

Scottish Pharmacy Review



ISSUE 125 - 2019

2019 WINTER SPECIAL THE COLD REALITY



MEDICATION WITHOUT HARM

The third Global Patient Safety Challenge

SCOTTISH PHARMACY AWARDS

Who will win?

PARKINSON'S AND ME

A personal journey

DRY EYE SYNDROME

Pharmacy's potential





Did you know...

“Early onset diabetic kidney disease can shorten life expectancy by up to 15 years”¹

Patients treated with Invokana were **70%** more likely to experience regression of albuminuria, over 6.5 years, compared to standard of care + placebo².

HR: 1.79 (95% CI, 1.51–1.91) Absolute benefit: 105.9 more instances of albuminuria regression per 1000 patient-years.

Invokana is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus.

Improvements in renal outcomes with Invokana are additional benefits only and not licensed indications.

*Regression of albuminuria:

- macro to micro / micro to normo / macro to normo.

Invokana[®]
canagliflozin tablets

The renal reason to intensify

INVOKANA[®] (canagliflozin) 100 mg & 300 mg film-coated tablets. PRESCRIBING INFORMATION. Please refer to Summary of Product Characteristics (SmPC) before prescribing. **INDICATIONS:** The treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes. **DOSAGE & ADMINISTRATION:** Adults: recommended starting dose: 100 mg once daily. In patients tolerating this dose and with eGFR \geq 60 mL/min/1.73 m² needing tighter glycaemic control, dose can be increased to 300 mg once daily. For oral use, swallow whole. Caution increasing dose in patients \geq 75 years old, with known cardiovascular disease or for whom initial canagliflozin-induced diuresis is a risk. Correct volume depletion prior to initiation. When add-on, consider lower dose of insulin or insulin secretagogue to reduce risk of hypoglycaemia. **Children:** no data available. **Elderly:** consider renal function and risk of volume depletion. **Renal impairment:** not to be initiated with eGFR < 60 mL/min/1.73 m². If eGFR falls below this value during treatment, adjust or maintain dose at 100 mg once daily. Discontinue if eGFR persistently < 45 mL/min/1.73 m². Not for use in end stage renal disease or patients on dialysis. **Hepatic impairment:** mild or moderate: no dose adjustment. Severe: not studied, not recommended. **CONTRAINDICATIONS:** Hypersensitivity to active substance or any excipient. **SPECIAL WARNINGS & PRECAUTIONS:** Not for use in type 1 diabetes. **Renal impairment:** eGFR < 60 mL/min/1.73 m²: higher incidence of adverse reactions associated with volume depletion particularly with 300 mg dose; more events of elevated potassium; greater increases in serum

creatinine and blood urea nitrogen (BUN); limit dose to 100 mg once daily and discontinue when eGFR < 45 mL/min/1.73 m². Not studied in severe renal impairment. Monitor renal function prior to initiation and at least annually. **Volume depletion:** caution in patients for whom a canagliflozin-induced drop in blood pressure is a risk (eg, known cardiovascular disease, eGFR < 60 mL/min/1.73 m², anti-hypertensive therapy with history of hypotension, on diuretics or elderly). Not recommended with loop diuretics or in volume depleted patients. Monitor volume status and serum electrolytes. **Elevated haematocrit:** careful monitoring if already elevated. **Genital mycotic infections:** risk in male and female patients, particularly in those with a history of GMI. **Lower limb amputation:** consider risk factors before initiating. Monitor patients with a higher risk of amputation events. Counsel on routine preventative foot care and adequate hydration. Consider discontinuing **Invokana** when events preceding amputation occur (e.g., lower-extremity skin ulcer, infection, osteomyelitis or gangrene). Urine laboratory assessment: glucose in urine due to mechanism of action. Lactose intolerance: do not use in patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. Diabetic ketoacidosis (DKA): rare DKA cases reported, including life-threatening and atypical presentation cases. Where DKA is suspected or diagnosed, discontinue **Invokana** treatment immediately. Interrupt treatment in patients who are undergoing major surgical procedures or have acute serious medical illnesses. Consider risk factors for development of DKA before initiating **Invokana** treatment. **Necrotising fasciitis of the perineum (Fournier's gangrene):** post-marketing cases reported with SGLT2 inhibitors. Rare but serious, patients should seek

medical attention if experiencing symptoms including pain, tenderness, erythema, genital/perineal swelling, fever, malaise. If Fournier's gangrene suspected, **Invokana** should be discontinued, and prompt treatment instituted. **INTERACTIONS: Diuretics:** may increase risk of dehydration and hypotension. **Insulin and insulin secretagogues:** risk of hypoglycaemia; consider lower dose of insulin or insulin secretagogue. **Effects of other medicines on Invokana:** enzyme inducers (e.g., St. John's wort, rifampicin, barbiturates, phenytoin, carbamazepine, ritonavir, efavirenz) may decrease exposure of canagliflozin; monitor glycaemic control. Consider dose increase to 300 mg if administered with UGT enzyme inducer. Cholestyramine may reduce canagliflozin exposure; take canagliflozin at least 1 hour before or 4-6 hours after a bile acid sequestrant. **Effects of Invokana on other medicines:** monitor patients on digoxin, other cardiac glycosides, dabigatran. Inhibition of Breast Cancer Resistance Protein cannot be excluded; possible increased exposure of drugs transported by BCRP (eg, rosuvastatin and some anti-cancer agents). **PREGNANCY:** No human data. Not recommended. **LACTATION:** Unknown if excreting in human milk. Should not be used during breastfeeding. **SIDE EFFECTS: Very common (>1/10):** hypoglycaemia in combination with insulin or sulphonylurea, vulvovaginal candidiasis. **Common (>1/100 to <1/10):** constipation, thirst, nausea, polyuria or pollakiuria, urinary tract infection (including pyelonephritis and urosepsis), balanitis or balanoposthitis, dyslipidemia, haematocrit increased. **Uncommon (<1/100) but potentially serious:** anaphylactic reaction, diabetic ketoacidosis, syncope, hypotension, orthostatic hypotension, urticaria, angioedema, necrotising fasciitis of the perineum (Fournier's gangrene)

(frequency not known), bone fracture, renal failure (mainly in the context of volume depletion), lower limb amputations (mainly of the toe and midfoot, incidence rate of 0.63 per 100 subject-years, vs 0.34 for placebo). **Refer to SmPC for details and other side effects. LEGAL CATEGORY:** POM. **PACK SIZES, MARKETING AUTHORISATION NUMBER(S) & BASIC NHS COSTS Invokana 100 mg film coated tablets:** 30 tablets; EU/1/13/884/002; £39.20. **Invokana 300 mg film coated tablets:** 30 tablets; EU/1/13/884/006; £39.20. **MARKETING AUTHORISATION HOLDER:** Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. * INVOKANA is a registered trade mark of Janssen-Cilag International NV and is used under licence.

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 Janssen-Cilag Ltd on 01494567447 or at dsafety@its.jnj.com.

FURTHER INFORMATION IS AVAILABLE FROM: Napp Pharmaceuticals Ltd, Cambridge Science Park Milton Road, Cambridge, CB4 0AB, UK. For medical information enquiries, please contact medicalinformationuk@napp.co.uk © 2017 Napp Pharmaceuticals Limited. **UK/INV-18164(1) Date of Preparation** January 2019. **References:** 1. Afkarian M, et al. J Am Soc Nephrol. 2013;24(2): 302-308 2. Neal B, et al. N Engl J Med. 2017;377(7):644-57.

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WELCOME

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EDITOR'S LETTER

Welcome to the latest edition of Scottish Pharmacy Review!

I'm notorious for ruining the endings of everything for myself. Books, films, TV shows – I read up on them first, consume the supposed surprises, and then – and only then – will I decide if my initial interest is worth pursuing. It's a frustrating trait, and I do know that (my friends and family remind all the time even if I didn't), but my justification stems from a stringent dislike of being caught off-guard.

The only other occasion when I see this habit filter into the rest of my life is during winter's impending arrival. My sandals are hastily replaced with boots; my well-worn blankets come out of hiding; and the tins of chocolates in my house are in a speedier rotation than the Magic Roundabout. Most importantly, though, I always try to protect myself against the threat which the colder weather poses to my health, and prepare to manage any ailments and conditions that I do encounter.

In this edition of SPR – the final one of 2019 – our winter special is dedicated to the importance of preparing ourselves and patients for the seasonal change, and the messages which we can deliver to them to make the process easier.

For example, given the weather's potential in aggravating existing health problems, Kidney Care UK present their

advice to pass on to kidney patients (page 22), and Dr Peter Kewin, Consultant in Respiratory and General Medicine, Queen Elizabeth University Hospital, investigates the factors which come into play for asthma patients (page 45). Additionally, with the norovirus likely to become much more widespread, Lesley Carter, Age UK's Clinical Lead for Professionals and Practice, overviews how we can help infected patients (page 16).

Elsewhere, Colin Cheesman poignantly shares his Parkinson's story (page 13), two pharmacists delve into their experience and advice for treating dry eye syndrome (page 19), and Gabriela da Silva Xavier, Senior Lecturer in Cellular Metabolism, provides the lowdown on hypoglycaemia and diabetes (page 42).

Make sure to check out the sterling work of our Scottish Pharmacy Awards finalists (beginning on page 23), and find out more about vulvodynia and the importance of raising awareness (page 48).

Happy reading – and see you next year!



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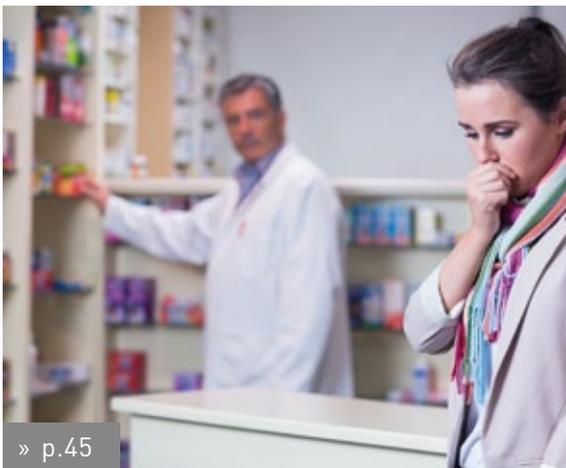
Stay in the know about diabetic neuropathy through the Diabetes Research & Wellness Foundation's exploration



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NEWS

TAKING THE LEAD

A University of Dundee physicist has been granted a substantial investment; supporting his mission to make the invisible visible.

The University of Dundee's Dr Tom Vettenburg has received £1.4 million in funding from UK Research and Innovation (UKRI) to develop the next generation of microscopes.

Dr Vettenburg, who was awarded a UKRI Future Leaders Fellowship, has said that because ordinary microscopes can't see through the outer 'skin' of a growing organism, they leave many questions unanswered – questions he intends to bring into focus by developing a computational microscope that can see beyond the blur of deep tissue.

'The invention of the optical microscope made it possible to highlight the fine features of living cells with unprecedented clarity,' explained Dr Vettenburg, Lecturer in Physics at the university's School of Science and Engineering.

'However, cells isolated on a microscope slide often do not behave as they would in their natural environment and despite the recent development of planar illumination light-sheet microscopes, which allow visualisation of transparent organisms during development, many tissues are simply too opaque to be studied.

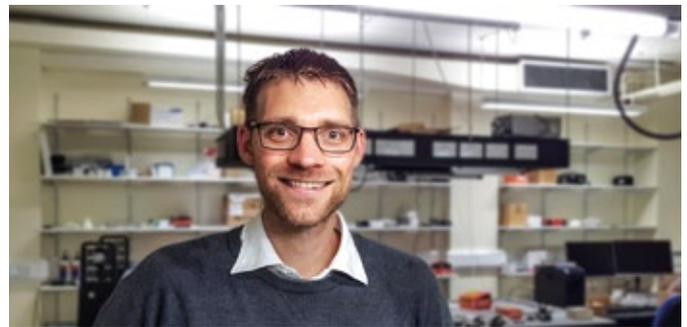
'We lack the tools necessary to keep track of cell migration and differentiation and all-too-often we only see a blurry haze beyond the first layers of cells. To deepen our understanding of nature, we first need to overcome the depth limit in microscopy.'

Dr Vettenburg believes that the grant will allow him and his team to visualise the biological development process as it happens, which in turn could benefit fields, such as regenerative medicine.

He added, 'Currently, an estimated 70 per cent of the UK's healthcare expenditure goes towards the management of chronic disease. Developing a direct view into the inner workings of the biological development process is essential to develop effective regenerative medicine therapies that can, in the long-term, turn chronic diseases into curable conditions.'

UKRI Future Leaders Fellowships support early-career researchers and innovators with outstanding potential. More than 70 top researchers from across the country receive a portion of a £78 million cash boost as part of the UKRI Future Leaders Fellowships.

The investment will propel the next generation of researchers as they lead cutting-edge projects.



