project focused on all patients who were referred for elective procedures requiring pre-operative assessment, and treated with antiplatelets or anticoagulants. By convening a wide stakeholder group of staff involved in care processes, improvements could be made in the care planning and medicines management elements, mitigating significant clinical risks with better support in clinical decision-making.

The intervention incorporated various steps, including using SEA and case studies to identify weaknesses in the current system which have led to variation in practice, waste and difference in outcomes; developing an action plan with discrete areas of work from SEA learning; and delivering on the action plan and reviewing outcomes of work. Patient representatives were also involved throughout the process, and each step was checked with expert opinion and evidence-based guidelines.

Following the effective implementation of this approach, clear patient information documentation and care plans were developed, and clear responsibilities for staff groups involved in this process were produced. Further benefits generated by the team's work have been the reduction of cancelled procedures and improved clinical pharmacist understanding of DOACs in perioperative period. There is also overall bolstered awareness in general practice of the perioperative procedure plans.

'We're truly overwhelmed and grateful for the effort and hard work of everyone who has worked with us.'

Anthony McDavitt and Team
Gilbert Bain Hospital
(NHS Shetland)

'Daiichi-Sankyo is absolutely thrilled to sponsor this award. The winner is very well-deserved.'

Joanne Jervis
Daiichi-Sankyo

MANAGEMENT OF SUBSTANCE DEPENDENCY IN THE COMMUNITY AWARD WINNER, MARK GREHAN, ROWLANDS PHARMACY, SPRINGBURN WAY, GLASGOW, WITH KEN SUTHERLAND, ETHYPHARM UK, AND DUNCAN HILL, SPECIALIST PHARMACIST IN SUBSTANCE MISUSE (NHS LANARKSHIRE)

WINNER

MANAGEMENT OF SUBSTANCE DEPENDENCY IN THE COMMUNITY

MARK GREHAN

ROWLANDS PHARMACY, SPRINGBURN WAY, GLASGOW

Sponsored by Ethypharm UK

Mark has showcased a keen awareness and insight into the issues faced by the patients he works with, and is driven by a deep empathy to not only support them with a team of well-trained and informed colleagues behind him, but to look for more opportunities to further outreach to other patients.

Since moving to Rowlands Pharmacy in 2016, Mark and the team have developed one of the most wide-ranging substance dependency support service programmes in Greater Glasgow & Clyde. They service roughly 90 ORT patients through their methameasure dispensing tool, and provide clean injecting equipment and appropriate advice to their substance dependency patients (roughly 400 transactions per month).

Two local initiatives which Mark has particularly championed within the pharmacy since completing his training in 2017 have been the take home Naloxone service (providing take home Naloxone kits and training in the pharmacy setting) and the Blood Borne Virus testing service (finger prick test in the pharmacy testing for active Hepatitis C and HIV infection). Since their commencement, the team have supplied 101 Naloxone kits and completed 88 BBV tests in the pharmacy (as of September 2019). Also notable is the team's provision of Hepatitis C treatment to patients that they have referred to Gartnavel Hospital from the positive BBV tests. Mark has prioritised these services in the pharmacy due to the local demographic.

The pharmacy's continually evolving focus on the substance dependency landscape is testament to Mark's forward-thinking and innovative leadership – especially in terms of the role of education.

Initially, both Mark and the other pharmacist manager were Naloxone / BBV trained, but they subsequently realised that it was necessary to train up the pharmacy team in order to scale up the service and get as much Naloxone and the associated training out to as many patients as possible. Spurred into action, Amanda Laird, the local lead substance dependency pharmacist, arrived at the branch to train five of the staff in BBV testing, while a number of staff members were also booked on to the Naloxone training.

To further bolster the team's knowledge and to ensure that they tap into ongoing changes and growing demands of the population, they have regular liaising with local CAT teams and John Campbell / Amanda Laird at the health board regarding training CPD events in substance dependency. Additionally, in late 2018, Mark attended the Scottish Drug Forum Conference on behalf of John Campbell and Rowlands Pharmacy to attempt to network with different healthcare professionals centring on the objective of reducing drug-related deaths.

Looking to the future, Mark recognises the benefits which the further cultivation of pharmaceutical care can reap for this patient group. To maximise on this opportunity, as an independent prescriber, he sees himself potentially further upskilling to hopefully one day support patients through this qualification. Also in line with his passion for the sector's scope to deliver so much more, Mark has agreed with Amanda Laird to pilot a local COPD service for their local substance dependency patients to get them diagnosed via consultants and into treatment.

> 'I am absolutely delighted to win this award on behalf of the pharmacy. Community pharmacy is obviously quite a challenging environment but I feel like we do a lot of really good work which wouldn't be possible without the team.'
>
> Mark Grehan
> Rowlands Pharmacy
> Springburn Way, Glasgow

> 'Congratulations to Mark for winning this award. It's great to see how much the pharmacy puts into the community. It's very well-deserved.'
>
> Ken Sutherland
> Ethypharm UK

DRINKS RECEPTION

1. Elaine Hancock and Libby Kennedy
2. Robin Hogarth and Scott Bryson
3. Lynsey Hyslop, Amy Paxton, Shirley Panter, Nicola Lyons, Amy Robinson and Kirsteen Graham
4. The setting for the evening
5. The Ogg & Co Pharmacy team
6. Zara Vafael, Graeme Carswell and Anahita Shiran
7. Stephen McBurney, Laura Fraser, David Coulson and Diane Robertson
8. The Cadham Pharmacy team
9. The Bannerman's Pharmacy team
10. The Kent Pharma team
11. The Napp Pharmaceuticals team
12. The Cegedim Rx team


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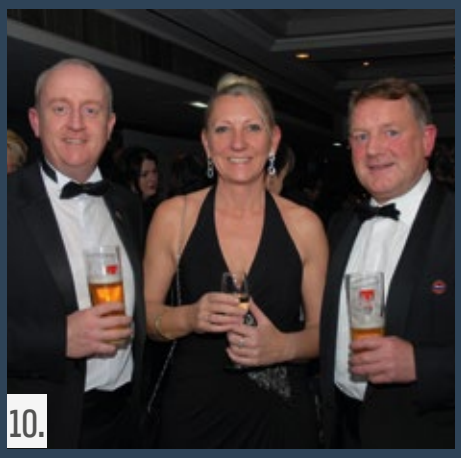
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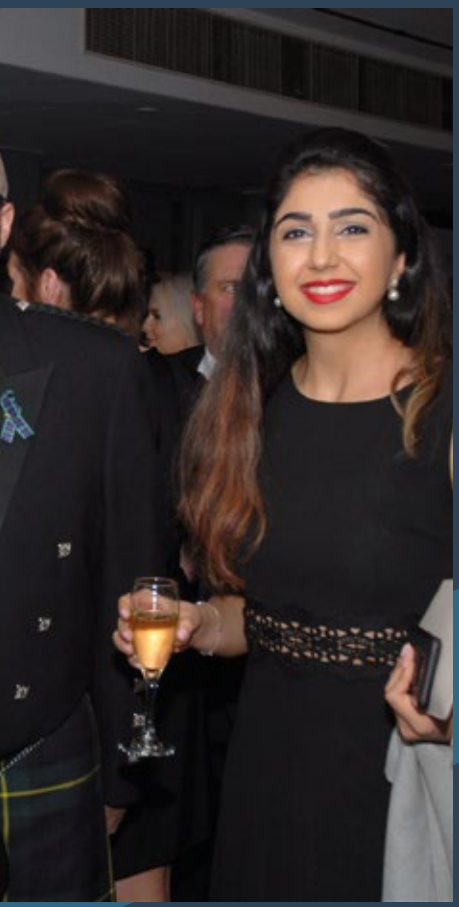


12.

SCOTTISH PHARMACY AWARDS 2019

DRINKS RECEPTION

13. Alison and Ian Wilson
14. Kirstie Hale and Lynne Davidson
15. Anne Boyter, Donald Cairns and Marion and George Romanes
16. Audrey and John McAnaw, and Kenny and Julie Halliday
17. Laura Wilson and Pernille Sorensen

13.


14.


15.


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17.

MDU

MEDICAL DEFENCE UNION

IN WITH THE NEW

With the beginning of a new year comes new year's resolutions. These often relate to our health and we often don't see them through to the end of the year, but there are some changes which are easy to achieve and might make a big difference to your day-to-day personal and professional life. Dr Kathryn Leask, Medico-Legal Adviser at the Medical Defence Union, shares a few resolutions to get the new decade off to a good start.

Dr Kathryn Leask

CHECK THAT YOUR CONTACT DETAILS ARE UP-TO-DATE

The General Medical Council expect you to let them know when your contact details change. Not doing so could run the risk of them not being able to contact you about important news or about your registration and revalidation. In the worst-case scenario, your registration could lapse with the risk of you finding that you have been working without General Medical Council registration or indemnity. It's also important to make sure that your Royal College and medical defence organisation also have your up-to-date contact details.