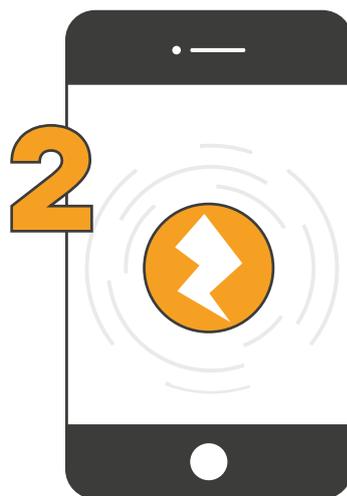
Dr Tom Vettenburg

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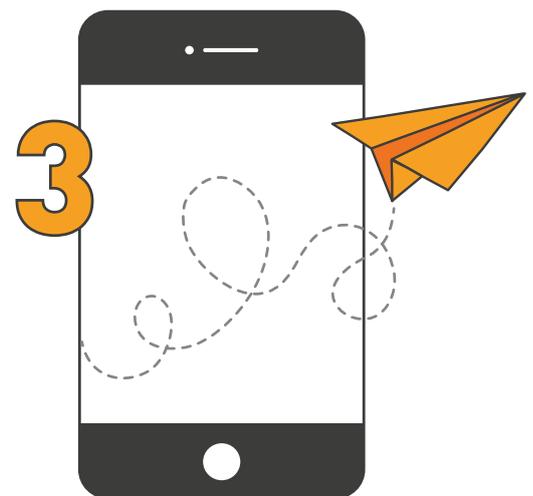
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MEDICATION WITHOUT HARM

THE THIRD GLOBAL PATIENT SAFETY CHALLENGE: MEDICATION WITHOUT HARM

In March 2017, the World Health Organisation launched its third Patient Safety Challenge – Medication Without Harm. In the first of a series of articles, Alpana Mair, Head of Effective Prescribing and Therapeutics at the Scottish Government, sets out the themes of the initiative, and delves into the role of patient safety as an important component of healthcare delivery which is essential to achieve universal health coverage and move towards the sustainable development goals.



Alpana Mair

It is estimated that over half of medicines globally are prescribed, dispensed, or sold inappropriately. Medicines are the most common therapeutic intervention and in recognition of this, the goal of the challenge is to reduce severe avoidable harm by 50 per cent, over the next five years. It is estimated that globally the annual costs associated with medication errors are US \$42 billion.

Like the previous challenges, this recognises that errors are not inevitable, but can be addressed by considering factors in the healthcare system. For example, human factors – such as fatigue – poor working environment, and staff pressures that might lead to errors during the stages of the medication process, which are prescribing, transcribing, dispensing, administration, and monitoring that result in harm and can result in death. Although the majority of errors occur on administration of medicines, they can occur at any stage of the process.

This article will set out the main themes of the challenge and the subsequent article will address more detail about the three flagship areas identified for initial work by each country, high-risk situations, polypharmacy and transitions of care.

The challenge sets out a strategic framework to consider the fundamental problems, and as pharmacists we might want to consider how we can play an active role in taking this forward:

PATIENTS AND THE PUBLIC

Health literacy may be poor for some patients so how can we support them to make taking their medications safer? In the World Health Organisation (WHO) pack, material for patients includes enabling them to ask basic questions on 'Know' (knowing what their medications are); 'Check' (patient using the medication the right way); and 'Ask' (attaining information from the healthcare professional about their medication which would support them to take this appropriately).

MEDICINES

Within the pharmacy, the complex names and packaging of medications that can either 'look alike or sound alike' can be a common source of error and medication-related harm that can be addressed. Information has also been produced to support patients with the safe management of their medication.

HEALTHCARE PROFESSIONALS

How do healthcare professionals need to work across the multi-professional teams to prevent any increase risk in harm to patients?

SYSTEMS AND PRACTICES OF MEDICATION

Consider how the process across the organisation could have an impact on the safety of medication use. For example, the process of prescribing medication for patients should be shared across the organisation so that the patient doesn't receive conflicting messages. The culture across the organisation should also support multi-professional discussions regarding medication.

In order for the challenge to make improvements, key stages of the medication process have been identified: prescribing, dispensing, administering, monitoring and use.

Early priority areas as described above are set out in summary and it is helpful to consider how you might identify areas to address within the pharmacy setting by considering the following scenario:

Mrs W is a regular customer who is 58 years old. She has a history of asthma and COPD and you regularly dispense inhalers for her. Recently you notice that she has not been herself and has bought some over-the-counter remedies for back pain; co-codamol tablets after an injury of falling off the pavement a couple of months ago when the weather was bad and the ground slippery. The pain has stopped her from doing her normal activities and she tells you that she's looking for some anti-inflammatories and something to pick up her mood and help her sleep. Her friend told her that Ibuprofen should help and St John's Wort is a pretty good pick-me-up and she's been taking these for the last month. She also presents a prescription for omeprazole for indigestion and heartburn.

The three early priority areas are:

MEDICATION SAFETY IN HIGH-RISK SITUATIONS

This will be considering either situations where medications are high-risk or inappropriate. In the scenario above, the high-risk situation is the lady buying multiple medications and also the fact that some of the medications she is self-medicating with are medications that are known to either cause admission to hospital or have a higher likelihood of causing harm.

MEDICATION SAFETY IN POLYPHARMACY

As people suffer from multiple morbidities, they take more medications. The challenge is to ensure that the patient will gain benefits from these medications as they are added in and not experience any harm. In the UK, up to 11 per cent of all admissions to hospital have been estimated to be due to medications, with half of these being preventable.

MEDICATION SAFETY IN TRANSITIONS OF CARE

It's important that as patients move to access care across care settings the same principles are applied. Therefore, as the lady approaches the pharmacy to add to her treatment we need to ensure that the medications are appropriate and that none of the medications are going to be harmful.

On 20th June the technical reports to support countries to implement this work were launched with a webinar and this can be found at:

www.who.int/patientsafety/medication-safety/webinar-launch.pdf?ua=1.

This year, the WHO agreed through the world assembly to establish the first World Patient Safety Day on 17th September.

ECZEMA: THE EARLY YEARS

Around 70 per cent of people will experience some form of eczema in their life (1), with around 70-to-90 per cent of cases occurring in children before five years of age (2), and there being a high incidence of on-set in the first year of life. When it comes to managing the symptoms of baby eczema, emollients are the first line of defence. Deborah Wyatt, Patient Engagement Specialist at talkhealth, explores their role further; from securing the appropriate choice and advising on application, to accessing additional channels of support.



Deborah Wyatt

The purpose of emollients is to soothe and hydrate the skin by occluding the skin barrier, which prevents water loss (trans-epidermal water loss or TEWL). Plus, medical emollients are fragrance-free and detergent-free.

Some emollients (humectants) also have natural moisturising properties which helps aid skin repair, and emollients with ceramides (also referred to as fats or lipids) replace fats around the skin.

Well-moisturised skin is crucial to the management of eczema as the emollient waterproof protective layer will help repair the faulty skin barrier.

BATHING AND WASHING INFANTS

Emollient bath oils and other emollient wash products clean skin without the damaging effects of soaps and detergents.

When washing with emollients or wash products, recommend that the parent covers the baby's body with a leave-on emollient or wash product before getting into the bath

and then soak off in lukewarm water. Using an emollient or wash product in the bath is an essential part of Complete Emollient Therapy, as described later, as it helps with skin hydration. Recommend that the parent applies leave-on emollients immediately after they bathe their baby to lock moisture into the skin.

RECOMMENDING THE RIGHT EMOLLIENT

There are a wide range of emollient treatments for babies with eczema that are available in different formulations. Finding the right emollient will vary from person-to-person and often it is down to trial and error.

- Lotions – are cooling, spread and absorb easily, but contain more water than oil-based emollients, so don't necessarily occlude the skin barrier well for babies with very dry skin
- Creams – are easy-to-use and absorb well, but need to be applied every three-to-four hours
- Humectant creams – are the same consistency as creams, but contain additional natural moisturising ingredients which help skin cells retain water, so these have a double action. They have a longer-lasting effect on the skin than creams and gels of around six-to-eight hours
- Gels – are light and non-greasy, despite a high oil content, so need to be applied to the skin every three-to-four hours. They can leave globules on the skin
- Ointments – leave a thick film on the skin to prevent water loss and help to repair the skin barrier. They contain less water, but are greasy and can be messy to use. Some parents may prefer only to use these at night
- Sprays – are ointment-based and give even body coverage, but can make the floor slippery so always recommend standing on a

towel / mat or apply standing in the bath on a bathmat

- Note – aqueous cream shouldn't be used for babies with eczema as a leave-on treatment because it contains sodium lauryl sulphate which can cause irritation and make eczema worse in some babies and children (3)

SOME EMOLLIENTS CONTAIN ADDED INGREDIENTS TO HELP WITH THE SYMPTOMS OF ECZEMA

- Antimicrobials – have antiseptics added to both wash products and leave-on emollients, which helps prevent infection
- Lauromacrogols and oatmeal – these ingredients have anti-itch properties
- Ceramides – restore the balance of fats around skin cells to help the functioning of the skin barrier

APPLICATION OF EMOLLIENTS – HOW MUCH AND HOW OFTEN?

Correct application and using the right amount of emollient is important. Emollients should never be rubbed into the skin as this could trigger itching, block hair follicles, and create more heat in the skin. Instead, advise parents to liberally apply the emollient by dotting it onto the skin, and then use long and gentle downward strokes, smoothing the emollient into the skin, to leave a thin film.

Emollients should be applied all over the baby's skin at least twice a day as a minimum, with additional applications whenever the skin appears dry and itchy.

A baby can have emollients applied at every nappy change and if they are scratching and show signs of dry skin.



Emollients should be recommended to use continually every day, even when the eczema appears clear, as regular use prevents eczema flare-ups.

COMPLETE EMOLLIENT THERAPY

Complete Emollient Therapy (CET) is a way of keeping the skin moisturised by using a combination of products, including an emollient-based cleanser or soap substitute, with regular application of creams or ointments throughout the day and at bedtime. Having a CET regime helps to support the skin's natural barrier, keeping moisture in and irritants out.

For babies with atopic eczema, it's important to explain to parents that everything that touches their baby's skin should be emollient-based and all soaps and detergents need to be replaced with an emollient wash, bath and shower products.

TWO-IN-ONE AND THREE-IN-ONE PRODUCTS

It might be appropriate to consider either a two-in-one or three-in-one product. A two-in-one product can be used as a wash / soap substitute and also as a leave-on emollient.

A three-in-one can be added to bath water, used as a wash product / soap substitute and a leave-on emollient.

Many emollients can be used as three-in-one products, with the exception of 50 / 50 white soft paraffin / liquid paraffin products.

EMOLLIENT CHOICE

Discuss the options available to find out what the parent prefers e.g. lotion, cream, gel etc. Some parents may prefer to use one emollient for both washing and moisturising the skin, while others might opt for a selection of different formulas e.g. a bath oil and / or wash, a cream for daytime and an ointment for night.

Factors to consider when recommending an emollient include where the baby will be during the day, e.g. at home or staying with a carer? Will they be at nursery? Does the parent prefer to apply something lighter on the skin during the day rather than heavier emollient options? Does their baby appear irritated by thick creams?

No two emollients or babies are the same and everyone will have different needs, so what suits one baby, may not suit another.

NICE GUIDANCE ON EMOLLIENTS FOR THE TREATMENT OF ATOPIC ECZEMA IN CHILDREN UNDER 12 YEARS STATES:

'Healthcare professionals should offer children with atopic eczema a choice of

unperfumed emollients to use every day for moisturising, washing and bathing. This should be suited to the child's needs and preferences and may include a combination of products or one product for all purposes.' (4)

CRADLE CAP (SEBORRHEIC DERMATITIS)

Cradle cap is often confused with eczema but is much less red and scaly and generally clears up by the time a baby is eight months old. It appears on the scalp, sides of the nose, eyelids and eyebrows, and behind the ears.

If a parent is worried about cradle cap, recommend washing their baby's hair once-a-day with a mild, tear-free baby shampoo and to gently remove the scales with a soft brush or a toothbrush.

It can also help to suggest that they apply a small amount of mineral oil or petroleum jelly to their baby's head, let it soak for a few minutes up to several hours, depending on the severity, and then gently brush, followed by shampooing their baby's hair.

EMOLLIENT HEALTH AND SAFETY

Some extra tips to recommend to parents include:

- Emollients and stinging – if your baby's skin is very dry and hot to the touch, keep your emollient in the fridge so it has a cooling effect on the skin when applied
- Safety in the bath – emollients may cause the bath or shower to become slippery, so a bathmat is always good to recommend to parents. There is also a fire hazard with paraffin-based emollients so when in contact with or near naked flames, warn parents to be careful as paraffin-soaked clothing / bandages are at risk of igniting

ADDITIONAL SUPPORT

In the UK, NHS guidance for the routine prescribing of some products has changed.

Prescriptions for silk clothing and emollients to treat eczema will now not be routinely prescribed. A recent talkhealth survey revealed that 68 per cent of 439 people surveyed were currently receiving bath or shower additives on prescription, and 56 per cent said they were not aware of the change in prescribing guidance. (5)

The same survey found that 87 per cent would find it helpful if their GP offered a support programme written specifically to help them manage their child's eczema.

Based on this research and having talked to 76 healthcare professionals and examined the gaps in NHS service delivery, talkhealth has created a free online support programme called myeczemachild. Written by medical

experts it provides evidence-based, unbiased guidance and information for parents around self-care.

talkhealth support programmes are already available in GP surgeries around the UK for healthcare professionals to offer to their patients.

To find out more about how talkhealth are supporting medical professionals with information they can give to their patients, visit talkhealth medical at www.talkhealthmedical.com.



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4. <https://www.nice.org.uk/guidance/qs44/resources/atopic-eczema-in-under-12s-pdf2098666709701>
5. talkhealthpartnership.com

ABOUT THE AUTHOR

Deborah Wyatt is a Patient Engagement Specialist; partnering with healthcare and pharmacy to provide effective patient programmes and solutions.