CHECK YOUR INDEMNITY

It's important that your indemnity provider has the correct information about your professional role, the hours you work, and any additional roles you may have, for example, if you help out at sporting events or carry out private work. Not keeping your medical defence organisation up-to-date could jeopardise any assistance you may need.

SET GOALS FOR YOUR PROFESSIONAL DEVELOPMENT

It's easier to ensure that you engage in an adequate amount of professional development if you make a plan for your next appraisal year. Make sure that you complete any mandatory training set by your employer and consider any gaps in your knowledge or areas of interest when planning your CPD. It's important not just to focus on clinical aspects of your role. A lot of the complaints which the Medical Defence Union assist members with involve responding to communication failure. Update your communication skills, conflict resolution training and breaking bad news training to avoid any difficult situations with patients that may lead to a complaint.

KEEP YOUR CPD LOG BOOK UP-TO-DATE

The emphasis on recording your professional development has changed over the last few years with less onus on collecting certificates and more on reflections and considering how what you have learned will impact on your practice. There are a number of apps and CPD diaries available which allow you to record your reflections immediately. Keeping on top of this ensures that you are ready for your appraisal and don't forget any of the key messages which you have learned.

MAKE TIME FOR YOURSELF

The media is full of reports of the workload which healthcare professionals face and stress and burn-out within the profession. Take time to look after your own physical and mental health by eating well, exercising and taking time out to relax and enjoy yourself. It's important to make sure that you address any of your own health concerns.

Remember that the General Medical Council expect doctors to seek and follow independent medical advice rather than diagnose and treat themselves.

CHECK YOUR SETTINGS

With such busy lives, social media makes it much easier to keep up-to-date with friends and family and find out what is happening in the world. Do you know who is following you or whether your privacy settings are set appropriately? Have you inadvertently become friends with a patient or could a journalist gain access to your Facebook account and photographs?

KEEP PATIENT DATA SAFE

Most breaches of confidentiality are made accidentally, whether this is during a discussion in a place that isn't private, or by leaving notes in view of others. The use of electronic devices and electronic means of communication are becoming more common and this comes with its own risks. Have you got confidential patient information on your laptop, tablet or phone? If so, what does your employer's confidentiality policy say about this? Is the information password-protected or encrypted so that the data is safe if the device fell into the wrong hands?

CHECK YOUR FINANCES

Whether you're just starting out in your career or you're thinking about retirement, it is important to have a handle on your finances. You might want to seek advice about additional voluntary contributions to your pension or how tax allowances might affect you. Have you got any policies in place that no longer cover your needs or do you need to think about what you would do if you were unable to work? Make sure that you declare any additional earnings to avoid any unpleasant surprises from the tax office.

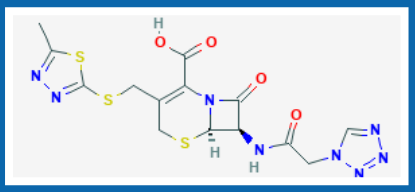
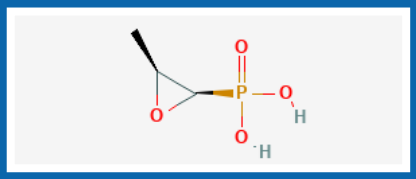
DON'T BE A VICTIM

Cyber fraud is an ever-growing problem and while internet banking is very convenient, it comes with its own risks. Is it time to change your passwords and increase your security settings for your bank account, credit card and mobile phone account? Some organisations allow you to set additional security features to increase the protection they provide. Keep a regular eye on your accounts so that you can spot any fraudulent activity early and keep the phone numbers you might need handy. Use passwords which you can remember and don't write them down anywhere they could be found.

For more information, visit www.themdu.com.

SPR EXAMINES TWO INTRAVENOUS ANTIBIOTICS CURRENTLY APPROVED FOR USE IN THE UK

Intravenous (IV) antibiotics are considered to be the most effective manner in which patients receive treatment for a wide range of infections including urinary tract, respiratory, skin / soft tissue and brain infections. The reason for this is that they are directly administered into the patients' bloodstream, therefore avoiding the process of being broken down and absorbed by the body itself. This ultimately leads to the antibiotic reaching the desired site more rapidly; subsequently promoting a reduction in the healing and recovery time.

IV Cefazolin		IV Fosfomycin
	**Chemical Structure**	
Cephalosporin antibiotic	**Group**	Phosphoenolpyruvate (PEP) analogue antibiotic
Powder for solution for injection/ infusion	**Pharmaceutical Form**	Fomicyt 40mg/ml powder for infusion
Inhibits cell wall synthesis by blocking penicillin binding proteins, such as transpeptidases, in the growth stage therefore resulting in bactericidal action	**Mechanism of Action**	Disrupts cell wall biosynthesis by inhibiting phosphoenolpyruvate synthethase therefore interfering with the production of peptidoglycan by blocking the formation of N-acetylmuramic acid
• Treatment of skin/ soft tissue infections and bone/ joint infections caused by cefazolin-susceptible micro-organisms • Perioperative prophylaxis for surgical operations that pose a higher risk of infections with anaerobic pathogens	**Therapeutic Indications**	Treatment , in adults, children and neonates, for: • Acute osteomyelitis • Complicated UTI • Nosocomial lower RTI • Bacterial meningitis • Bacteraemia associated with, or suspected to be associated with the above infections
• Adults and adolescents over 12 years of age and at least a bodyweight of 40kg • Infections caused by sensitive micro-organisms: 1g – 2g daily divided equally across 2 – 3 doses • Infections caused by moderately sensitive micro-organisms: 3g – 4g daily divided equally across 3 – 4 doses	**Posology**	• Dosage regimen of IV fosfomysin ranges depending on the severity of the infection • General dosage range is 12-24g daily, in equal divided doses (max8g per dose) • Indication for IV therapy should be reviewed daily
Administered by slow intravenous injection or intravenous infusion after it has been diluted (single does of 1g or more should be given as I-V infusion)	**Method of Administration**	Administered by slow intravenous infusion after it has been diluted in normal saline
• Hypersensitivity to cefazolin and/ or cephalosporin antibiotics • History of severe hypersensitivity to any other type of beta-lactam antibacterial agent • Cefazolin solutions containing lidocaine should never be administered intravenously	**Contraindications**	Hypersensitivity to fosfomycin
• Anticoagulants • Vitamin K1 • Probenecid • Nephrotoxic substances	**Interactions**	No currently known major interactions
As a precautionary measure, as cefazolin reaches the embryo/ foetus via the placenta, it is preferable to avoid the use of cefazolin 2g powder for solution for injection/ infusion, if the use is not needed	**Pregnancy**	Use only if potential benefit outweighs risk to patient
• Injection side reactions • Diarrhea • Stomach pain/ cramps • Tiredness • Headaches	**Side-Effect Profile**	• Diarrhoea • Headache • Nausea and vomiting • Fatigue • Oedema • Dyspnoea
• Store below 30oC • Keep vial in the outer packaging and avoid from light	**Storage**	• Store between 15oC and 30oC • Keep vial in the outer packaging and avoid from light

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STEPPING UP TO THE PLATE

Amber Knight, Scientific and Regulatory Executive at the British Specialist Nutrition Association, investigates the role of the healthcare professional in paediatric food allergies and intolerances.

Infancy and young childhood are periods of significant growth and development. Good nutrition, in the form of adequate energy and sufficient nutrients (protein, carbohydrate, fat, vitamins and minerals), is key in supporting health and development during this time. However, managing the nutritional intake of children with food allergies and intolerances presents a challenge for parents, carers and healthcare professionals alike. Food allergies affect three-to-six per cent of children in the developed world (1) and are becoming more common. Beyond the immediate risk of anaphylaxis, poorly-managed allergies and intolerances put infants and young children at greater risk of developing nutritional disorders and faltering growth. (2)

FOOD ALLERGY VS. FOOD INTOLERANCE

Food allergies and intolerances are often confused, but are distinctly different. The primary difference between a food allergy and a food intolerance is the involvement of the body's immune system in an allergic response, meaning that a food allergy has the potential to be life-threatening. Food allergies can be further categorised into IgE-mediated, non-IgE-mediated or a mixture of both.