Such a lack of support back in 2000 prompted the idea of talkhealth, following the birth of Deborah's daughter with a chronic eczema condition. The talkhealth team are very aware of how time-consuming it is piecing together all the disparate information that is available across the internet, plus most importantly understanding its trustworthiness.

Secondly, they also understand the wish for people to be able to easily communicate directly with others in a similar position. Chronic health conditions can be very alienating and there is only so much you can repeatedly discuss with family and friends. Talking openly with others who fully understand health issues is a very important part of the talkhealth community experience.

BRAIN TUMOURS

COMING TO A HEAD

A surge of optimism beckons as new research and efforts march towards the transformation of the brain tumour landscape. Erica Moyes, from the Brain Tumour Charity, explains.



Erica Moyes



If you ever hear that someone has a brain tumour, it could be one of 150 different types. Uniquely, brain tumours have wide-ranging effects depending on their location, size, and infiltration into the surrounding brain. They can change your mood, physical abilities, and even inhibitions – the things that make you you. It can take just days for a brain tumour to grow, yet brain tumours reduce life-expectancy by 20 years on average – the highest of any cancer – and it can take years to find new treatments. This simply isn't good enough. A cure can't wait!

To date, we've committed over £52 million to the highest quality international research. We're dedicated to bringing about global collaboration to speed up the time it takes to turn discoveries into treatments and cures.

Dr Gelareh Zadeh, in Toronto, Canada, is a prime example of the impactful researchers we fund. As a Neurosurgeon, Dr Zadeh provides the opportunity for her patients to contribute directly to her meningioma research. Clinically-aggressive meningiomas arise from the membranes surrounding the brain and spinal cord in adults, and often recur after surgery and radiotherapy. We fund Dr Zadeh's work, which has resulted in a clinical tool to predict this recurrence, and will help clinicians to prescribe more appropriate treatments.

We're also advancing understanding and clinical practice for children with brain tumours. Since 2001 we have funded the lab-based work of Professor Steven Clifford at Newcastle University. Professor Clifford has dedicated his career to learning more about medulloblastoma and improving survival rates for children diagnosed with this tumour. Medulloblastoma is the most common high-grade (fast-growing) brain tumour in children. Because of work that we funded, Professor Clifford was a key contributor to a consensus paper that described four medulloblastoma sub-types: WNT, SHH, Group 3 and Group 4.

Importantly, this paper showed that WNT tumours have a very good prognosis. We were instrumental in driving this knowledge into the clinic by funding molecular testing for all childhood medulloblastomas in the UK. This testing enabled children to be enrolled onto the European clinical trial, PNET5, where they can access the most cutting-edge treatment.

As well as the UK's molecular testing for PNET5, we also fund the Quality of Survival aspects for all participants in Europe. This is vital because we are at a key point in medulloblastoma treatment where we are starting to reduce treatment to enhance quality of life, especially for the WNT subgroup.

Average survival rates for all high-grade tumours are just 14 per cent and treatments have barely changed in 40 years. This is unacceptable.

We are developing a new kind of clinical trial in the name of the late Cabinet Minister, Dame Tessa Jowell: the Tessa Jowell Brain-MATRIX. We worked closely with Baroness Jowell until her death from a glioblastoma (a high-grade brain tumour) in May 2018. She advocated for a change in the design of clinical trials to enable new treatments to get to people faster. The Tessa Jowell Brain-MATRIX will initially be available from 10 centres around the UK. Adults and children with grade 2, 3 and 4 tumours will be eligible as long as they are fit for surgery to obtain a tumour sample for molecular assessment. The trial has been designed to incorporate new molecularly-targeted treatments as they become available, avoiding the need to set up a whole new trial. This removes a systemic delay and will significantly hasten patients' access to precision treatments.

Before people can access treatments they need an accurate diagnosis and they need it urgently.

HEADSMART

Our evidence-based campaign, HeadSmart, raises awareness of the signs and symptoms of childhood brain tumours. So far, HeadSmart has helped to reduce average diagnosis times for childhood brain tumours from 13 weeks to 6.5. Now we want to accelerate awareness of symptoms and see diagnosis times reduced to four weeks.

Building on the success of HeadSmart, we will soon launch an adult early-diagnosis campaign to decrease the delay from presentation to diagnosis.

Getting a brain tumour diagnosis can make patients feel like their world has stopped – which is exactly why we won't. Every day, we're actively researching, campaigning, and growing our passionate community to accelerate progress towards a world without brain tumours.

The Brain Tumour Charity is striving for a world where brain tumours are defeated, by doubling survival and halving the harm of brain tumours and their treatments. We understand that our goals are ambitious, but by joining together, we know that we can reach them faster.

For more information, visit www.thebraintumourcharity.org or email research@thebraintumourcharity.org.

ABOUT THE BRAIN TUMOUR CHARITY

The Brain Tumour Charity is the world's leading brain tumour charity and the largest dedicated funder of research into brain tumours globally. Committed to saving and improving lives, we're moving further, faster, to help every single person affected by a brain tumour.

NTM-LUNG DISEASE

NTM-LUNG DISEASE: IS IT ON YOUR CLINICAL RADAR?

Despite the rising incidence of a rare lung infection that is challenging to both diagnose and treat, leading respiratory physicians have said that there is light at the end of the tunnel. Ian Mason explains.

Mycobacteria – a family of small, rod-shaped bacilli – have proved a scourge throughout human history. They are responsible for some truly terrible diseases including tuberculosis (mycobacterium tuberculosis) and leprosy (mycobacterium leprae).

Other members of this troublesome family are responsible for a growing number of serious lung infections. (1) The culprits are called nontuberculous mycobacteria (NTM) – and if you took a shower or bath this morning, you may have inhaled scores of these potential pathogens. (2)

They thrive in drinking water, household plumbing, peat rich soils, brackish marshes and drainage water. Even hospital water systems, haemodialysis centres and dental surgeries have been found to harbour high rates of NTM colonisation. (3)

In susceptible individuals, NTM can cause progressive inflammatory lung damage, a condition termed ‘NTM-lung disease’ (NTM-LD), sometimes also referred to as NTM-pulmonary disease (NTM-PD). However, just to confuse the picture, these bacteria can also be occasional or permanent lung residents without causing NTM-LD. (4)

Those most at risk of developing overt NTM-LD include immunosuppressed individuals or those with pre-existing lung damage from chronic diseases such as asthma, COPD, bronchiectasis, pneumoconiosis or aspergillosis (4) – however NTM-LD may occur in people with no overt immune deficiency. (5)

Studies from many countries point to an increasing prevalence of NTM-LD over time, leading some authors to conclude that ‘NTM are emerging worldwide as significant causes of chronic pulmonary infection, posing a number of challenges for both clinicians and researchers.’ (6)

WHAT'S HAPPENING IN THE UK?

In England, Wales and Northern Ireland, the reported rate of NTM isolation (from humans) more than doubled between 1996-and-2006. A more recent study found that incidence of NTM isolation rose from 5.6-to-7.6 per 100,000 between 2007-and-2012. The organisms most frequently cultured from pulmonary isolates were members of the mycobacterium avium-intracellulare complex family (MAC), and the incidence of pulmonary

MAC increased significantly from 1.3-to-2.2 per 100,000 between 2007-and-2012. The majority of these individuals were over 60 years old. The authors concluded that, ‘The incidence of NTM has continued to rise since the last national analysis. Overall, this represents an almost 10-fold increase since 1995. Pulmonary MAC in older individuals is responsible for the majority of this change.’(5)

These findings are reflected at the sharp end of clinical practice. Professor James Chalmers, Consultant Respiratory Physician at the University of Dundee School of Medicine, says that he is seeing more patients with NTM-LD, commenting, ‘Rates are clearly going up, predominantly in the elderly and in people with existing respiratory illness. When I first started in my clinic, we saw very few patients with NTM-LD, but now we find this in around one-in-10 of our bronchiectasis patients.’

‘We face enormous challenges when treating these patients. For those who do not manage this disease every day, there is a lack of dependable specialist advice. Patients may have multiple comorbidities, their clinical course is difficult to predict, the drugs we currently use to treat NTM-LD can be toxic, and we have real difficulties managing those toxicities.’

HIGH RISK OF MORTALITY

A recent research publication (7) by Dr Marc Lipman, Division of Medicine, University College London and Royal Free Hospital NHS Foundation Trust, notes the rising incidence of NTM-LD caused by MAC in apparently immune-competent people. Dr Lipman’s review also described the potential seriousness of these infections.

‘Most studies in patients with MAC pulmonary disease (NTM-PD) document a five-year all-cause mortality exceeding 25 per cent, indicating poor prognosis... these findings emphasise the need for more effective management,’ the review concluded.

The concern of Dr Lipman and his colleagues is reflected by a growing interest in NTM-LD at major respiratory meetings, such as the European Respiratory Society and the British Thoracic Society (BTS), with new disease registries and major research projects underway in many countries.



NTM-LUNG DISEASE

In the UK, the BTS published new guidelines on the management of NTM-LD (4) in 2017, the first update since 2000. These echo the need for more effective and more tolerable NTM treatment regimens, stating, ‘Why is this important? We currently use combination antibiotic regimens that are often associated with significant toxicity, require prolonged administration, and particularly in the case of mycobacterium abscessus frequently fail. There remain considerable challenges in co-ordinating and funding multicentre studies of novel drugs or new combinations of existing drugs for NTM infections.’

Given this, it’s perhaps unsurprising that adherence with treatment guidelines is poor. (8) Speaking at a BTS winter meeting (London 5th-to-7th December 2018), Dr Jennifer Quint, Reader in Respiratory Epidemiology, National Heart and Lung Institute, Imperial College, London, said that only around half of NTM disease patients who are managed in primary care are treated according to guidelines. (9)



The complexity and potential toxicity of current treatment regimens has spurred interesting research in which a pharmacist took increased responsibility for the management of NTM-LD. Pharmacy staff were trained to identify, resolve, and prevent drug-related adverse events. A pilot study found a high level of patient-satisfaction when a pharmacist took a leading role in the multidisciplinary care team and furthermore that specialist non-physician healthcare workers can act as both a patient’s support and advocate. (10)

IF IN DOUBT... REFER

The published BTS guidelines also underscore the importance of the time-honoured clinical maxim – if in doubt refer to a specialist centre. The guidelines are clear that ‘individuals with NTM-PD should be managed in collaboration with a physician experienced in managing NTM-PD.’

Professor Chalmers agrees, saying, ‘I see patients whose diagnosis of NTM-LD has been delayed. For example, they are treated for bronchiectasis but nobody thinks about NTM. Clear clinical pointers such as a non-productive cough are ignored. The patient has been given multiple therapies without anyone stopping to say ‘this is not behaving like asthma or bronchiectasis’ or classic features of NTM-LD are not reported by the radiologist. Out there in the majority of respiratory clinics NTM is not top of the agenda and it is part of

our job to make this top of the agenda, because this is a much bigger problem than previously recognised.’

In order to address some of these shortcomings, Professor Chalmers and Dr Marc Lipman have co-founded NTM Patient Care UK, a new charity (and the first in the UK), specifically devoted to the empowerment, education, and advocacy of people with NTM disease and their carers.

‘What else can we do in the next five years that will make a difference? We need more burden of disease data for NTM-LD, better diagnostics and better treatments. We need to educate GPs and hospital physicians who do not have this on their radar, that this is something they should think about so that patients with COPD, bronchiectasis or other underlying lung disease get referred to an NTM specialist,’ said Professor Chalmers.

KEY FACTS ABOUT NTM

- More than 150 different species of NTM have been described, however pulmonary infections are most commonly due to mycobacterium avium complex, mycobacterium kansasii, and mycobacterium abscessus (3)
- Although NTM infection has traditionally been associated with immunosuppressed individuals or those with severe underlying lung damage, NTM-LD may occur in people with no overt immune deficiency (5)
- NTM-LD requires a multidisciplinary approach and may require input from hospital specialists in respiratory medicine, pharmacy, infectious diseases, paediatrics, microbiology, immunology and radiology (10, 11)
- NTM are aerobic, non-motile and ubiquitous in the environment with the heaviest concentrations found in soil and water sources. An unusually thick cell wall and a preference to live in biofilms make it difficult for disinfectants or antibiotics to kill them. They are easily aerosolized with associated risk of inhalation and infection (3)
- The treatment of NTM-LD involves complex drug regimens that are commonly associated with intolerance and toxicity (4)

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KEEP YOUR COOL

Dr Edward Farnan, Medico-Legal Adviser at the Medical Defence Union, details the best response when contending with patients who are displaying challenging or threatening behaviour.



Dr Edward Farnan

The majority of consultations go well, with both the medical professional and the patient feeling that their expectations have been met.

Unfortunately, in a minority of cases, some consultations can escalate to aggressive behaviour or even violence. While such incidents are rare, it's understandably distressing for the staff directly involved – and also highlights the risks which healthcare staff can be exposed to.

A 2017 report in the BMJ looking at crime figures obtained from UK police forces showed a nine per cent rise in the overall number of recorded crimes committed on GP premises and health centres; from 1,974 crimes in 2015-to-2016 to 2,147 in 2016-to-2017. The figures showed a rise in assaults, harassment and threatening behaviour, illustrating that physical attacks can just be the tip of the iceberg when it comes to dealing with challenging behaviour.

REASONS FOR AGGRESSION

There are a number of reasons why patients may

become violent or aggressive. In some cases, threatening behaviour may be explained by an underlying medical problem. Patients with an acute physical or mental illness may behave in a way which is not in-keeping with their character when they are well. Patients who are unwell, afraid, or in pain may react in an unpredictable way.

It is particularly challenging if a patient whose previous behaviour has never been a concern suddenly becomes aggressive if they feel that their requests are not being taken seriously, or if a clinician does not appear to be acknowledging their distress.

Other factors which may contribute to disruptive behaviour include communication or language problems, frustration, previous poor experience, and unrealistic expectations.

PREVENTING CHALLENGING BEHAVIOUR

Often, the first step is being aware of the potential for a situation to escalate even with patients who have no history of threatening or aggressive behaviour. Be aware of the patient's body language, what they say, and how they say it. By acknowledging that a patient is unhappy, and indicating that you wish to understand why, may sooth a patient who otherwise could become aggressive.

Listening to the patient, asking open-ended questions, and avoiding encroaching on the person's personal space are all ways of reducing tension. NICE has published guidance on how to manage violence and aggression in a healthcare setting.

If a patient becomes aggressive or violent in spite of these steps, then it may be appropriate to consider what follow-up action is required.

It's sensible to have a clear policy in place, setting out how abusive and threatening behaviour from patients will be treated. This should be readily available – for example a notice in the patients' waiting room, or on the practice website.

WARNING PATIENTS

If you feel that it's appropriate to warn a patient about their behaviour then remember to deal with this separately from any other issues, for example, a response to a patient complaint.

The possibility of a warning should be discussed within the practice beforehand, and the discussion recorded. In the Medical Defence Union's (MDU) experience, warnings about behaviour, or removal from a practice list, can result in a complaint; it's helpful to be able to show that the decision taken was reasonable and proportionate.

The General Medical Council, and the standard GP contract, usually require a warning to have been issued before a patient is removed from a practice list. However, if there has been a threat of violence, or actual violence, it's appropriate to call the police and removal from the practice list without prior warning may be possible. Consider carefully how much confidential information might justifiably be released to the police and get advice from the MDU or your own MDO.

Appropriate staff training may also mitigate the risks, as might giving careful consideration to the layout of consulting rooms, or the use of panic alarms.

VISITING THE PATIENT AT HOME

It can be especially challenging if a patient becomes aggressive during a home visit as the environment will be less familiar and help may be less readily available. You may wish to defuse the situation, but it's also acceptable to end a consultation and leave, particularly if there seems to be an imminent risk of physical aggression.

If a patient who has previously been aggressive requires a home visit, and is unable to come to the surgery, then a risk assessment may be necessary. It may be appropriate to visit with a colleague (staff numbers and workload permitting). Phoning in advance to find out who will be there, to agree what behaviour will be acceptable, and to get a general feel for the patient's mood may also be helpful.

Challenging consultations with patients or relatives are unusual but it is worth reviewing your practice policy on this issue, including security in the practice and on home visits and staff training to ensure that you minimise the risk of patients becoming violent or aggressive.

NEWS

PIONEERING APP TO HELP PEOPLE WITH SUBSTANCE USE LAUNCHED IN STIRLING

A new digital platform has been introduced to provide support to those affected by substance use in the Stirling and Clackmannanshire areas.

The Forth Valley Recovers App is the first project of its kind in Scotland and will offer important information to individuals; direct them to local and national support, and encourage engagement with services.

Developed by award-winning company, Faff Digital, in conjunction with the local recovery community, the software will assist people in their recovery via a range of interactive features, and help users understand the impact of drugs and / or alcohol on their health, as well as its effect on others.

Although the app is aimed at people in recovery, it can also be utilised by families, workers, and the wider community to bolster knowledge and promote services.

According to the Office of National Statistics, 94 per cent of households in Scotland are estimated to own a mobile phone, with usage increasing, while 85 per cent have access to a personal computer and the internet. A digital presence can therefore reduce stigma and discrimination for those who may find it difficult to approach services in person.

Dr Graham Foster, Director of Public Health, NHS Forth Valley, said, 'NHS Forth Valley works closely with key partners to offer support to families and communities affected by substance use. It is a key priority in our local health

improvement strategy.

'The Forth Valley Alcohol and Drug Partnership Team estimates that for every person who has problems with substance use there are likely to be two or three other people who are directly affected. These include spouses, partners, children, and siblings, as well as co-workers and friends.

'Families have a critical role to play in helping people on the road to recovery by engaging more fully in their recovery plan and this pioneering app is an important step forward in providing vital support and advice.'

For more information, visit www.forthvalleyrecovers.com.



DRUG TRIAL OFFERS HOPE OF IMPROVED OVARIAN CANCER TREATMENTS

Women with a rare type of ovarian cancer could benefit from a drug that quadruples the likelihood of response compared with standard therapies. Showcasing further promise, the clinical trial of women with low-grade serous ovarian cancer also found that the treatment can halve the speed of relapse.

Experts have explained that the randomised trial of a drug called trametinib paves the way for better outcomes in that, until now, low-grade serous ovarian cancer has been particularly difficult to treat.

260 patients were involved in the clinical trial, which was led by the University of Texas' MD Anderson Cancer Centre and the University of Edinburgh's Nicola Murray Centre for Ovarian Cancer Research – part of the Cancer Research UK (CRUK) Edinburgh Centre.

The individuals were randomly assigned either trametinib – previously employed to treat melanoma – daily, or their doctor's choice of any five currently-available therapies, known as standard of care.

The average follow-up was around two-and-a-half years, in which patients who received trametinib demonstrated a chance of progression-free survival that was more than double that of those who received standard of care treatment. Additionally, the percentage of patients whose tumour shrank was more than four-times higher in trametinib patients compared to those treated with the standard of care.

Professor Charlie Gourley, Clinical Director of the CRUK Edinburgh Centre, and Director of the Nicola Murray Centre for Ovarian Cancer Research at the University of Edinburgh, commented, 'Low-grade serous ovarian cancer is different from other ovarian cancers because it affects younger women and is often resistant to chemotherapy. This is the first positive, randomised trial in this disease and represents a major breakthrough for patients with this type of ovarian cancer.'

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PARKINSON'S AND ME

Adjusting to a Parkinson's diagnosis can be a perplexing and overwhelming process, so it's important to make the individual feel as supported as possible. Colin Cheesman shares his story – helping us to channel the patient's journey, and the factors which have been impactful in managing his condition.



Colin Cheesman

'I'm sorry to spoil your evening, but you have Parkinson's.' The consultant neurologist carried on writing his notes, and I sat in silence for what seemed like an age, but was probably only a few seconds. I had understood the words, but could not grasp their relevance to me. Parkinson's? Surely, that was something that affected elderly people. I was a physically fit and apparently healthy 54-year-old.

'You are in the very early stages and it is unlikely to affect you significantly for some time,' continued the consultant. As he carried on speaking, it began to sink in that he really did mean me. He went on, 'At this stage it is not necessary to begin treatment. I suggest that we review the position in six months. In the meantime, just get on with your life.'

I made my way home to my wife. We had both thought that my troublesome aches and the mild loss of co-ordination were something trivial, so she had not come with me to the appointment. We sat and looked at each other. Neither of us had had the faintest idea of the potential diagnosis nor did we have any knowledge of Parkinson's.

My life is dramatically different from the future I had expected. At the age of 54, I was the head of a large public body – at the top of my career as it were. Less than a year later, my wife and I had both retired and were starting to build a different life in the knowledge that I had Parkinson's.

It's 18 years on since I had that diagnosis and I am now into my 70s. I still regard myself as basically fit and healthy. Medication has largely kept pace with the progression of the condition, but that is only half of the story.

Although drugs can help manage the symptoms of Parkinson's, they can't halt the inevitable progression of the condition. Even with good medication, life is a daily battle to keep the progression at bay. I use the word 'battle' deliberately. Like many people with Parkinson's, I find it helps to personalise the condition and focus on Parkinson's as a virtual enemy which has invaded my body and wants to control more and more of it each day.

Parkinson's is progressive and, currently, incurable. Does that mean that there is nothing more that can be done other than to let Parkinson's take its course?

I passionately believe that there is more that we can do, based on the experience of managing my own condition and of working within the world of Parkinson's for over 15 years.

SELF-BELIEF

A positive attitude and a strong desire to maintain one's independence are critical. It can be very easy to be shocked and distressed by the diagnosis. Without support at this critical time some people with Parkinson's may sink into depression from which it is hard, and for some people, impossible, to recover.

DETERMINATION

Taking on the fight against Parkinson's requires a streak of determination. This might be categorised as pig-headedness, but it shows itself in a refusal to be constrained by the limits that Parkinson's wants to place on the individual's capacity to act.

FITNESS

It's generally acknowledged that the single most important factor in modifying or slowing the progression of Parkinson's is regular exercise structured to the individual's

needs.

LEARNING AND AWARENESS

Every person with Parkinson's is different. They will have a unique portfolio of symptoms, will have a different rate of progression, and will respond differently to treatments. This means that the selection of medication is a matter for careful discussion with the consultant. The patient can play his or her part by becoming sensitive to the impact and side-effects of the medication, how the condition is changing, or whether the drugs are wearing off. The treatment programme is a collaboration between the consultant and the aware patient.

THERAPEUTIC ASSISTANCE

It's fair to say that until recently, very little attention or priority was given to the therapeutic aspects of an individual's treatment compared with the medical. This is changing as we now realise that we have been missing a trick by not being more rigorous in emphasising the importance of having good access to physio and occupational therapies as well as less formal exercise classes such as yoga and Pilates. We should be aiming for early assessment and review of the appropriate therapeutic programme for the newly-diagnosed.

My message for you to give to those who receive a diagnosis of Parkinson's is to be positive and plan for the future. Life will be different – but not necessarily worse.

ABOUT THE AUTHOR

Colin was a solicitor by profession. He spent his career entirely in local government. He was diagnosed with Parkinson's in 2001. Colin was chief executive of a major local authority at the time of his retirement in 2002. As a volunteer he became involved with Parkinson's UK, where he was a trustee for nine years. He has a number of other voluntary sector interests and is currently a public governor of the Walton Centre NHS Foundation Trust.

PARKINSON'S

PARKINSON'S: BREAKING NEW GROUND

SPR rounds up some of the latest research for Parkinson's – and how it's striking hope and inspiration into our future management of the progressive neurological condition.

This article was sourced from news stories highlighted by The Cure Parkinson's Trust.

PARKINSON'S, LEPROSY AND CROHN'S

Researchers at the University of Ottawa have announced a new discovery associated with a genetic form of Parkinson's. Individuals with a genetic variation in a region of DNA for leucine-rich repeat kinase-2 (or simply LRRK2) have a higher risk of developing Parkinson's, as well as leprosy, and Crohn's disease. Why this is the case has been a mystery for a long time.

Now, the Canadian scientists have found that mice with a LRRK2 genetic variation differ in how they are able to deal with bacterial and viral infections. Curiously, mice with the LRRK2 genetic variation can handle a bacterial infection better than normal mice, but they fail to recover from certain viral infections.

Interestingly, the researchers found that this effect was most prominent in female mice in particular. In general, men are approximately 1.5 times more likely to develop Parkinson's than women, but this trend isn't observed in people with LRRK2-associated Parkinson's where women have an equal chance of developing the condition.

The research also shows that LRRK2 increases inflammation, which could explain the link between Parkinson's, leprosy, and Crohn's disease – all medical conditions associated with inflammation. There are currently inhibitors of LRRK2 that are being clinically tested for the treatment of Parkinson's. This new research suggests that some caution may be required in not reducing the levels of LRRK2 activity too low.

ON THE MOVE

The Parkinson's community has long been told that exercise is important for maintaining a sense of wellbeing and better quality of life – but recently there have been some hints that high-intensity aerobic exercise might actually help reduce the symptoms of Parkinson's. In fact, researchers at the Radboud University Medical Centre in Nijmegen (the Netherlands) published the results of a clinical trial evaluating an 'at-home' high-intensity exercise regime in people with Parkinson's, and they found that it had a positive effect.

The team – led by Professor Bas Bloem (The Cure Parkinson's

Trust Tom Isaacs Award winner for 2018) – recruited 130 people with Parkinson's for the 'Park-in-Shape' study, and randomly assigned them to either the 'aerobic intervention group' (who trained on a stationary exercise bike at home) or the 'active control group' (stretching exercises). The participants were instructed to do their exercise for 30-to-45 minutes, three times per week for six months. Both of the groups in the study received a motivational app and remote supervision throughout the study, and they were clinically assessed before and after the six-month period.

The results suggest that after the six months of these two treatments, there was a statistically-significant difference between the groups in their clinical motor scores (as measured by the MDS-UPDRS) of 4.2 points in favour of aerobic exercise. That is to say, while the 'active control group' had an increase in their clinical motor score of 5.6 (indicating progression in the condition), the 'aerobic intervention group' increased their score by only 1.3 points, suggesting a slowing of disease progression.

The researchers note that a replication of the study is required to determine the long-term effectiveness of this intervention and to investigate the possible disease-modifying mechanisms that could be involved. But the study provides an example of the positive potential benefits from an exercise routine that can be performed at home.

Professor Bas Bloem commented, 'This study is very important. We can now start researching whether much more long-term cycling can also slow the disease progression. Also, this new 'exergaming' approach that we have developed is very suitable to achieve long-term improvements in exercise behaviour for patients with a range of other disorders that could also benefit from regular exercise.'

A NEW BIOMARKER FOR PARKINSON'S?

Researchers at Stanford University in America looking for new biomarkers of Parkinson's recently identified a protein called MIRO that in initial data very accurately identifies people with the condition.