	Food Allergy		
	IgE-Mediated	Non-IgE-Mediated	Food Intolerance
Trigger	A specific protein within a food	A specific protein within a food	A food or food component (not necessarily a protein)
Mechanism	The body's immune system identifies the specific protein as a threat and produces IgE antibodies which in turn release histamine into circulation	Mechanism is not well understood, the immune system is involved, but IgE antibodies are not released	Many possible mechanisms; lack of enzymes, the food itself. Does not involve the immune system
Symptoms	Mild to moderate: redness, swelling, itchiness and increased mucus production by the nose Severe: swollen tongue, difficulty breathing, anaphylaxis	Gut symptoms: abdominal pain, vomiting, reflux, constipation, diarrhoea, feeding difficulties Skin symptoms: redness, itchiness, worsening of eczema	Abdominal pain, diarrhoea, bloating, cramping, constipation, rashes, rhinitis, wheezing, headaches
Onset of Symptoms	Minutes to hours	Hours to days	Dependent on quantity consumed
Diagnosis	Skin-prick testing and / or blood test for specific IgE antibodies	No clinical tests, diagnosed using a trial of elimination and reintroduction	No clinical tests, diagnosed using a trial of elimination and reintroduction
Treatment / Management	Allergen avoidance Mild symptoms can be treated with anti-histamines and severe symptoms require adrenaline (EpiPen / Jext)	Elimination of specific protein containing food	Elimination of identified food
Example	Peanut, egg allergy etc.	Cow's Milk Protein Allergy	Lactose intolerance

CHALLENGES OF DIAGNOSIS IN THE PRIMARY CARE SETTING

The increasing prevalence of allergies and intolerances in the population has intensified reliance on primary care physicians for the diagnosis and management of mild to moderate cases. (3) Primary care service providers often feel poorly equipped to diagnose and manage specific cases involving food allergies and intolerances. (4) Research conducted in the UK and Ireland found that only nine-to-23 per cent of primary care referrals to allergy clinics resulted in an allergy diagnosis and that with adequate training, half of those referrals could have been appropriately managed in primary care. (5, 6, 7)

Allergy diagnosis and management resources for healthcare professionals:

- NICE Guidelines Food Allergy in Under 19s: Assessment and Diagnosis (8)
- EATERS (9)
- RCPCH: Allergy Care Pathways for Children (10)
- The Milk Allergy in Primary Care (MAP) Guideline 2019 (11)
- World Allergy Organisation (WAO) Diagnosis and Rationale for Action Against Cow's Milk Allergy (DRACMA) Guidelines 2010 (12)

ALLERGIES AND INTOLERANCES IN INFANTS 0-TO-SIX MONTHS OLD

Breastfeeding is unequivocally the best way to feed an infant, with the health benefits to both mother and baby being well-established. The immunologically active components and indigestible sugars contained within human breastmilk have the potential to protect against disease. (13) Breastfeeding, with the elimination of allergens via the maternal diet, is the best treatment option for infants who present with an allergy. While true lactose intolerance is extremely rare in breastfed

infants it is important for healthcare professionals to be aware of its distinction from Cow's Milk Protein Allergy.

Cow's Milk Protein Allergy (CMPA)

CMPA, an allergy to milk proteins casein and / or whey, is the most common and most complex food allergy in infants and young children. According to Allergy UK, CMPA affects two per cent to three per cent of infants living in the developed world. There are two types of CMPA:

1. Immediate or IgE-mediated allergy
2. Delayed or non-IgE-mediated allergy

Exposure can occur either through breastfeeding (via cow's milk protein in the maternal diet) or when an infant is fed standard infant formula. The type of CMPA determines severity of symptoms, with the worse-case scenario being anaphylaxis. Once diagnosis is confirmed, strict avoidance of cow's milk protein is the safest management strategy. For an infant with CMPA who is exclusively breastfed this is achieved through elimination of cow's milk protein in the mother's diet, managed by a qualified healthcare professional. For an infant that receives mixed feeds or relies solely on formula, an extensively hydrolysed formula (eHF) or an amino-acid based formula (AAF) can be prescribed. (11, 14)

Lactose Intolerance

Not to be confused with CMPA, infants with lactose intolerance have the inability to digest the carbohydrate lactose due to a complete or partial absence of the enzyme lactase. There are three different types of lactose intolerance:

- Hereditary: an infant is born without any lactase. The condition is extremely rare and symptoms typically occur after first feeds. Hereditary lactose intolerance is managed with a special formula containing an alternative carbohydrate source to lactose to ensure the continued nourishment, development and health of the child
- Primary: an infant is born with lactase, but the quantity decreases over time and symptoms increase. Primary lactose intolerance does not typically become apparent until after weaning
- Secondary: a temporary, but common, condition where GI illness induces a short-term state of lactase deficiency. Breastfeeding mothers are advised to continue to breastfeed and formula-fed infants are advised to be switched to a lactose-free infant formula for six-to-eight weeks after which standard infant formula can be gradually reintroduced (15)

Allergies and Intolerances When Weaning

While an exciting milestone, the introduction of complementary foods into an infant's diet can be a nerve-wracking time for parents. Healthcare professionals have an important role in assisting parents to safely introduce allergenic foods into their child's diet.

Prior to weaning it is important to consider a child's risk of allergy. Infants are at a higher risk of developing a food allergy if they have eczema (particularly early-onset or moderate-severe eczema) or already have a diagnosed food allergy (e.g. CMPA). Research suggests that infants at a higher risk of developing a food allergy may benefit from the introduction of egg and peanut from four months, alongside other non-allergenic foods. (16)

It is recommended that once an infant shows the appropriate developmental signs, small amounts of non-allergenic pureed vegetables, fruit, starchy foods or protein may be offered. Allergenic foods can then be introduced one at a time with sufficient periods between introductions to allow potential reactions to become evident. It is important that parents and carers are made aware of the symptoms of an adverse reaction to aid diagnosis and ensure the safety of their child.

After a potentially allergenic food has been introduced into a baby's diet, and no adverse reaction has been observed, inclusion should be continued and the food given at least twice a week. For further resources on the introduction of allergenic foods, visit Allergy UK and BSACI.

Signs of a Reaction to Food

IgE-Mediated Allergy	Non-IgE-Mediated Allergy	Food Intolerance
• Red, itchy skin, hives	• Red, itchy skin	• Abdominal pain
• Swelling around lips, eyes and mouth	• Atopic eczema	• Bloating
• Swelling of lips, tongue and palate	• Reflux	• Flatulence
• Colicky abdominal pain	• Loose / frequent stools	• Diarrhoea
• Nausea, vomiting, diarrhoea	• Abdominal pain	• Skin rash
• Nasal itching, sneezing, congestion	• Blood / mucus in stools	• Skin itching
• Coughing, chest tightness, wheezing	• Constipation	
• Anaphylaxis	• Tiredness	
	• Infantile colic	
	• Food refusal	

Post-Weaning Allergy Management

Primary care providers with a paediatric patient who presents with signs of an adverse reaction to a food should follow their relevant care pathway. When managing the treatment of an infant or child with a food allergy or intolerance, healthcare professionals are advised to closely and regularly monitor the growth of their patient and be aware of signs of malnutrition. The management of food allergies and intolerances requires either total or partial elimination of offending foods. The nutritional complications of this elimination can lead to a higher risk of growth failure, low intake of micronutrients, deficiency and feeding difficulties. (2) It is the responsibility of the healthcare professional, in partnership with parents and carers, to support an infant or child with allergies or intolerances to thrive.

Infants and young children with mild to moderate non-IgE-mediated allergies and food intolerances can often grow out of their condition, enabling the safe incorporation of triggering food/s in their diet. Any re-introduction of an allergen must occur in a supervised manner and in accordance with relevant clinical guidelines. For example, children who have non-IgE-mediated CMPA may be reintroduced to cow's milk in a step-wise manner, as outlined in the iMAP Milk Ladder. (17)

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

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Date of preparation: October 2019 | ANUKANI190323

AXIAL SPONDYLOARTHRITIS: THE (GENDER) GAP IN KNOWLEDGE

ONE OF THE MAJOR HURDLES THAT HAS SCUPPERED THE SECTOR'S AWARENESS AND MANAGEMENT OF AXIAL SPONDYLOARTHRITIS (AXSPA) IS THE LONG-ENTRENCHED PERCEPTION THAT IT'S MALE-SPECIFIC. IN FACT, THE ROLE OF GENDER IN THIS CHRONIC, INFLAMMATORY RHEUMATIC DISEASE MIGHT JUST SURPRISE YOU. SPR INVESTIGATES WHY THE DISEASE'S IMPACT HAS BEEN DISCOUNTED IN THE FEMALE POPULATION, AND HIGHLIGHTS THE IMPORTANCE OF MORE BEING DONE FOR WOMEN TO ENSURE THAT THEY GET THE RIGHT DIAGNOSIS, AT THE RIGHT TIME, AND RECEIVE THE TREATMENT THEY NEED.

Historically Axial Spondyloarthritis (axSpA) has been considered a disease that primarily affects men – however the emergence of new evidence is shifting our focus and opening up a new path for clinical consideration. In terms of this, it is now known that a significant proportion of women also suffer from axSpA. This prevalence is further fuelled by the discovery and concern that while diagnosis of axSpA has improved over the years, women still experience much longer diagnostic delay than men. As the burden is greater for women, increasing axSpA disease awareness will ultimately lead to better diagnosis and treatment for those affected by this condition.

AXSPA: FACING THE FACTS

As the mission for a more axSpA-educated society marches on, the National Axial Spondyloarthritis Society's website helps SPR get to grips with the severity and symptoms of the condition we're dealing with.

WHAT IS AXSPA?

axSpA is a chronic, inflammatory rheumatic disease that affects the axial skeleton, causing severe pain, stiffness and fatigue. The disease typically starts in early adulthood, a critical period in terms of education and beginning a career path. One-in-200 of the adult population in the UK are impacted – that's twice as many as multiple sclerosis and Parkinson's disease.

WHAT ARE THE SYMPTOMS?