MIRO is a small protein that attaches to small structures inside our cells called mitochondria. Mitochondria are the power stations of cells, providing the energy for most biological activity. They are moved around inside of cells to wherever energy demands are greatest. MIRO is involved with moving mitochondria.

The researchers at Stanford, however, noticed that while in cells collected from healthy individuals damaged or stressed mitochondria will release the MIRO protein, in people with Parkinson's MIRO remains firmly attached to the mitochondria. In fact, in more than 70 samples of cells from people with Parkinson's, MIRO remained attached to mitochondria in 93 per cent of the cases (vs 0 per cent in the healthy control samples). The investigators are proposing that MIRO could be a useful biomarker to aid in the diagnosis of Parkinson's as this phenomenon was also not observed in samples of cells from people with other similar neurodegenerative conditions.

The researchers next screened for and identified a number of molecules that can remove MIRO from mitochondria in cells for people with Parkinson's. When they tested those molecules in models of Parkinson's, the investigators found that the treatment rescued those models. Importantly, the researchers have now started a biotech company (CuraX) to further explore the utility of MIRO as a biomarker and to develop novel therapies targeting this protein.

Ipinnia[®] XL

ropinirole prolonged-release tablets



Flexibility in dose-titration options...^{1,2}

A wide range of dose strengths, including 3 mg and 6 mg prolonged-release tablets unique to Ipinnia[®] XL, offering flexibility in dose-titration regimens to suit the needs of your Parkinson's patients.^{1,2}



Tablets are for illustrative purposes only and are not to scale.

...with the potential for a substantial 55% saving to the NHS[†]

Writing a prescription for branded Ipinnia[®] XL in place of generic ropinirole XL and branded ReQuip XL^{*} may provide a potential saving of up to 55% to the NHS.²

† Branded Ipinnia[®] XL may provide a 55% saving vs. a generic prescription for 2, 4 and 8 mg doses.

* Requip[®] XL is a registered trademark of the Glaxo Group Ltd.

References: 1. Ipinnia[®] XL prolonged release tablets Summary of Product Characteristics. Available at: <https://www.medicines.org.uk/emc/product/1791/smpc>. Last accessed October 2019. 2. British National Formulary; Ropinirole. Available at <https://bnf.nice.org.uk/medicinal-forms/ropinirole.html> (last accessed October 2019).

Item code: UK-IPN-6 Date of Preparation: October 2019.



Prescribing Information for Ipinnia[®] XL (ropinirole hydrochloride) prolonged-release tablets. See Summary of Product Characteristics (SPC) before prescribing.

Presentation: Available in a range of doses. Each prolonged-release tablet contains the following amounts of ropinirole (as hydrochloride): 2 mg, 3 mg, 4 mg, 6 mg or 8 mg. **Indication:** For the treatment of Parkinson's disease under the following conditions: initial treatment as monotherapy, in order to delay the introduction of levodopa; in combination with levodopa, over the course of the disease, when the effect of levodopa wears off or becomes inconsistent and fluctuations in the therapeutic effect occur ("end of dose" or "on-off" type fluctuations). **Dosage and Administration:** Swallowed whole, do not chew, crush or divide these tablets. Take at a similar time each day (with/without food) and maintain the patient on the lowest dose that achieves symptomatic control. For the initial titration, start with 2mg once daily for a week; if this is not tolerated, switch the patient to immediate-release ropinirole film-coated tablets. For patients that tolerate the initial dose, increase the dose to 4mg once daily and if required by a further 2mg once daily at weekly or longer intervals to a dose of 8mg once daily. A further gradual increase can be done to a maximum dose of 24mg once daily. See SPC for details on therapeutic regimen and switching from immediate-release ropinirole tablets to Ipinnia XL. **Dose interruption or discontinuation:** If treatment is interrupted for one day or more, re-initiation by dose titration should be considered. If it is necessary to discontinue treatment, this should be done gradually by reducing the daily dose over the period of one week. **Renal impairment:** No dosage adjustment is necessary in mild to moderate renal impairment (creatinine clearance 30 - 50 ml/min). In patients with end stage renal disease (on haemodialysis) dose adjustments are required. Lack of data in severe renal impairment (creatinine clearance less than 30 ml/min) without regular haemodialysis. **Hepatic impairment:** No data, therefore not recommended. **Elderly:** No dose adjustment required, however, dose should be individually titrated, with careful monitoring of patients. In patients aged 75 years and above, slower titration during treatment initiation may be considered. **Paediatric population:** Not recommended for use in children and adolescents below 18 years of age due to a lack of data. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Severe renal impairment (see above).

Hepatic impairment. Warnings and precautions: Due to the risk of hypotension, monitor blood pressure, particularly when initiating therapy in patients with severe cardiovascular disease. Patients with major psychiatric or psychotic disorders, or a history of these disorders, should not be treated with dopamine agonists unless the potential benefits outweigh the risks. **Impulse control disorders (ICD):** Monitor for the development of ICD which may be controlled using lower doses or tapered discontinuation. **Somnolence:** Sudden sleep onset without awareness or warning has been reported. See below for advice on driving. **Neuroleptic malignant syndrome (NMS):** Abrupt withdrawal of dopaminergic therapy can precipitate NMS; tapering treatment is important. Ipinnia XL tablets are designed to release medication over a 24hr period. If rapid gastrointestinal transit occurs, there may be risk of incomplete release of medication, and of medication residue being passed in the stool. **Dopamine agonist withdrawal syndrome:** Taper dose to discontinue treatment. Non-motor adverse effects may occur when tapering or discontinuing treatment, therefore patients should be warned before tapering and monitored regularly thereafter. In case of persistent symptoms, it may be necessary to increase the ropinirole dose temporarily. **Hallucinations:** Inform patients that this can occur as it is a known side effect. **Excipients:** Contains lactose monohydrate, therefore, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. The castor oil in the tablets may cause stomach upset and diarrhoea. **Interactions:** No dose adjustment required when used with levodopa or domperidone. Avoid concomitant use with neuroleptics and other centrally active dopamine antagonists (such as sulpiride or metoclopramide). In patients already receiving hormone replacement therapy (HRT), initiate ropinirole in the normal manner. Adjust dose if HRT is stopped or introduced during treatment with ropinirole. Ropinirole is principally metabolised by the cytochrome P450 isoenzyme CYP1A2: adjust the dose when co-administered with CYP1A2 inhibitors (e.g. ciprofloxacin, enoxacin, cimetidine or fluvoxamine). Adjust ropinirole dose if patients stop or start smoking during treatment because smoking induces CYP1A2. **Fertility, pregnancy and lactation: Fertility:** No data. **Pregnancy:** No data (do not use, unless the potential benefit to the patient outweighs the potential risk to the foetus). **Breast-feeding:** Do not use. Ropinirole may inhibit lactation. **Effects on ability to drive and use machines:** May cause

adverse effect. Patients with somnolence and/or sudden sleep episodes must not drive or engage in activities where impaired alertness may put themselves or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved. **Undesirable effects:** Adverse drug reactions reported in Parkinson's disease clinical trials with ropinirole prolonged-release tablets at doses up to 24 mg/day. **In monotherapy: very common (≥1/10):** somnolence, nausea; **common (≥1/100 to <1/10):** hallucinations, dizziness (including vertigo), sudden onset of sleep, constipation, peripheral oedema. **In adjunct therapy (to levodopa): very common (≥1/10):** Dyskinesia, in patients with advanced Parkinson's disease, dyskinesias can occur during the initial titration of ropinirole, in clinical trials it was shown that a reduction of the levodopa dose may ameliorate dyskinesia; **common (≥1/100 to <1/10):** hallucinations, somnolence, dizziness (including vertigo), sudden onset of sleep, postural hypotension, hypotension, nausea, constipation, peripheral oedema. See above for dopamine agonist withdrawal syndrome and impulse control disorders. **Refer to SPC for other side effects. Overdose:** The symptoms of ropinirole overdose are related to its dopaminergic activity. These symptoms may be alleviated by appropriate treatment with dopamine antagonists such as neuroleptics or metoclopramide. **Marketing Authorisation Number and Basic NHS Price:** All strengths are sold in packs of 28 prolonged-release tablets. Ipinnia XL 2 mg PL 01883/0326 - £5.64; Ipinnia XL 3 mg PL 01883/0327 - £8.46; Ipinnia XL 4 mg PL 01883/0328 - £11.29; Ipinnia XL 6 mg PL 01883/0329 - £15.32; Ipinnia XL 8 mg PL 01883/0330 - £18.95. **Marketing authorisation Holder:** Macarthy's Laboratories Ltd T/A Martindale Pharma, Bampton Road, Romford, RM3 8UG. **Legal Category:** POM. **Further information:** Martindale Pharma, Bampton Road, Romford, RM3 8UG. Tel: 01277 266 600. **Date of Preparation:** March 2019.

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

NOROVIRUS

BUG OFF

FLICKERING FIRES, COSY KNITWEAR AND FESTIVE MUSICAL FAVOURITES – THEY'RE JUST A FEW OF THE THEMES WHICH SPRING TO MIND AS WE WELCOME THE SEASONAL SHIFT. HOWEVER, FOR A LARGE NUMBER OF HEALTHCARE PROFESSIONALS DEALING WITH INFECTED PATIENTS, THIS TIME OF YEAR IS ALSO SYNONYMOUS WITH THE NOROVIRUS. HELP INDIVIDUALS WARD OFF THE RISK, AND FIND OUT MORE ABOUT ITS ORIGINS, AS LESLEY CARTER, AGE UK'S CLINICAL LEAD FOR PROFESSIONALS AND PRACTICE, EXPLORES THE WINTER VOMITING BUG.

As the winter months draw in, the norovirus – commonly known as the winter vomiting bug – becomes much more widespread.

Although more common during the colder months November-to-April, the norovirus can actually be caught at any time of the year. It's highly contagious and unpleasant and can affect anyone at any age. Those who are the most vulnerable when they catch the infection are older people, young children and those with low immune systems.

Unfortunately, a person can be infected with the norovirus several times because the virus is always changing.

SEEING THE SIGNS

It's important to be alert to the signs and symptoms. Because of its highly infectious nature, the norovirus spreads quickly through community environments with high concentrations of vulnerable people who are especially susceptible. This makes schools, care homes and hospitals especially high-risk and it causes logistical problems, when staff and patients alike are infected, placing a strain on the health and social care infrastructure.

If people have contracted the norovirus, it's important that they are advised not to visit hospitals as a visitor or a patient, their GP surgery, friends and relatives, or to visit people in care homes or other public spaces.

This is because of the ease of spread of the norovirus to other people, and potentially to people who already have poor health. Those infected should stay away from work or school for 48 hours after the last attack of vomiting or diarrhoea.

It's easy to become infected and this can happen via several routes, often by accidentally inhaling small airborne particles of the virus, through touching contaminated surfaces such as door handles, loo seats, or eating contaminated food.

The norovirus causes gastroenteritis and symptoms tend to come on suddenly, with little warning; nausea, persistent projectile vomiting and watery diarrhoea. Tummy cramps are also common and in some cases it can cause fever, a temperature over 38C together with flu-like aches, and pains in arms and legs. Although very unpleasant, the symptoms are short-lived for one or two days and should be out of the system within another one-to-two days. However, if symptoms carry on for more than three or four days, or there are concerns, call 111 for advice or contact the GP. They will be able to give advice about what to do and assess if further examination is needed.

NOROVIRUS

PREVENTION AND TREATMENT

There's no specific medicine to treat the norovirus and antibiotics won't work because it's a viral infection, not a bacterial one. The best thing is to manage the norovirus symptoms; stay hydrated, replacing the fluid lost through vomiting and diarrhoea.

Watch out for dehydration; it's the main risk of the norovirus infection, particularly if symptoms are severe. Children under five years and babies under six months old are at particularly high-risk. Dehydration in adults is more likely to be in older people and those with low immune systems. Dehydration has serious implications. Look out for the signs, initially, these include passing little very dark urine, a dry mouth, dry cracked lips, weakness, lethargy, irritability and confusion.

If a patient thinks that they or someone else is severely dehydrated, call the GP surgery or NHS 111.

Health and social care professionals must recognise that some people can be at a greater risk of the consequences of the norovirus. For example, an older person living alone may find it a challenge to manage sudden violent bouts of diarrhoea and vomiting, and there is the risk that this leaves them exhausted, weak, dehydrated and at risk of experiencing more serious results. People in this situation will need help and support from services.

Often hospitals and care homes when they have the norovirus pose a blanket ban on visitors to patients and residents. This can present a physical and emotional blow to people who have a diagnosis of dementia.

Without contact with their familiar family carers to reassure and support them, hospitals become hostile and frightening places and people with dementia will have poorer outcomes of care.

The national guidance on the prevention and control of infection in care homes from the Department of Health and the Public Health Agency does not advise that carers be banned entirely.

Providing carers are not symptomatic themselves – and if they have suffered from the norovirus they have been clear from symptoms for at least 48 hours – they are not an infection risk (and let's face it - when people suffer from the norovirus, they will probably be feeling so ill that they can't make it to the care home anyway – and these carers would not want to put their loved one at risk). Organisations should take a case-by-case approach.