The typical symptoms of axSpA include:

- Slow or gradual onset of back pain and stiffness over weeks or months, rather than hours or days
- Early-morning stiffness and pain, wearing off or reducing during the day with exercise
- Persistence for more than three months (as opposed to coming on in short attacks)
- Feeling better after exercise and worse after rest
- Weight loss, especially in the early stages
- Fatigue or tiredness
- Feeling feverish and experiencing night sweats

WHAT HAPPENS?

Although the painful form of inflammatory arthritis mainly affects the spine, it can also have an impact on other joints, tendons and ligaments. Other areas, such as the eyes and bowel, can sometimes be involved too:

- Inflammation occurs at the site where ligaments or tendons attach to the bone. This is known as enthesis
- The inflammation is followed by some wearing away of the bone at the site of the attachment. This is known as enthesopathy
- As the inflammation reduces, healing takes place and new bone develops
- Movement becomes restricted when bone replaces the elastic tissue of ligaments or tendons
- Repetition of this inflammatory process leads to further bone formation and the individual bones which make up your backbone (vertebrae) can fuse together

Continued onto next page

AXSPA: THE FEMALE FOCUS

Explore the gender spectrum of axSpA – and why we must use it as a stepping stone for future change.

Instrumental to our treatment of axSpA and how we communicate it to patients must be the understanding that the condition is not troublesome for men alone – women have a greater, but different, burden to contend with. But why has the sector grappled with this realisation for so long – and what have been the drivers behind the misinformation regarding the female experience of the condition?

It used to be thought that three-times as many men as women had the disease, yet this was based on a diagnosis of the disease using x-ray. Men are more likely than women to experience changes to the bones and fusion, and thus they were being picked up using x-ray. Over time, however, a change in the sector's approach to the condition occurred, contributed by the development of MRIs which could identify inflammation as women are more likely than men to experience inflammation rather than fusion.

To incorporate these changes in diagnostic techniques, the term axSpA was developed. This is an umbrella term and it includes:

- Ankylosing Spondylitis (AS) or radiographic axial spondyoarthritis – where changes to the sacroiliac joints or the spine can be seen on x-ray
- Non-radiographic axial spondyloarthritis (nr-axial SpA) – where x-ray changes are not present but inflammation is visible on MRI or you have symptoms

The prevalence of nr-axial SpA vs. AS is thought to be a ratio of one:one, while around seven-in-10 people with nr-axial SpA have visible inflammation in the sacroiliac joints or the spine when an MRI of the back is carried out.

Around three-in-10 may not have any inflammation visible on MRI despite symptoms of back pain. Some may never go on to develop visible inflammation on MRI – the reasons for this are still not well-understood, but may be due to the sensitivity of MRI.

Women with axSpA present differently to men and experience greater:

- Disease activity
- Widespread pain
- Peripheral involvement
- Functional impairment
- Fatigue

WOMEN AND THE WIDER IMPACT OF AXSPA

From the under-the-surface mental health hindrance, to the limitations imposed upon their daily life pursuits, the less visible complications of axSpA can be incredibly debilitating for female sufferers. Many will experience severe fatigue, as well as a flare at some point which can make socialising, work and exercising problematic. The overwhelming feeling of not being able to be 'normal' when suffering from fatigue or in a flare also leads to the development of stress, anxiety and other related disorders.

The invisibility of the condition means that it is often difficult to communicate its impact to loved ones, leading to a profound effect on relationships – compounded by the findings that those with it are more likely to remain single or divorced than the general population, and women in particular are less likely to have children.

WHAT'S NEW?

SPR recaps some of the recent research on axSpA and how it's offering enlightenment regarding the onset of the condition comparable between men and women.

BEHIND THE MANIFESTATIONS

In recent years, more and more studies have been homing in on the manifestations of axSpA and the underpinning factors. In particular, a key study presented at the 2016 American College of Rheumatology / Association of Reproductive Health Professionals Annual Meeting in Washington explored how gender and disease duration can help predict which axSpA patients will develop extra-articular manifestations, such as uveitis, or inflammation of the eye.

Gillian Fitzgerald, MD, Rheumatology Specialist Registrar at St. James' Hospital in Dublin, and one of the authors of the study, explained that traditionally the condition was 'thought to be a disease that almost exclusively affected men. However, more recently this has been shown not to be the case. Women can be affected almost as often as men. Therefore, we are very interested in looking at the gender differences in axSpA, and we specifically wanted to look at whether there are any differences between genders in the prevalence of these extra-articular manifestations.'

The researchers performed a standardised, detailed clinical assessment on 564 patients, and found that prevalence of uveitis is significantly higher in women (46.7 per cent vs. 32.3 percent), and that IBD prevalence is significantly higher in women (16.5 per cent vs. 7.7 per cent).

The data additionally demonstrated that being female and having axSpA disease for more than 10 years is predictive of uveitis, and being female, having an elevated CRP at baseline and peptic ulcer disease are predictive of IBD.

BEHIND THE BURDEN

More recently, a 2018 review, 'Gender Differences in Axial Spondyloarthritis: Women Are Not So Lucky' by T Rusman, R F van Vollenhoven, and I van der Horst-Bruinsma, has provided evidence which helps dismantle the view that axSpA is a male-specific disease and demonstrates the complex burden for women in more detail.

Some of the findings reported include:

- The age of onset of AS does not differ between males and females, but females seem to have a relatively longer delay in diagnosis
- Despite the improvement in delay of diagnosis in women with axSpA, there is still a longer delay and more often misdiagnosis in women, which increases the disease burden in the female patient group
- Female axSpA patients showed a higher disease burden concerning disease activity and pain scores
- Females corresponded with a significantly lower quality of life
- Despite the fact that male axSpA patients have more radiographic damage compared to females, female patients have a higher disease burden due to a longer diagnostic delay, higher disease activity, and a lower efficacy of treatment

Scottish Pharmacy Review

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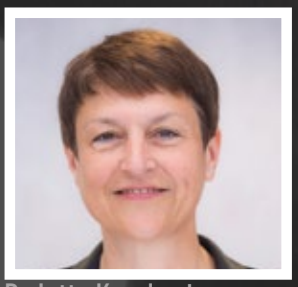
PUTTING A PLAN IN PLACE

As conversation centring on parenteral nutrition and nutritional complications in intestinal failure continues to pick up pace, SPR wants to find out more. We interview two members of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition's (ESPGHAN) Committee on Nutrition: Dr Jutta Koeglmeier, Paediatric Gastroenterologist at Great Ormond Street Hospital, and Dr Barbara de Koning, Paediatric Gastroenterologist at Erasmus MC, Sophia Children's Hospital, The Netherlands.



Dr Jutta Koeglmeier

INTESTINAL FAILURE

WHAT IS INTESTINAL FAILURE?

Patients suffer from intestinal failure when there is a critical reduction of the small intestinal gut mass or function below the minimum necessary for maintaining health or growth.

Intestinal failure can be caused by a number of factors, including substantial surgical resection or extensive intestinal atresia resulting in short bowel syndrome. Other causes of intestinal failure are motility disorders, such as chronic intestinal pseudo-obstruction, and intrinsic disorders of the epithelium (enteropathies), including rare diseases, such as microvillus inclusion disease.

WHAT ARE THE SIGNS, SYMPTOMS AND RISK FACTORS OF INTESTINAL FAILURE?

Intestinal failure may be identified through a number of non-specific signs and symptoms. These can include diarrhoea or a high-output stoma, abdominal pain, vomiting, dehydration, weight loss and malnutrition.

The primary risk factor for intestinal failure is a resection or loss of a large part of the small bowel. Additionally, the performance of the nutrient absorption capacity of the small intestine should be taken into account when considering the likelihood of intestinal failure.

WHAT ARE THE EFFECTS OF INTESTINAL FAILURE ON A PATIENT?

Patients with intestinal failure are unable to meet their nutritional requirements or hydration with oral food and drink intake. As a consequence, parenteral nutrition is given into a central venous catheter and many patients will require parenteral nutrition on a daily basis.

Intestinal failure is a complicated chronic condition which can have a profound physical and psychological impact on a patient, especially as patients often have to tolerate recurrent medical procedures such as surgery and central venous catheter insertion. A proportion will have a stoma or enteral feeding device.

Prolonged hospitalisation can be particularly distressing for children and their families, and many have to deal with distressing symptoms, such as diarrhoea. Patients with extended or irreversible intestinal failure are usually managed at home using home parenteral nutrition. Although the aim is to support as normal a life as possible, home parenteral nutrition also requires a significant amount of time and care. However, quality of life on home parenteral nutrition can be good.

WHAT ARE THE TREATMENT OPTIONS FOR INTESTINAL FAILURE?

The aim of intestinal failure treatment is to provide adequate macro- and micronutrients and fluids to allow for homeostasis in adults and growth in children. Modern intestinal failure management has improved long-term survival dramatically and the focus is to avoid long-term complications such as catheter-related blood stream infections, loss of central venous access sites, intestinal failure-associated liver disease, metabolic bone disease and renal problems while receiving parenteral nutrition.

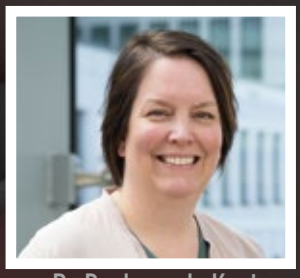
Where possible, the long-term goal is to achieve intestinal autonomy and remove the need for parenteral support through a multidisciplinary support team. Good dietetic management to maximise the ability of the gut to absorb nutrients, speech and language therapy to further oral intake in patients with food aversion, and careful adjustments of the parenteral nutrition prescription according to the patients' needs are essential.

Surgical strategies for short bowel syndrome as a causative factor for intestinal failure can be considered and include different techniques of intestinal lengthening. Evolving evidence supports the use of medication to promote gut adaptation. These drugs work by promoting mucosal growth and where possible, restoring gastric emptying and secretion.

In patients with irreversible intestinal failure who have developed serious complications or have a poor quality of life, intestinal transplantation can be considered as a cure. Life-long immunosuppression is however required and transplantation in itself is associated with mortality and graft loss.

WHAT ARE THE KEY CONSIDERATIONS WHEN MANAGING INTESTINAL FAILURE?

Intestinal failure patients with congenital enterocyte defects, particularly those with microvillus inclusion disease, or those with intestinal pseudo-obstruction, will have very high requirements of fluid and electrolytes. Additional intravenous fluid and parenteral nutrition are often needed.



Dr Barbara de Koning

PARENTERAL NUTRITION

WHAT IS PARENTERAL NUTRITION AND WHEN SHOULD IT BE RECOMMENDED?

Parenteral nutrition is a nutritional formulation that is administered intravenously and which contains all necessary macronutrients (amino acids, carbohydrates and lipids) and micronutrients (electrolytes, trace elements and vitamins). Parenteral nutrition is formulated according to the individual needs of the patient and can either provide the total or a partial amount of their nutritional intake.

Parenteral nutrition should be administered on a patient when they are not able to function effectively or grow through enteral nutrition. This can either be caused by enteral malabsorption or a severe intolerance to enteral nutrition.

Nutrients and fluid requirements have to be tailored to the patient's needs. In growing children, calorie needs will change over time and should be reviewed on a regular basis. Height, weight and hydration status have to be monitored and regular monitoring of blood and urine parameters is important to avoid inadequate supply. Home parenteral nutrition is considered in patients with prolonged or irreversible intestinal failure. Children likely to need parenteral nutrition for more than three months can be discharged on home parenteral nutrition as soon as they are clinically stable. This improves quality of life, encourages normal childhood development and family life, and is associated with less complications compared to remaining admitted in hospital.

Where applicable, medication and non-transplant surgical options should be considered. Management within a multidisciplinary team is essential for a favourable outcome and avoiding parenteral nutrition should be attempted whenever possible.

WHAT ARE THE NUTRITIONAL COMPLICATIONS IN INTESTINAL FAILURE?

The nutritional complications of intestinal failure can be a consequence of inadequate or excessive supply of micro-and macronutrients. Inadequate calorie supply can lead to poor growth and weight gain in children.

However, an excess of glucose should be avoided due to the risk of hyperglycaemia and the associated increased lipogenesis and fat tissue deposition in the liver. While intravenous lipid emulsions should be part of a parenteral nutrition regime used for children, an excess can again contribute to the development of liver disease. Protein is needed for growth but an excess puts a negative strain on the kidneys.

Appropriate amounts of calcium, vitamin D, phosphate and magnesium are needed for optimal growth and bone mineralisation. Metabolic bone disease is a known complication of intestinal failure and fractures have been reported in these patients.

Patients who have lost a significant amount of weight prior to the start of parenteral nutrition are at risk of developing potentially life-threatening refeeding syndrome, which is why management by an experienced nutrition care team is always advised.

WHAT ARE THE KEY CONSIDERATIONS FOR THE MANAGEMENT OF PARENTERAL NUTRITION?

Each patient will require a tailored approach, considering the type and position of central venous access, as well as fluid, electrolyte, micro and macronutrient needs. It is very important that complications are avoided and they should be actively and regularly screened for. Removing the need for parenteral nutrition and introducing oral feeding should be considered as soon as possible.

Where patients have prolonged (three months-plus) or irreversible intestinal failure, and they are stable, home parenteral nutrition should be considered. Parents and patients should be trained for one-to-two weeks in the hospital to administer the parenteral nutrition and take care of the CVC. A care plan should also be introduced for intestinal rehabilitation with the aim of achieving partial or complete enteral autonomy. The social situation of each patient also requires attention and they should be offered psychological support.

It is well-known that a multidisciplinary team approach is associated with improved outcomes and an early referral to an intestinal failure rehabilitation unit should be considered.

WHAT ARE THE BENEFITS OF PARENTERAL NUTRITION?

Modern parenteral nutrition has significantly improved the survival of patients with intestinal failure and reduced the complication rates. It now allows both adults and children suffering from intestinal failure to achieve a good quality of life. It means that patients with prolonged or irreversible failure can be safely discharged home to enjoy family life, school attendance, and normal work and daytime activities.

ARE THERE ANY DISADVANTAGES OF PARENTERAL NUTRITION?

Parenteral nutrition is very time-consuming, especially for a patient on home parenteral nutrition who needs to dedicate a significant amount of time to catheter care, connection and disconnection. In addition, patients will need to visit their outpatient departments for ongoing monitoring.

Complications can occur and include CVC-related complications, sepsis, liver damage and osteoporosis. This burden can be increased by acute complications, such as catheter-related bloods stream infections, which can lead to recurrent hospitalisation, be life-threatening, and lead to long-term issues such as liver disease or loss of central venous access. Parenteral nutrition is also an expensive treatment which poses a significant financial cost to healthcare systems.

WHAT DOES THE FUTURE HOLD FOR PARENTERAL NUTRITION?

The management of parenteral nutrition is improving all the time as we develop our understanding of the complications associated with it, and prevent these from occurring. This is aided by the development of novel drug therapies which are expected to contribute to gut adaptation, resulting in fewer patients needing parenteral nutrition support and, in some cases, any support at all. Further improvements, such as modern lipid emulsions, heightened longevity of central venous catheters and greater multidisciplinary team working, have also had a favourable impact on the outcomes of intestinal failure.

ANTICOAGULATION

A CLASS ACT

With the current use of direct acting oral anticoagulants in the UK on the rise – SPR takes a look at a specific reversal agent, andexanet alfa, to be used when life-threatening or uncontrollable bleeds occur and what this means for healthcare professionals.

Direct acting oral anticoagulants offer many advantages over the traditional vitamin K antagonists e.g. warfarin, such as a reduced risk of bleeding. Their fixed dosage regimen, along with predictable pharmacokinetic and pharmacodynamics profile, anticoagulant effects, eliminates the need for the level of routine monitoring that would be required with a drug with such a narrow therapeutic index. The majority of studies carried out indicate that the rates of major bleeding and intracranial haemorrhage with DOACs are, at worst, similar to or lower than with warfarin. However, despite the clinical advantages of DOACs, all anticoagulants may cause major bleeding which may be life-threatening.

DIRECT ACTING ORAL ANTICOAGULANT	OCCURENCE OF MAJOR BLEEDING IN COMPARISON TO WARFARIN (STROKE PREVENTION)	OCCURENCE OF MAJOR BLEEDING IN COMPARISON TO WARFARIN (DVT / PE)
Apixaban	Reduced	Reduced
Dabigatran	Similar	Similar
Edoxaban	Reduced	Reduced
Rivaroxaban	Similar	Reduced

In December 2015, the first agent licensed in the UK for reversal of anticoagulant effects of a non-vitamin K antagonist oral anticoagulant was launched, idarucizumab ▼, which is specific to dabigatran ▼. It has been estimated that up to 6.5 per cent of patients receiving anticoagulant therapy may experience uncontrollable or major bleeding in the gastrointestinal tract or urinary tract and that 1per cent of patients may experience an intracranial haemorrhage.

Since idarucizumab was launched a new agent has come to market, andexanet alfa ▼. Andexanet alfa is a recombinant modified human factor Xa decoy protein used to rapidly reverse the antifactor Xa activity in those with acute major bleeding associated with rivaroxaban or apixaban.

Andexanet alfa exerts its effect at the final stage of the coagulation cascade by binding directly to factor Xa inhibitors floating in the blood plasma – as a consequence of this interaction, the concentration of free unbound factor Xa inhibitor rapidly decreases and the decrease in factor Xa inhibitory activity halts the anticoagulant effect.

Clinical trial studies from the ANNEXA-A and ANNEXA-R (phase III) trials showed over a 90 per cent reversal of anti-FXa activity within two minutes after bolus administration and is maintained throughout the two-hour infusion. All 145 patients in this study were healthy older volunteers who had either been treated with apixaban (5mg twice daily) or rivaroxaban (20mg once daily). Throughout the ANNEXA-A and ANNEXA-R trials, no serious or severe adverse drug reactions were reported.