TOP TIPS FOR PATIENTS ON LOOKING AFTER THEMSELVES AND OTHERS

- Keep your hands out of your mouth
- Wash your hands – the norovirus is spread by touch so make sure that you wash and dry your hands often and thoroughly with soap and warm water, especially after going to the toilet or before preparing food, is essential to prevent spreading the illness to others
- Don't rely on alcohol hand gels alone
- Don't spread it. Stay at home. Wait 48 hours after the last bout of sickness or diarrhoea
- Drink enough fluids. Sip water little and often. Check with the pharmacy about over-the-counter rehydration solutions which contain the right balance of sugars and salts for your body to encourage rehydration
- Check with a pharmacist about over-the-counter medicines, such as paracetamol, which could be useful to help reduce or relieve symptoms, such as fever or stomach pain
- Disinfect surfaces. Thoroughly clean hard surfaces, such as door handles, taps and kitchen surfaces, with detergents and disinfectant
- Keep toilets and toilet areas clean. Don't share towels
- Don't prepare food for other people until you're fully recovered – at least 48 hours after your symptoms have gone away

SCOTTISH MEDICINES CONSORTIUM

CROSSING THE LINE

As the national source of advice on the clinical and cost-effectiveness of all new medicines, the Scottish Medicines Consortium's guidance is heavily instilled in NHS Scotland's next steps. SPR takes a look at its latest selection for acceptance.

AUGUST 2019

MEDICINE

Inotersen (Tegsedi)

FOR THE TREATMENT OF...

Polyneuropathy (a form of nerve damage) in adults with hereditary transthyretin amyloidosis

Venetoclax (Venclyxto)

In combination with another cancer medicine, called rituximab, in patients who had received at least one previous treatment for chronic lymphocytic leukaemia (a type of blood cancer)

Buprenorphine (Buvidal)

Dependence on opioid (narcotic) drugs, such as heroin or morphine, in those patients not suitable for treatment with methadone

Tildrakizumab (Ilumetri)

Moderate-to-severe plaque psoriasis (a disease causing red, scaly patches on the skin) in adults

SEPTEMBER 2019

MEDICINE

Tisagenlecleucel (Kymriah)

FOR THE TREATMENT OF...

Adult patients with diffuse B cell lymphoma (a type of blood cancer) who have relapsed or not responded after two previous lines of treatment

Pembrolizumab (Keytruda)

Metastatic squamous non-small cell lung cancer, following consideration through the PACE process

Dacomitinib (Vizimpro)

Another form of non-small cell lung cancer

Dapagliflozin (Forxiga)

Type 1 diabetes in combination with insulin

Ospemifene (Senshio)

Vulvovaginal atrophy (dryness, irritation and soreness around the genital area, and causing painful sexual intercourse) in post-menopausal women

OCTOBER 2019

MEDICINE

Axicabtagene ciloleucel (Yescarta)

FOR THE TREATMENT OF...

Lymphoma (a type of blood cancer)

Pembrolizumab (Keytruda)

Metastatic non-squamous non-small cell lung cancer

Triptorelin acetate (Decapeptyl SR)

Early-stage breast cancer

Risankizumab (Skyrizi)

Moderate-to-severe plaque psoriasis

DRY EYE SYNDROME

SETTING THEIR SIGHTS HIGHER

Pharmacists are often at the helm of patient care – offering convenient access to a comprehensive range of services. However, too high a proportion of the population still remain unaware that the sector's scope extends to help with dry eye syndrome too. SPR chats to two pharmacists about their encounters with the condition, and gauge their advice for providing much-needed relief to distressed individuals.

**GILL HARRINGTON,
PHARMACY MANAGER,
RIGHT MEDICINE
PHARMACY IN KYLE OF
LOCHALSH**



HOW REGULARLY IS YOUR ADVICE SOUGHT ON EYECARE CONCERNS?

We are asked advice on eyecare most days of the week, and sometimes several times a day. Some of these queries can be answered by our trained counter assistants but some need input from the pharmacist.

HAS THIS INCIDENCE INCREASED OVER TIME? DO YOU THINK IT WILL CONTINUE TO CHANGE?

We have noticed an increase in these types of query in general and think that this trend can be attributed to several different factors:

- We are situated in an area where there is an ageing population, who may be more prone to getting dry eyes
- There is an increase in the number of people who work regularly using computer screens
- We are a rural region and have extremes of often cold, windy outdoor weather combined with increasingly air-conditioned or centrally-heated interiors
- The number of medications which can

contribute to dry eyes is rising, as is the number of patients who have complex pharmaceutical needs to manage their conditions

- A popular young optician has just opened a practice in town, making eyecare more high profile and because we have a good relationship with him, we are able to cross-refer patients between us
- With increased pressure on GP time, many patients are looking to self-medicate where appropriate

With these factors in mind I can only foresee our professional expertise being increasingly in-demand.

WHAT POTENTIAL DO PHARMACISTS REPRESENT IN HELPING PATIENTS WITH DRY EYE SYNDROME?

Pharmacies are open seven days a week with no appointment necessary so patients can readily access expert advice when they need it. We are able to discuss advantages and disadvantages of the various products and engage with patients to find the most appropriate product for each individual. Pharmacists are able to respond rapidly to more complex situations and advise referral / signpost for more specialist attention to either GPs or opticians.

WHAT LEADS TO THE CONDITION'S OCCURRENCE?

As previously mentioned, increasing age, computer work, environmental conditions, and medication can be contributing factors. Wearing contact lenses, smoking, alcohol consumption and some medical conditions can also be contributing factors.

CAN YOU DESCRIBE THE TREATMENT PROCESS FOR DRY EYE SYNDROME?

General advice for patients would be:

- Keep your eyes clean and don't rub them
- If you are using a computer screen for long periods, make sure that you take regular breaks and increase your fluid intake
- Use a humidifier or turn the heating down and avoid being in direct line of hot air heaters
- If you wear contact lenses make sure that you allow your eyes to rest by wearing glasses part of each day
- If you think that your medication is causing the problem, arrange to speak to your GP but don't stop taking the medication meanwhile

More specifically, we would have a conversation about the use of drops and ointments to lubricate the eye. Drops tend to be shorter-lasting and more appropriate during the day, while gels and ointments tend to cause some blurriness and may be more useful at night and in the morning.

An area which is expanding is the use of non-preservative-containing products since information is now being produced about the damage to the eye that can be caused by long-term contact with preservatives. Also, we would have a discussion about whether it was an occasional issue where single-dose unit forms might be appropriate or whether a larger dose container would be appropriate.

We would inform the patients about the importance of avoiding direct contact with the eye and eyelashes and being aware of the 28-day expiry information, and explain about the risks of infection if this is not complied with.

Where appropriate we would be able to supply the products on the Minor Ailment Scheme. Finally, we would invite them to return if they have further issues or if the condition does not improve within a few weeks they may want to speak to their GP.

DRY EYE SYNDROME

WHAT VALUE DOES THE AVAILABILITY OF OVER-THE-COUNTER DRY EYE RELIEF PROVIDE FOR THE PATIENT AND PHARMACIST ALIKE?

It gives easy access and informed advice to patients and enables the pharmacist to interact with individual patients directly, promoting good relationships which may enable patients to feel more confident in asking advice on other matters. It allows us to promote the Minor Ailments Scheme to patients as appropriate. Patients also benefit from our good relationships with other healthcare professionals.

WHAT ARE THE RISKS OF LATE TREATMENT?

If left untreated dry eye can cause more severe complications such as inflammation, damage to the surface of the cornea, ulcers and vision problems. It can also affect the quality of life for an individual which then may affect their mental health and wellbeing.

CALUM MURRAY,
PRIMARY CARE CLINICAL
PHARMACIST, EAST & MID
ROSS PHARMACY TEAM,
COUNTY COMMUNITY
HOSPITAL



HOW OFTEN DO PATIENTS WITH EYE PROBLEMS PRESENT TO PHARMACISTS? AND IN PARTICULAR, HOW RECURRENT ARE CASES OF DRY EYE SYNDROME?

It is a condition that community pharmacists deal with on a daily basis. It is a very common condition that can affect people of all ages, but it is more common in those over 50 years of age and is more common in females. It can be a chronic condition that remits and relapses so recurrent symptoms can be common. There is usually no cure but symptomatic management can be provided in community pharmacies.

WHAT SIGNS AND SYMPTOMS OF DRY EYE SYNDROME ARE EXHIBITED?

Signs and symptoms can vary from person-to-person but they are usually bilateral. Signs and symptoms include irritation or discomfort (often described as burning, stinging or a 'gritty' sensation), dryness, intermittent blurred vision, redness of eyelids or conjunctiva, itching, photosensitivity, mucous discharge, and ocular fatigue.

WHAT ARE THE MAIN CAUSES OF THE CONDITION?

Dry eye can be caused by a number of factors. These include, meibomian gland dysfunction, blepharitis, age-related lacrimal gland deficiency, low blink rate, vitamin A deficiency, malposition of the eyelids, environmental causes (high wind, allergens etc.), contact lenses, certain medication, ocular surgery, and underlying medical conditions.

WHAT BENEFITS DO PHARMACIES BOAST AS A SOURCE OF EYECARE ASSISTANCE?

Community pharmacies are ideally placed to help with dry eye syndrome for a number of reasons. They are accessible so patients do not have a delay in being seen, given advice, or a product to help. Most pharmacies stock a wide range of products to help with dry eyes. Pharmacists are well-equipped to give advice on common eye conditions such as dry eye syndrome.

ARE PATIENTS SUFFICIENTLY AWARE OF THE HELP WHICH IS AT HAND FOR EYECARE VIA PHARMACIES?

Pharmacy is becoming increasingly popular as

the first port-of-call, especially for a common condition such as dry eye syndrome.

HOW CAN THIS BE IMPROVED?

There is still work to be done to promote the Pharmacy First model. The more patients that have a positive experience in their community pharmacy, the more likely they are to tell their friends and relatives, which will encourage more patients to seek help from a community pharmacy before going to their GP or optometrist.

WHAT STEPS DO YOU RECOMMEND FOR SELF-MANAGEMENT OF DRY EYE SYNDROME?

There are a number of self-management techniques that can help. Using a warm compress, lid hygiene and massage are particularly helpful if the cause of the dry eye is blepharitis or meibomian gland dysfunction.

If contact lenses are the cause, wear them for shorter periods or not at all during a bout of dry eye. If environmental factors are the cause, patients should spend less time looking at computer or phone screens, avoid air-conditioned environments, increase relative humidity, avoid alcohol and exposure to cigarette smoke.

WHAT TREATMENT PATHWAYS ARE PURSUED?

The first line of treatment is tear supplements, which there are a large amount of products available over-the-counter. Drops are helpful for daytime symptoms and ointments or gels should be reserved for use before bed because they can cause blurred vision but are longer-lasting to prevent the eye drying out overnight. There are also preservative-free formulations available if a patient is intolerant to the preservative in tear supplements.

WHEN IS FURTHER TREATMENT REQUIRED FROM A GP OR OPHTHALMOLOGIST?

Urgent referral to ophthalmology is required if the patient is suspected of having a serious eye condition such as acute glaucoma, keratitis, iritis or corneal ulcer. Children should be referred urgently if they have any corneal change. Routine referral should occur if the diagnosis is unclear, they are suspected of having an underlying condition, if they have not responded to treatment after 12 weeks, or if they have an abnormal lid anatomy or function.

Clinitas[®] dry eye soothing solutions



Dry eye is a common condition that can easily be treated and managed in community pharmacy. Trust the Clinitas[®] range of drops to quickly and effectively relieve the sensations of dry, irritated and gritty eyes. Dry eye is a growing market, increasing by 6.5% a year. This is a significant opportunity for pharmacy, as the NHS continues to advise health boards not to routinely prescribe for dry eye as the condition is appropriate for self-care.



MULTI dose

single DAY vial

NEW

Clinitas[®] 0.2% and Clinitas[®] Multi 0.2%

- 0.2% sodium hyaluronate
- Extends established range
- Preservative free and contact lens friendly
- 30 day vials and multidose options



MULTI dose



single DAY vial

Clinitas Hydrate[®]

- 0.2% Carbomer
- Easy to use liquid gel drop
- Ideal overnight / first thing



liquid GEL

Clinitas Soothe[®] and Soothe[®] Multi

- 0.4% sodium hyaluronate
- Highest strength sodium hyaluronate available
- Preservative free and contact lens friendly
- Multi-dose and unit-dose offering to suit patient needs

Clinitas[®] Eye Compress

- Heat in the microwave or the oven
- Reusable – can be used over 365 times
- Removable and washable cover for hygiene
- Adjustable comfort strap



The range to help your business and your dry eye patients
AVAILABLE FROM ALL WHOLESALERS

KIDNEY DISEASE

BREAKING THE ICE

Cold weather and seasonal bugs can aggravate existing health problems, making people with long-term conditions, such as kidney disease, more vulnerable to illnesses. Even if people are managing their long-term condition well, and leading otherwise healthy lives, it's important that they continue to protect themselves. Kidney Care UK advise on the information which patients should be equipped with in order to keep well throughout winter.



Chronic kidney disease (CKD) affects around three million people in the UK. Most of these people will not go on to develop stage 5 CKD, requiring renal replacement therapy with dialysis or a transplant. However, people at all stages of CKD need the support of their local pharmacist to make sure that they are able to live well with their kidney disease.

Kidney Care UK are the UK's leading kidney patient support charity. They have put together five top tips to pass on to kidney patients this winter:

DON'T WAIT

Patients are advised to seek early advice to avoid exacerbations of coughs and colds. So, their local pharmacist is likely to be one of their first ports-of-call, especially if they have to wait for a GP appointment.

PLAN AHEAD

Kidney patients need to maintain their stocks of medication, especially over the Christmas holiday or when bad weather is forecast when pharmacies or GP surgeries are likely to be closed or difficult to access.