The ANNEXA-4 (phase IV) trial was comprised of 352 patients who were taking one of apixaban ▼, rivaroxaban ▼, edoxaban ▼ or enoxaparin within 18 hours and had presented with a major bleed. Any patient with an ICH with Glasgow Coma Score under seven or estimated intracerebral haematoma volume greater than 60ml were excluded. Other exclusion criteria applied were planned surgery within 12 hours, use of PCC, rfVIIa, vitamin K antagonist dabigatran or whole blood / plasma in the last seven days or a recent history of diagnosed thrombotic event.

This trial found that in patients with acute major life-threatening uncontrollable bleeding associated with the use of a factor Xa inhibitor, andexanet alfa achieved a 92 per cent reduction in anti-Xa activity, a demonstrable haemostatic efficacy of 82 per cent (excellent or good) and a survival rate of 86 per cent at 30 days (14 per cent 30-day mortality).

The European Society of Cardiology has stated that andexanet alfa is recommended for reversal of life-threatening bleeding associated with apixaban and rivaroxaban by way of a bolus injection over 15-to-30 minutes followed by a two-hour infusion. In addition, the European Stroke Organisation has recommended that in patients with intracranial haemorrhage (ICH) during FXa (apixaban or rivaroxaban) treatment, andexanet alfa should be used. It should be noted that andexanet alfa is not licensed for the reversal of edoxaban.

Andexanet alfa has two licensed dosage regimens including low dose and high dose. The dose is dependent on the specific FXa inhibitor administered, the dose of the FXa inhibitor and the time that has lapsed since the last dose. The following tables outline what regimen should be used and when:

FXa inhibitor	Dose	Time Since Last Dose <8h	Time Since Last Dose >8h	Time Since Last Dose Unknown
Apixaban	<5mg	LOW	LOW	LOW
	>5mg	HIGH	LOW	HIGH
	Unknown	HIGH	LOW	HIGH
Rivaroxaban	<10mg	LOW	LOW	LOW
	>10mg	HIGH	LOW	HIGH
	Unknown	HIGH	LOW	HIGH

Following the administration of andexanet alfa and the subsequent cessation of the uncontrollable or major bleed, re-starting anti-coagulation therapy should be considered. This is to ensure that a further major bleed/ thrombotic event caused by the patients pre-existing medical condition does not occur.

With respect to the financial implications of treating a patient with andexanet alfa, one pack (containing four vials) costs £11,100 plus VAT. This equates to a single low dose treatment (five vials) costing £13,875 plus VAT while one single high dose treatment (nine vials) would cost £24,975 plus VAT.

When considering how andexanet alfa is used in primary and secondary care, the immediate need for administration in acute circumstances would indicate that all hospitals should carry stock. The specific number of vials held at any one time would be determined by the volume of patients in that region (either in primary or secondary care) currently using either apixaban or rivaroxaban.

There is no doubt that andexanet alfa is vital for patients with a major or uncontrollable bleed who are receiving apixaban or rivaroxaban treatment. While it is estimated that possibly only 1 per cent of these patients may need treatment with this specific reversal agent it could be the difference between life and death.

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Ondexxya® (andexanet alfa) – **The only authorised antidote** for quick reversal of factor Xa inhibitor-induced anticoagulation due to apixaban or rivaroxaban[1]

NEW! NOW AUTHORISED

Indication[1]

Adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

- Ondexxya reverses factor Xa inhibition by more than 90 percent within 2 minutes.[1]
- Ondexxya leads to a good to excellent hemostasis in over 80 percent of patients.[2]
- Ondexxya is recommended by the European Stroke Organisation (ESO) as first-line therapy.[3]*

This medicinal product has been authorised under a so-called "conditional approval" scheme. This means that further evidence on this medicinal product is awaited.[1]

Ondexxya® andexanet alfa

* in case of intracranial bleeding under apixaban or rivaroxaban treatment

1. Ondexxya SmPC May 2019
2. Connolly SJ et al. Full Study Report of Andexanet Alfa for Bleeding Associated with Factor Xa Inhibitors. N Engl J Med 2019 Apr 4;380(14): 1326 – 1335. doi: 10.1056/NEJMoa1814051. Epub 2019 Feb 7
3. Christensen H et al. European Stroke Organisation Guideline on Reversal of Oral Anticoagulants in Acute Intracerebral Haemorrhage. Eur Stroke J 0(0): 1 – 13. doi.org/10.1177/2396987319849763

PORTOLA

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ABBREVIATED PRESCRIBING INFORMATION

ONDEXXYA ▼ 200 MG POWDER FOR SOLUTION FOR INFUSION (ANDEXANET ALFA)
Refer to full Summary of Product Characteristics [SmPC] before prescribing.

Presentation
Each vial contains 200 mg of andexanet alfa.
After reconstitution, each mL of solution contains 10 mg of andexanet alfa.

Indication
For adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Dosage and administration
Refer to full SmPC for full information on posology and administration.
Recommended dosage:
Ondexxya is initially administered as an intravenous (IV) bolus at a target rate of approximately 30 mg/min at either a low dose of 400 mg over 15 minutes followed by a continuous infusion of 480 mg at 4 mg/min, or a high dose of 800 mg over 30 minutes followed by continuous infusion of 960 mg at 8 mg/min over 120 minutes.
Reversal of apixaban; The recommended dose regimen of Ondexxya is based on the dose of apixaban the patient is taking at the time of anticoagulation reversal, as well as on the time since the patient's last dose of apixaban. Where the last dose of apixaban was ≤ 5 mg the low dose is used. Where the last dose of apixaban was > 5 mg or unknown and was given < 8 hours or an unknown time before Ondexxya administration the high dose is used. Where the last dose of apixaban was > 5 mg or unknown but was known to be given ≥ 8 hours before Ondexxya administration the low dose is used.
Reversal of rivaroxaban; The recommended dose regimen of Ondexxya is based on the dose of rivaroxaban the patient is taking at the time of anticoagulation reversal, as well as on the time since the patient's last dose of rivaroxaban. Where the last dose of rivaroxaban was ≤ 10 mg the low dose is used. Where the last dose of rivaroxaban was > 10 mg or unknown and it was given < 8 hours or an unknown time before Ondexxya administration the high dose is used. Where the last dose of rivaroxaban was > 10 mg or unknown but was known to be given ≥ 8 hours before Ondexxya administration the low dose is used.
Restarting antithrombotic therapy; Following administration of Ondexxya and cessation of a major bleed, re-anticoagulation should be considered to prevent thrombotic events due to the patient's underlying medical condition. Antithrombotic therapy can be re-initiated as soon as medically indicated following treatment if the patient is clinically stable and adequate haemostasis has been achieved. Medical judgement should balance the benefits of anticoagulation with the risks of re-bleeding.
Elderly patients; (aged 65 years and over); No dose adjustment is required.
Renal impairment; The effect of renal impairment on andexanet alfa exposure levels has not been evaluated. Based on the existing data on clearance, no dose adjustment is recommended.
Hepatic impairment; Based on the existing data on clearance of andexanet alfa, no dose adjustment is recommended. The safety and efficacy have not been studied in patients with hepatic impairment.
Paediatric population; The safety and efficacy of andexanet alfa in children and adolescents have not been established. No data are available.

Method of administration:
Intravenous use; After an appropriate number of vials of Ondexxya has been reconstituted, the reconstituted solution (10 mg/mL) is transferred to a suitable empty IV polyolefin (PO) or polyvinyl chloride (PVC) bag without further dilution, prior to administration by IV infusion using a 0.2 or 0.22 micron in line polyethersulfone (PES) or equivalent low protein-binding filter.

For instructions on reconstitution of the medicinal product before administration, refer to full SmPC.

Contraindications
Hypersensitivity to active substance or any excipient. Known allergic reaction to hamster proteins.

Warnings and precautions
Limitations of use; Clinical efficacy is based upon reversal of anti-FXa-activity in healthy volunteers dosed with apixaban or rivaroxaban. Andexanet alfa is not suitable for pre-treatment of urgent surgery. Use for edoxaban- or enoxaparin-reversal is not recommended due to lack of data. Andexanet alfa will not reverse the effects of non-FXa inhibitors. Although determination of anti-FXa-activity in emergency situations is increasingly recommended, no recommendation for adapted andexanet alfa dosage is available. Therefore, treatment monitoring should be based mainly on clinical parameters indicative of appropriate response (i.e., achievement of haemostasis), lack of efficacy (i.e., re-bleeding), and adverse events (i.e., thromboembolic events).
Dosage recommendation is based upon data-modelling in healthy volunteers. Validation has not been successful, yet. Data from bleeding patients are limited. Preliminary data suggest higher risk of thrombosis for patients receiving the higher dose of andexanet, previous lower dose of the anti-FXa inhibitor, and patients on rivaroxaban. In ANNEXA-4, intracranial haemorrhage (ICH) patients (GCS > 7 and haematoma volume < 60 mL) have been included. Treatment of patients with more severe ICH with andexanet alfa has not been studied.
Thrombotic events; Thrombotic events have been reported following treatment with andexanet alfa. Patients being treated with FXa inhibitor therapy have underlying disease states that predispose them to thrombotic events. Reversing FXa inhibitor therapy exposes patients to the thrombotic risk of their underlying disease. In addition, independent pro-thrombotic effect of andexanet alfa cannot be ruled out. Duration of this effect in bleeding patients is not known. Laboratory parameters as anti-FXa activity, endogenous thrombotic potential (ETP), or markers of thrombosis might not be reliable for guidance. To reduce this risk, resumption of anticoagulant therapy should be considered as soon as medically appropriate after completion of treatment. In healthy volunteers, dose-dependent increases in coagulation markers F1+2, TAT, and D-dimer after administration of andexanet alfa were observed, but no thromboembolic events were reported. These markers were not measured in patients enrolled in the ANNEXA-4 study, but thromboembolic events have been observed. Monitoring for signs and symptoms of thrombosis is, therefore, strongly recommended.
Use of andexanet alfa in conjunction with other supportive measures; Andexanet alfa can be used in conjunction with standard haemostatic supportive measures, which should be considered as medically appropriate. The safety of andexanet alfa has not been evaluated in patients who received prothrombin complex concentrates, recombinant factor VIIa, or whole blood within seven days prior to the bleeding event, as they were excluded from clinical trials. Pro-coagulant factor treatments (e.g., 3- or 4-factor prothrombin complex concentrate (PCC)/activated PCC, recombinant factor VIIa, fresh frozen plasma) and whole blood should be avoided unless absolutely required, due to lack of data in combination with these treatments.
Infusion-related reactions; In case of mild or moderate infusion reactions, careful observation may be sufficient. For moderate symptoms, consideration may be given to a brief interruption or slowing of the infusion with resumption of the infusion after symptoms subside. Diphenhydramine may be administered.

Please see full SmPC for specific information concerning: (a) interaction with other medicinal products and other forms of interaction; (b) fertility, pregnancy and lactation: (c) effects on ability to drive and use machines: (d) overdose.

Undesirable effects
The most frequently reported adverse reactions in clinical trials in healthy subjects with Ondexxya were mild or moderate infusion-related reactions comprising symptoms such as flushing and feeling hot (very common), and cough, dysgeusia and dyspnoea (common). Transient elevations of D-dimer and F1+2 fragments were also very common in healthy subjects. Other common side effects observed in healthy subjects were urticaria, dizziness postural, headache, palpitations, abdominal discomfort or pain, dry mouth, nausea, pruritus (generalised), back pain, muscle spasms, chest discomfort, hyperhidrosis and peripheral coldness.

Amongst bleeding patients commonly reported side effects were ischaemic stroke and pyrexia, with uncommonly reported side effects of cerebral infarction, cerebrovascular accident, transient ischaemic attack, acute myocardial infarction, cardiac arrest, myocardial infarction, deep vein thrombosis, iliac artery occlusion and pulmonary embolism.

Refer to full SmPC for further information on side effects reported with Ondexxya.

Legal Category
POM

Package quantities & Basic NHS costs
£11,100 (4 vials per pack)

Marketing Authorisation Holder
Portola Netherlands B.V., Prins Bernhardplein 200, 1097 JB Amsterdam, Netherlands

Marketing Authorisation Number
EU/1/18/1345/001

Further information available from:
e-mail: Info@portolaEU.com

Prescribing information last revised
May 2019

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

Adverse events can also be reported to Portola Pharma UK Ltd. by following email **Info@portolaEU.com or by phone (Toll Free) Tel: 0800 069 8041 or (Toll) +31 20 225 4560.**

Ondexxya® ▼
andexanet alfa

Herpes Viruses Association

A SORE THING

Marian Nicholson, Director of the Herpes Viruses Association & Shingles Support Society, helps you to unravel the recurrence of cold sores for patients; tackling the causes of an outbreak, treatment options, and how the virus can be kept at bay.

Marian Nicholson

WHAT CAUSES COLD SORES?

Cold sores, also known as fever blisters, are caused by a herpes simplex virus. There are two types, called type one and type two. Most facial cold sores are caused by type one. A World Health Organisation report estimates that two-thirds of the world's population have caught cold sores by the age of 25. However, the majority of people who have been infected will never experience symptoms.

HOW ARE COLD SORES CAUGHT?

Cold sores are usually caught by being kissed by someone who has cold sore virus on their mouth. In some cases, a cold sore may then appear within a few days. Symptoms normally clear up in a week or 10 days.

It's possible to catch the virus and never have symptoms – or perhaps develop the first noticeable cold sore symptoms months or years later. This is known as a having a dormant infection.

A person with facial cold sores may infect a partner when performing oral sex if sufficient virus is present on the mouth at the time. This is now a common cause of genital herpes. The resulting genital infection will be type one.

The virus is sometimes caught in other areas, such as hands / fingers, if there is broken skin there at the time of contact with another person's infection. A cold sore on the finger is called a whitlow.

Cold sores are only caught by direct skin contact, with the affected area, usually the lips. They are not caught through sharing cups, cutlery, towels, lipsticks, etc. (unless there is warm pus on the item). Medical experts are clear about this, although unreliable sources on the internet and elsewhere may make misleading statements. (1)

DO COLD SORES CAUSE AN ILLNESS?

Sometimes a first cold sore may be accompanied by ulcers inside the mouth and throat as well as, or instead of, sores on the lips. During this first infection, there may be fever, headache, swollen glands in the neck and other flu-like symptoms. Painkillers can help at this stage.

WHAT ARE COLD SORES LIKE?

1. First, a small red patch appears
2. A blister or cluster of blisters develops
3. The blister bursts, leaving a raw area
4. The raw area begins to scab and heal
5. Scabs may crack when the lips move and this may delay healing. The individual should try to keep the skin moisturised – see suggestions later in the article
6. Picking at the scab will delay healing
7. Wash hands before and after applying cream
8. The sore will heal by itself without scarring, usually in about seven-to-10 days

MUST A FIRST INFECTION BE TREATED?

Treatment is optional. In a bad case, antiviral medication started as soon as symptoms appear may shorten the duration of the outbreak. Symptoms will heal with or without treatment.

WHY DO COLD SORES SOMETIMES RETURN?

The virus stays dormant in two nerve junctions, behind each ear, and symptoms may sometimes reappear, often at times of stress or poor general health.

CAN COLD SORES APPEAR ANYWHERE ELSE?

This is unlikely as cold sores usually reappear in the same place; however, some people get them elsewhere on the face. A facial infection can't cause symptoms on other parts of the body. Antibodies made by the immune system in response to the infection will normally prevent reinfection in different areas.

ARE THERE WARNING SIGNS BEFORE A COLD SORE APPEARS?

There may be an itch, tingle or shooting pain on part of the lip at first. Repeat cold sores are usually much milder and shorter than the first ones.

WHAT CAUSES A RECURRENCE?

Triggers vary from person-to-person. Common triggers are stress, tiredness, being run down, having a period, drinking too much alcohol, or ultra-violet light, from the sun or from sun-beds.

SELF-HELP SUGGESTIONS FOR HOW YOUR PATIENTS CAN PREVENT COLD SORES

A healthy lifestyle can help to keep the immune system in good shape and make cold sores less likely.

These are possible triggers:

- Lack of sleep
- Poor diet
- Exposure to bright sunlight / ultra-violet light, outdoors or when using sunbeds. A good quality sunblock, especially on the lips, is recommended

WHAT MEDICINE CAN PREVENT FREQUENT COLD SORES?

Antiviral tablets may be prescribed. People with a high frequency of cold sore outbreaks should see a doctor. Antiviral tablets are a more effective way of treating and preventing cold sores than antiviral creams.

WHAT TREATMENTS ARE AVAILABLE FROM CHEMISTS' SHOPS?

There are different types of creams:

1. Some creams contain anaesthetics (e.g. lidocaine five per cent, benzocaine, prilocaine or tetracaine) which will stop any soreness if a cold sore breaks through. A small trial found that lidocaine five per cent ointment prevented cold sore outbreaks in one-in-three people and shortened the outbreaks that did appear from five days to two days. (2) No prescription is needed and cold sores are an indication for lidocaine purchase from a registered pharmacy

Continued onto next page

COLD SORES

2. Antiviral creams containing aciclovir are widely available. If used at the 'tingle' stage, they can shorten outbreaks by 12 per cent (from an average of seven days down to six ¼ days). (3) A newer antiviral cream, Fenestil, contains penciclovir one per cent, and has a similar benefit

SELF-HELP TIPS THAT MAY BE WORTH INVESTIGATING

Some people with cold sores have found these ideas helpful – they are not medically tested:

- Cold damp teabags applied hourly: applying a well-wrapped ice pack to the area for up to 90 minutes at the tingle stage
- A cream containing lemon balm mint (melissa officinalis), such as Lomaherpan, has been shown to minimise outbreaks if used promptly. This plant contains molecules which prevent the virus from entering skin cells (4)
- Geranium oil, lavender oil, or diluted tea tree oil are claimed to soothe
- Vaseline (petroleum jelly) can help to keep the skin supple and prevent it from cracking and may prevent scabs from coming off before healing is complete

CAN THERE BE MEDICAL COMPLICATIONS?