GET THE FLU JAB

Dialysis and transplant patients of all ages are at-risk groups eligible for flu vaccination from their pharmacist or GP. Since both the trivalent and quadrivalent vaccines are inactivated, they can safely be given to kidney patients, including immunosuppressed transplant recipients. Specialist advice should be sought before administering the live attenuated flu vaccine to children with kidney disease.

LOOK AFTER YOURSELF

To reduce the risk of colds, kidney patients are advised to rest, avoid dehydration, and optimise nutrition. Some over-the-counter cold remedies that may affect kidney function (e.g. those containing a non-steroidal anti-inflammatory drug) are contraindicated in CKD.

KEEP WARM

People with kidney disease often feel the cold and are advised to heat their home to at least 18c in winter.

People with CKD are at higher risk of acute kidney injury. This rapid deterioration in kidney function is linked to infection and dehydration, and any patient reporting frequent episodes of vomiting and diarrhoea is at risk. As a general rule, if a patient has had a fever, has not been able to keep fluids down for 24-to-28 hours, and has not

been passing as much urine as usual, they need an urgent blood test to check their kidney function.

While some kidney patients can be managed in the community by their GP (in consultation where applicable with the specialist renal team), others will need hospital admission for rehydration and monitoring of kidney function. It's also important to ensure that any prescribed medications, which may have been stopped under 'sick day rules', are restarted when kidney function has returned to baseline.

Eating well is important for people with kidney disease. However, dialysis patients have to cope with a side range of dietary restrictions (e.g. avoiding foods high in potassium or phosphorus). Kidney Care UK want to help bring enjoyment back into food, and pharmacists can now signpost patients to the Kidney Kitchen – a website featuring recipes and video demonstrations to help highlight all the foods patients can eat, rather than focusing on all those they can't.

Eating healthy, nutritious food, keeping well, and keeping warm are all important for people with kidney failure, and are all things that they can do for themselves at home. But that's not the only thing that happens at home. Of the 60,000 people in the UK with kidney failure, more than 1,000 dialyse at home. They therefore rely on their access to both electricity and water supply, which is why Kidney Care UK have been working with Thames Water and UK Power Networks to encourage kidney patients to register with the Priority Services Register.

By being on the register patients are prioritised and given extra help in an unplanned power cut, and they will be given advance notice of disruption should there be any planned works in their area. It is hoped that this pilot will pave the way towards the ultimate aim of addressing the need for a single central Priority Services Register used by all customers and utility providers.

For more information about Kidney Care UK, visit www.kidneycareuk.org. The Kidney Kitchen can be found at www.kidneykitchen.org.

NICE guidance on acute kidney injury is at www.nice.org.uk/guidance/cg169/chapter/1-Recommendations#managing-acute-kidney-injury.

For information on the Priority Services Register, visit www.kidneycareuk.org/get-support/priority-services-register-psr.





SETTING THE SCENE

Having firmly embedded itself in the fabric of Scotland's tradition, we have been counting the days until our annual opportunity to express gratitude to the sterling members of our pharmacy service. And that time is finally upon us – with the 2019 Scottish Pharmacy Awards.

The 2019 Scottish Pharmacy Awards ceremony is driving the heart of the sector together on 6th November; taking place at the Crowne Plaza Hotel, Glasgow, and navigated by esteemed host, Shereen Nanjiani.

The evening – punctuated by a delightful dinner and networking opportunities – will bestow honour on those who not only demonstrate excellent character, but who have cultivated much-needed change in the industry during the last 12 months and beyond.

The finalists in each of the 10 categories have been selected following a hard-fought application process, and the winners will be revealed on the night; culminating with the announcement of this year's Lifetime Achievement Award recipient.

The evening's nominated charity is the Scottish Association for Mental Health (SAMH). Around since 1923, SAMH is Scotland's national mental health charity which works in over 60 communities with adults and young people, providing mental health social care support, and services in primary care, schools and further education, among others. These services – together with the national programme work in See Me, respectme, suicide prevention and active living – inform SAMH's policy and campaign work to influence positive social change.

This year's categories are:

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

Good luck to all of our finalists! Learn about their stories – and underlying motivation – over the following pages.

DELIVERY OF PHARMACEUTICAL CARE

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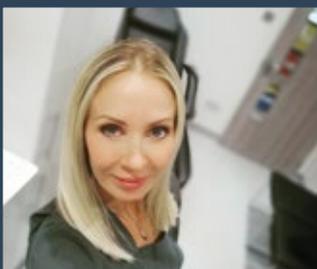
The Community Pharmacy Pharmacotherapy Service NHS Ayrshire & Arran

The initiative established an opportunity for a collaborative approach to improve patient care and outcomes, as well as prescribing efficiencies, in line with the current

direction of travel of healthcare in Scotland.

From the outset the ambition was to assess the possibility of transferring specific elements of the pharmacotherapy service to community pharmacy, with a view to – among other objectives – redesign the pharmacy work flow to enable GPCPs and CPs to spend more time with their patients, and increase the clinical role of community pharmacists by identifying pharmacotherapy activities that could be delivered in their pharmacy.

Four elements of the pharmacotherapy service were subsequently identified as appropriate for a community pharmacist to manage in their pharmacy: prescription requests; medication queries; medication reviews (high-risk medicines, polypharmacy); and clinical treatment reviews (asthma).



Sinead Collins and Team Holburn Pharmacy, Aberdeen

Striving to wield the highest quality assistance for the public, the pharmacy offers several services for patients with substance misuse issues. These include the provision

of consume-on-the-premises methadone / subutex / suboxone, needle exchange facilities, naloxone provision and training, safer injection technique counselling, and confidential advice on blood-borne diseases.

The team attended a substance misuse seminar earlier this year; sparking the ability to highlight patients who were at risk of overdose due to polydrug use; those who were becoming more erratic in their drug use and behaviour; and those who were injecting in an unsafe manner who would benefit from advice and counselling.



The Care at Home Pharmacy Technician Service NHS Ayrshire & Arran

The Care at Home Pharmacy (CAP) Technician Service in East and South Ayrshire represents an excellent demonstration of

partnership working to deliver the highest level of safe, patient-centred care.

The pharmacy technician works with elderly and / or vulnerable residents within the Health & Social Care Partnership area who have been identified by a health or social care professional as requiring help with a medication-related problem. This is particularly pertinent to those patients recently discharged from hospital, but also regards those living at home and experiencing difficulty with their medicines. The CAP technician visits patients in their own homes to review concordance and compliance with medicines, with onward referral to other services where required.



David Morrison and Team Health Centre Pharmacy, HMP Perth

Following both the reclassification of gabapentanoids to schedule 3 controlled drugs and the increasing number of drug-related deaths in Scotland – and specifically Tayside – a novel way to undertake polypharmacy reviews specifically aimed at these medications was designed.

Showcasing the team's innovative spirit, patients thus began to attend for review either with David, as an independent prescribing pharmacist, or a GP. The in-depth dialogue centred on the drug-related death figures, in which the patient's views were sought. This allowed for a very open and honest channel of communication to be opened between the clinician and the patient.

Patients who were initially resistant to the reviews were now more willing to actively participate; equipped with the relevant knowledge and information required to help bolster their safety.



Rebecca Allan and Team Lloyds Pharmacy, Tannahill Centre, Paisley

Over the past year Rebecca has been involved in running a pilot drop-in diabetes clinic within Lloyds Pharmacy in Ferguslie Park in Paisley, for patients who have a type 2 diabetes diagnosis.

The drop-in clinic aims to review patients' medication management, as well as facilitate education on their condition and how they can actively manage this through nutrition and exercise.

Patients can attend just once or on multiple occasions to obtain the information and guidance in question, following which they can be signposted to a multitude of other services within the area that can help them effectively self-care. Examples of this incorporate podiatry services and weekly nutrition and cooking classes.

STUDENT LEADERSHIP

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The Pharmacists' Defence
Association



Erin Gilmour
Robert Gordon University

As president of the student-led Aberdeen Interprofessional Education Society, Erin is heavily involved in chairing the organisation, as well as promoting its offerings to students, and organising learning events, social activities and committee meetings throughout the year.

Since taking up the position, Erin has been armed with the resolve to grow the society, achieve broader representation, and attain greater support from lecturers.

Pursuing platforms for greater engagement, Erin updated all of the society's social media outlets and agreed a standard format with the committee as to how information would appear on their website, Twitter and Facebook pages. The interest subsequently expressed has been notable as at the end of the year the society finished with their highest number of members ever at 256; being the largest society at RGU.



Sagarika Ojha
University of Strathclyde

Throughout her time at university Sagarika has effectively utilised the information available to make evidence-based decisions while interacting with her fellow classmates in order to present her vision of the future of pharmacy. A key example of this was during her BPSA representatives training

which provided a platform for the attendees to learn how to further improve themselves as BPSA representatives, and to conduct discussions centred on real-world data and evidence from past BPSA and the Royal Pharmaceutical Society records.

Sagarika has additionally participated in long-term mentoring in the form of the Outward-Bound Leadership Course; enthusiastically fulfilling a series of difficult academic and physical activities.



Conor Thorne
Robert Gordon University

Displaying the industriousness and compassion to not only seek ways to address his own gaps in knowledge, but to help his peers too, Conor liaised with

his lecturer and fellow students to set up a study group. As a result of his efforts, each Wednesday during the semester, students who needed extra support would meet and discuss a topic which they deemed difficult.

Eager to continue paving a positive path for students, Conor entered the MPharm student elections and was successfully selected as an academic representative on the Robert Gordon University (RGU) Pharmacy Committee – a position which he held for two sessions after being re-elected. Conor is also currently in his second year as the publications officer for the RGU Pharmacy Law and Ethics Group; creating the group's newsletter every semester.



Kelsey Drummond
Robert Gordon University

Kelsey's leadership skills have flourished as a result of her role as Northern area co-ordinator of the British Pharmaceutical Students Association (BPSA) – a post which entails her working with a team of 17 other executive members, and co-ordinating a group of representatives from Robert Gordon, Strathclyde,

Sunderland and Newcastle Universities.

Kelsey is currently organising a conference at Newcastle University on the topic of 'Vulnerable Groups', which aims to support pharmacy students throughout their studies and add a greater depth to their knowledge.

Keen to represent the views of the student members and make their voices heard, Kelsey attended the Scottish Pharmacy Board in July and has been engaging with the Royal Pharmaceutical Society in Scotland to identify ways in which to implement the desired changes.



Vivien Yu
Robert Gordon University

As Vivien has developed throughout her course, she has been introduced to the limitless opportunities that having a Pharmacy degree can offer, and motivated to showcase these prospects to her fellow peers at every chance available. By involving and immersing herself in various societies, she has been impactful in enhancing the morale of

other students by sharing and encouraging their involvement too.

Through her role as the preliminary BPSA representative this year, Vivien has helped to inspire others to also apply by detailing her own responsibilities and contributions, answering any questions, and simultaneously easing their concerns and boosting their confidence. This ultimately benefitted the BPSA and the Northern area co-ordinator as they ended up over-subscribed with applications.

INNOVATIVE USE OF TECHNOLOGY IN COMMUNITY PHARMACY

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Cegedim Rx



Bethany Potter and Team
Dickies Pharmacy,
Summerhill,
Aberdeen

Due to the ageing population and an increase in co-morbidities etc., home delivery of medication

has emerged as a service which is increasingly requested. Seeking to provide the highest quality of care for patients and fulfill their needs, all of the branches now offer a free home delivery service, and the team have trialed numerous ways to manage this service in an efficient and safe manner.

As a result of the high number of home delivery patients, and with new GDPR laws coming in stating that consent is now required for delivery, an opportunity was identified for seeking exciting new ways of managing their deliveries. This resulted in the implementation of Pro Delivery Manager, which after being trialed in one branch – and reaping tremendous results – has been rolled out across the other sites too.

The positive impact which the technology has had on the different corners of the business has been far-reaching. For example, deliveries are now more efficient; reducing paper records and making a clearer audit trail of deliveries; and the workload of staff has significantly decreased, as adding in deliveries to the system is easy and saves large amounts of time. The safety of the process has vastly improved, too, in that consent is clearly stated on each patient's record – lessening incidents of data breaches.



Bernadette Colford and Team
Cadham Pharmacy Health Centre,
Glenrothes

Technology is at the heart of the sector, and despite the challenges which this might present, Bernadette and the team have been persistent and enthusiastic in their approach to embracing the new era of digital pharmacy.

Testament to the pharmacy's success has been the staff who have worked hard to learn new machines, support the introduction of huge screens, develop private travel and aesthetics services, and implement innovative NHS offerings that meant going back to university for the pharmacists.

The pharmacy introduced a fundamental piece of technology earlier this year with the aim of enhancing accessibility for patients – an NHS-approved app, HEALTHERA. Launched in August after a three-month training and planning phase, the initiative aligns with Bernadette's dream for the pharmacy to truly become digital and meet the changing expectations of consumers.

The pharmacy's first robot was installed four years ago and provided an outstanding example to Bernadette as to how technology could help her to protect, nurture and grow the family business. The team introduced the pill pouch-maker, and evidenced the benefit which this brought to the community at the NHS hearing. Currently, the team are working towards improving their social media employment and creating a better website, as well as setting up an online shop, and offering a 24 / 7 click and collect service.



Noel Wicks and Team
Right Medicine Pharmacy Group

The introduction of the team's project is indicative of their determination to not only advance patient safety and support families caring for loved ones, but to also ensure the appropriate deployment of

NHS and council resources, all the while keeping people healthier and independent in their homes for longer.