Medical attention is rarely necessary for straightforward cold sore infections but there can occasionally be complications.

In rare cases, a cold sore infection may recur in one eye (but not both at the same time). This will usually follow the initial infection, but may occur simultaneously. If one eye is tingling and sore or red, a GP or an optician can carry out a fluorescein stain test to see if the cause is herpes simplex virus. If it is, the patient may be referred to an eye specialist.

Patients with areas of broken skin (such as eczema) should be advised to be careful during their first infection as sores may spread over these areas. This is called eczema herpeticum. It is most likely to happen during a first infection, but can be caused by a recurrence.

Patients with weakened immune systems (e.g. those taking cancer treatment drugs, or those who have had an organ transplant) may need to be prescribed antiviral medication to prevent constant cold sores.

Neonates should not be exposed to cold sore virus – they should not be kissed by family members or friends with cold sores as their immune systems are too immature to cope with the infection. If their mother has had cold sores from before the pregnancy, the baby will have transplacental protection and the mother's virus is not likely to cause neonatal herpes. (5)

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Abbott

For healthcare professionals only

Are you considering the immune challenges surrounding infants with cow's milk allergy?

A critical time of life

Breast milk is the gold standard in the first year of life, providing not only nutrition, but protection and support for the developing immune system.[1,2]

Immunologically vulnerable

Without the protective benefits of breast milk, formula-fed infants with cow's milk allergy are at higher risk of several inflammatory and allergic conditions.[1,3–6]

A new infant formula

Abbott will soon launch EleCare®, by Similac®, the first amino-acid based infant formula in the UK with 2'-FL HMO*, designed to support the infant's developing immune system.

To find out more contact your Abbott Account Manager, or call our Freephone Nutrition Helpline on 0800 252 882

IMPORTANT NOTICE: Breastfeeding is best for infants and is recommended for as long as possible during infancy.

*Not sourced from human milk.

2'-FL HMO: 2'-fucosyllactose human milk oligosaccharide. HMOs are a diverse group of bioactive, non-digestible carbohydrates and the third most abundant solid component of breast milk.[7,8]

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ANUKANI190277i January 2020

For healthcare professionals only

DON'T LET AMR* SPIRAL OUT OF CONTROL...

In Scotland, resistance rates of *E. coli* to trimethoprim are >33%, versus <2% to nitrofurantoin†[1]

"The choice of antibiotic should largely be driven by minimising the risk of resistance" – NICE[2]

MANAGE IT WITH MacroBID® (nitrofurantoin) 100mg Prolonged-release Capsules

MacroBID® is indicated for the treatment of and prophylaxis against acute or recurrent, uncomplicated lower UTIs or pyelitis either spontaneous or following surgical procedures, in patients over 12 years of age[3]

PRESCRIBING INFORMATION. Macrobid 100mg Prolonged-release Capsules (nitrofurantoin) Presentation: Hard gelatin capsule containing the equivalent of 100mg of nitrofurantoin in the form of nitrofurantoin macrocrystals and nitrofurantoin monohydrate. **Indications:** *Adults and children over 12 years of age:* Treatment of and prophylaxis against acute or recurrent, uncomplicated lower urinary tract infections or pyelitis either spontaneous or following surgical procedures. Specifically indicated for the treatment of infections when due to susceptible strains of *Escherichia coli, Enterococci, Staphylococci, Citrobacter, Klebsiella* and *Enterobacter.* **Dosage and administration:** For oral use. *Adults and children over 12 years of age: Acute or recurrent uncomplicated UTI and pyelitis:* 100mg twice daily for 7 days. *Surgical prophylaxis:* 100mg twice daily on the day of the procedure and 3 days thereafter. *Elderly:* Unless significant renal impairment exists, dosage as for normal adult. *Children under 12 years:* Not recommended. **Contraindications:** Hypersensitivity to nitrofurantoin, other nitrofurans or to any of the excipients. Patients suffering from renal dysfunction with an eGFR below 45 ml/minute. G6PD (glucose-6-phosphate dehydrogenase) deficiency. Acute porphyria. In infants under three months of age as well as pregnant patients at term (during labour and delivery). **Precautions and warnings:** Not effective for the treatment of parenchymal infections of a unilaterally functioning kidney. Nitrofurantoin may be used with caution as short-course therapy only for the treatment of uncomplicated lower urinary tract infection in individual cases with an eGFR between 30-44 ml/min to treat resistant pathogens, when the benefits are expected to outweigh the risks. A surgical cause for infection should be excluded in recurrent or severe cases. Caution is advised in patients with pulmonary disease, hepatic dysfunction, neurological disorders, allergic diathesis, anaemia, diabetes mellitus, electrolyte imbalance, debilitating conditions, vitamin B (particularly folate) deficiency. Acute, subacute and chronic pulmonary reactions have been observed in patients treated with nitrofurantoin. Nitrofurantoin should be discontinued immediately in case of any pulmonary reactions and at any signs of haemolysis in those with suspected G6PD deficiency. Chronic pulmonary reactions (including pulmonary fibrosis and diffuse interstitial pneumonitis) can develop insidiously and may occur commonly in elderly patients. Peripheral neuropathy and susceptibility to peripheral neuropathy, which may become severe or irreversible has occurred and may be life threatening. Treatment should be stopped at the first signs of neural involvement. Close monitoring of patients receiving long-term therapy is warranted (especially in the elderly). May discolour urine and cause false positive urinary glucose test. Gastrointestinal reactions may be minimised by taking the drug with food or milk, or by adjustment of dosage. Hepatic reactions, including hepatitis, autoimmune hepatitis, cholestatic jaundice, chronic active hepatitis, and hepatic necrosis occur rarely. Fatalities have been reported. Patients should be monitored periodically for changes in biochemical tests that would indicate liver injury. The drug should be withdrawn immediately if hepatitis occurs and appropriate measures should be taken. Patient should be monitored closely for appearance of hepatic or pulmonary symptoms and other evidence of toxicity for long-term treatment. Discontinue treatment if otherwise unexplained pulmonary, hepatotoxic, hematological or neurological syndromes occur. **Interactions:** Food or agents delaying gastric emptying, magnesium trisilicate, probenecid, sulfinpyrazone, carbonic anhydrase inhibitors, urine alkalising agents, quinolone anti-infectives, oral typhoid vaccine, interference with some tests for glucose in urine. **Pregnancy and lactation:** Should be used at the lowest dose as appropriate for a specific indication, only after careful assessment. Contraindicated in infants under three months of age and in pregnant women during labour and delivery because of the possible risk of haemolysis of the infants immature red cells. Nitrofurantoin is detected in trace amounts in breast milk. Breastfeeding an infant known or suspected to have an erythrocyte enzyme deficiency (including G6PD deficiency), must be temporarily avoided. **Undesirable effects:** *Serious:* Acute pulmonary reactions (commonly manifested by fever, chills, cough, chest pain, dyspnoea, pulmonary infiltration with consolidation or pleural effusion on chest x-ray, eosinophilia), chronic pulmonary reactions, pulmonary fibrosis; possible association with lupus-erythematous-like syndrome, collapse, cyanosis, cholestatic jaundice, chronic active hepatitis, autoimmune hepatitis, hepatic necrosis, peripheral neuropathy including optic neuritis, exfoliative dermatitis, erythema multiforme (including Stevens-Johnson syndrome), Lupus-like syndrome associated with pulmonary reaction, drug rash with eosinophilia and systemic symptoms (DRESS syndrome), cutaneous vasculitis, anaphylaxis, angioneurotic edema, agranulocytosis, leucopenia, granulocytopenia, haemolytic anaemia, thrombocytopenia, glucose-6-phosphate dehydrogenase deficiency, megaloblastic anaemia and eosinophilia. ***(Please refer to the Summary of Product Characteristics for detailed information)*** **Overdose:** *Symptoms:* Gastric irritation, nausea and vomiting. *Management:* Nitrofurantoin can be haemodialysed. Standard treatment is by induction of emesis or by gastric lavage in cases of recent ingestion. Monitoring of full blood count, liver function tests and pulmonary function, are recommended. A high fluid intake should be maintained to promote urinary excretion of the drug. **Legal category:** POM. **Basic NHS price:** £9.50 per pack of 14 capsules. **Marketing authorisation number:** PL 12762/0052. **Marketing authorisation holder:** Mercury Pharmaceuticals Ltd (a member of the Advanz Pharma group of companies), Capital House, 1st Floor, 85 King William Street, London EC4N 7BL, UK. **Date of preparation:** April 2012. **Date of revision:** March 2019 [ADV/MAB/PI/0001].

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 **Advanz Pharma Medical Information** via telephone on **+44 0 8700 70 30 33** or via e-mail at **medicalinformation@advanzpharma.com**

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ADVANZ PHARMA

*** AMR: Antimicrobial resistance; UTI: Urinary tract infection.**

† Bacteria must develop multiple step-wise mutations to become resistant to nitrofurantoin, which is a low-probability event[4-7]