The new form of technology introduced is an electronic MDS solution that prompts patients to take medicines and incorporates GSM technology in order to give SMS alert messages in the event of any forms of non-compliance, as well as monitor and record medicines adherence. The system is called the YOURmeds Alert Medpack and the group are Scotland's first and only provider.

The main objective of this innovation was to encourage the use of device technology to support an existing delivery of care package around medicines management for people within an independent living setting. This included improving medicines adherence, safety, and maintaining independence for service-users through a tailored and person-specific approach. A further aim focused on producing a more streamlined service for both the team members of the service provider, the service-user, and the pharmacy staff.

HOSPITAL PHARMACY TEAM OF THE YEAR

Sponsored by Ethypharm UK



The Care at Home Pharmacy Technician Service
NHS Ayrshire & Arran

The Care at Home Pharmacy (CAP) Technician Service in East and South Ayrshire has propelled partnership working

into the spotlight; indicating how it can deliver the best level of care across transitions.

The service initially focussed on elderly people discharged from hospital with a care package, but now receives referrals from the multidisciplinary team involved in adult care: social work, care managers, homecare managers, district nurses, occupational therapists, enablement teams, and third sector organisations.

The CAP technicians receive a list of all patients discharged from hospital which they review, and then contact the patient or carer to assess the need for pharmaceutical input. Having access to both health and social care IT systems, the team can determine what level of care is currently provided to the patient and ascertain whether this may need changed.



The Lauriston and Chalmers Pharmacy Team
NHS Lothian

The specialist pharmacy outpatient team have stood out for their consistent high-quality delivery of 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.

The team support four dermatology and four HIV clinical sessions per week; up to 35 patients may require dispensing +/- clinical pharmacist input (e.g. patient counselling or medication review) during each session. They also work closely with the other HIV multidisciplinary team based at the Regional Infectious Diseases Unit at WGH and remotely support the dermatology service based at St John's, Roodlands and WGH.

The team's day-to-day contribution to NHS Lothian is exemplary, as 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 New Craigs Pharmacy Team
NHS Highland

The specialist mental health pharmacy team are based within the in-patient service, but as the number of hospital beds has gradually reduced over the years, their workload has evolved from being entirely in-patient-focussed to also providing clinical pharmacy input to out-patient care on an ad-hoc basis.

As an increasingly valuable asset to the sector, the team assure that quality patient-centred pharmaceutical care is delivered to patients with mental health conditions through safe, evidence-based and cost-effective use of medicines. Demonstrative of this, the team implemented a 12-month pilot in two general practices in remote and rural Scotland, with patients with a diagnosis of depression and / or anxiety referred by general practitioners to specialist mental health pharmacist independent prescribers from their team for review and any necessary follow-up to ensure the safe and effective use of medication.

The project's results provided evidence that specialist mental health pharmacist independent prescribers delivered quality care to patients with diagnoses of moderate-to-severe depression and / or anxiety.



The Rheumatology Pharmacy Team
NHS Greater Glasgow & Clyde

Equipped with a core understanding of the rheumatic disease states, along with the complexities of drug therapies and adverse effects, the team are ideally placed to contribute effectively to patient management and wellbeing.

The team are comprised of three specialist pharmacists, each based in the three different sectors within NHS Greater Glasgow & Clyde, who meet on a regular basis to discuss relevant issues, tackle service problems, and plan audit work / projects. Each individual derives from an extensive background in the hospital sector and, specifically, clinical pharmacy. Completing post-graduate training and qualifications, including the clinical diploma, MSc in Clinical Pharmacy, and most recently, independent prescribing, has enabled them to deliver services at the top of their license.

In their advanced practitioner roles, the team run pharmacist-led rheumatology clinics with the overall aim to provide optimum pharmaceutical care to patients. Objectives included switching to biosimilars, biologic dose tapering, and reducing consultant waiting times.

INNOVATIONS IN CLINICAL DEVELOPMENT IN CARDIOLOGY PHARMACY

Sponsored by Daiichi-Sankyo



Clodagh Clarke
William Street Clinic, NHS
Greater Glasgow & Clyde

The primary aim of the service development was to measure self-reported cardiology training needs of general practice clinical pharmacists (GPCPs) and provide information to support the design of cardiology-specific elements of a local education

and training programme to support the evolving role.

Initially, the project evaluated the cardiology learning needs of GPCPs and results were then used to develop a programme of learning to support unmet training needs. Face-to-face training sessions were delivered and electronic resources have been produced, containing information about less well-understood cardiology medication. Existing supporting materials, references, guidelines, and links to external training courses have also been collated and incorporated into staff training to address unmet learning needs around cardiac conditions and clinical skills examination.

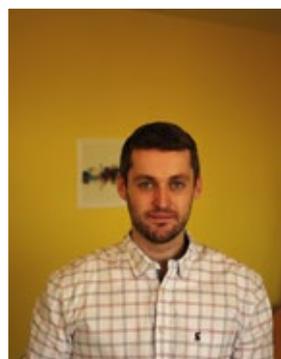


Kenneth Halliday
Crieff Blue Medical Practice,
NHS Tayside

The driver for the heart failure clinic arose from a collaborative approach with the practice GP lead for cardiovascular patients in which it was identified that patients with a diagnosis of heart failure weren't being treated as per evidence-based guidelines.

Additional inspiration stemmed from Kenneth's long-time interest in cardiovascular treatment as a result of a previous pharmacy post at the London Chest Hospital, and the completion of a diploma in Chronic Heart Failure at Glasgow Caledonian University.

The cohort of patients chosen were patients with heart failure associated with left ventricular systolic dysfunction due to the fact that an audit of medical treatment revealed that this group of patients weren't being managed optimally, and that improvements could be made in their medical therapeutic treatment.



Anthony McDavitt and Team
Gilbert Bain Hospital, NHS
Shetland

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 heterogeneous case mix.

Oral anticoagulants (OAC) and the planning required are a complex clinical area for the team to manage effectively. The POA nurses have to ensure that the patient has the right plan for them based on their risk of bleeding and VTE.

This initiative utilised significant event analysis to review previous issues OACs presented POAC staff with. The 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.



Rachel Bruce
Crail Medical Practice, NHS
Greater Glasgow & Clyde

The roots of the project were forged following the practice's awareness that their patient journey for management of hypertension was sub-optimal, with patients being passed between the healthcare assistant, practice nurse, and a variety of GPs for hypertension management – particularly for those

newly-diagnosed, and those with uncontrolled hypertension. To secure a more seamless care pathway, it was identified by the pharmacist and the practice staff that setting up a pharmacist-led hypertension clinic would streamline the patient journey, improve continuity of care, and result in better patient care and clinical outcomes.

The weekly pharmacist hypertension clinic was subsequently established; providing nine or 10 appointments per week.



Lynne Davidson and Team
Pharmacy Department, Aberdeen
Royal Infirmary, NHS Grampian

Sparked by her attendance at a national heart failure conference, Lynne became aware of the 'teach and treat' programme and contacted the project lead, Paul Forsyth, for further details – keen to establish a local service in Grampian.

The post-MI LVSD patient cohort was chosen, as this was already an evidence-based intervention which had been successfully attempted in other areas of Scotland. This was also a group who currently don't have any defined local follow-up contact with secondary care / specialist services.

Patients were invited to attend the pharmacist clinic, which was stand-alone, where they would undergo medication review, including review of haematology and biochemistry results, clinical examination, and recent symptom history taking as part of the consultation.

INNOVATIONS IN PRESCRIBING, QUALITY AND EFFICIENCY IN SCOTLAND

Sponsored by
Napp Pharmaceuticals Limited



The Community Pharmacy Pharmacotherapy Service Team
NHS Ayrshire & Arran

General practices clinical pharmacists have been experiencing an increasing workload – confronted with traditional prescribing efficiency work,

coupled with the demand of the pharmacotherapy service, part of the new General Medical Services Contract. This project thus centred on a test of change to evaluate whether specific elements of the pharmacotherapy service can be delivered through community pharmacy.

Positive outcomes were achieved, in which the clinical role of the community pharmacist was optimised, and overall patient care was enhanced. Additionally, there was an increased awareness within this patient group of the role of the community pharmacist in medicines management and supporting patients to manage stable long-term conditions.



Keith Maclure and Kirsty Lamb
Borders General Hospital,
NHS Borders

The aim of the initiative was to create a prescribing policy that could be used by all practices in NHS Borders to ensure a unified model of working between different practices. The policy specifies the procedures associated with all prescribing tasks and is designed to

aid members of the prescribing support team in working within a variety of practices.

An initial step was to obtain the prescribing policies from the NHS Borders GP practices and extract the most common / appropriate aspects from the individual policies to create a Unified Prescribing Policy. It was subsequently sent to stakeholders for review and feedback, in addition to other members of the team, before being taken to the local Pharmacotherapy Oversight Group and Practice Managers Meeting.



Amy Robinson and the Wigtownshire Prescribing Support Team
NHS Dumfries & Galloway

The roll-out of the pharmacotherapy service presented the team with an opportunity to seek new ways of delivering extended services.

In particular, a pharmacy hub emerged as a beneficial platform; enabling the team's offerings to derive from a central point using their varied skillmix, as well as providing peer support and training; cutting down travelling; and maximising the number of hours spent on supplying their specialist services.

The initiative has paved the way for a multitude of advantages; notably, facilitating the chance for a GPCP pharmacist, a trained and a trainee technician, and two prescribing support officers to work together in one room, to flow work across the team, and to provide peer support in a supervised training environment.



The Health and Social Care Moray Pharmacy Team
NHS Grampian

The new GP contract prompted the team to seize an initiative in making improvements in GP practice pharmacy in the areas of safe, efficient, cost-effective and appropriate prescribing. Together with the primary care improvement plan and integrating with the Grampian Primary Care Group, they recruited and developed a pharmacotherapy team alongside the existing practice pharmacist and technician input.

In accordance with their collaborative approach, existing SOPs were shared and guidelines were developed in order to promote consistency in working practice across Moray.

Further boosting the project's morale, new pharmacists and pharmacy technicians were employed, and regular meetings were conducted with the aim of encouraging colleagues to voice their ideas.



The East Renfrewshire Medication Support Service Team
NHS Greater Glasgow & Clyde

The Medication Support Service in East Renfrewshire is a pharmacy technician-led service which provides comprehensive medicines support for adult patient residents in the community. This includes medicines reconciliation for patients who have recently come out of hospital, or who have been referred to the service. Referrals may be made by any member of the health and social care team, or patients may self-refer.

The team play a key role in cultivating excellent patient care by providing expert medication advice to not only the individual, but their family / carers too, supporting them to manage their medicines independently at home.

The service is fully integrated within the HSCP and the technicians work closely with others involved with individual patients, including GPs and community nurses.

MANAGEMENT OF SUBSTANCE MISUSE IN THE COMMUNITY

Sponsored by Ethypharm UK



Bethany Potter
Dickies Pharmacy,
Summerhill,
Aberdeen

Around 80 patients on opiate substitution therapy attend the pharmacy either daily or

numerous times a week, and throughout the last few years the team have worked incredibly hard to get to know these patients so that they can create a safe and non-judgmental environment to help support them through their recovery. This has resulted in excellent relationships being forged between the patients and the staff and pharmacist, which has thus led to the further development of services. The strides undertaken by the pharmacy for the benefit of the community include naloxone supply and training and hepatitis C testing and treating.

Demonstrative of their multidisciplinary nature, too, the team work successfully with the local substance misuse clinic and CPN.

Mark Grehan
Rowlands Pharmacy,
Springburn Way,
Glasgow



Since moving to Rowlands in 2016, Mark and the team have developed one of the most wide-ranging substance misuse support service programmes in Greater Glasgow & Clyde. They service roughly 90 ORT patients through their methameasure

dispensing tool, and provide clean injecting equipment, in addition to the appropriate advice to substance misuse patients.

Two especially impactful local initiatives which Mark has 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).



Clair Smith
The Community Prescribing
Team, NHS Lanarkshire

Working as a locum sessional pharmacist within the CPS in Lanarkshire, Clair assists patients in a variety of settings, such as community pharmacy, a social work building, and several primary and secondary care locations.

With a caseload comprising over 70 patients, Clair is unfaltering in her commitment to their pharmaceutical care, and in particular, her provision of support and prescriptions relating to their substance misuse. As such, her expertise includes opiate substitution therapy, overdose awareness training, naloxone provision, BBV testing and motivational interventions. Clair also refers to other NHS services and signposts to third sector agencies.

As part of Clair's CPS role, she has recently undertaken a new clinic within two GP practices.



Elizabeth Marr and Clair
Smith
NHS Lanarkshire

Working with two GP practices, the team's objective has been to identify patients who are either on above recommended doses of opiate painkillers or over-

using their prescribed opiates, following which assistance would be supplied by reducing their dose to the minimum required. Additionally, for people whose original illness has recovered, the painkiller was to be discontinued altogether.

A variety of methods have been adopted in order to develop the programme among the staff, such as conducting meetings to brainstorm; reading other trials around the same patient group; and holding a training day for prescribing support pharmacists.

The impact of their work on the wider healthcare team has been exceptional, and the surgeries involved have now been able to implement good prescribing practice for opiates.



Seonaid Campbell
Rowlands Pharmacy,
Coatbridge

Seonaid's enthusiasm for this field has translated to her work as an independent prescriber within the Lanarkshire Addiction and Recovery Team, in which she has garnered a unique insight into the pharmaceutical care of this vulnerable group.

As a result of being in a key position to offer an enhanced level of service to these patients, Seonaid has led her team to adopt a holistic approach to substance misuse patients – looking at patients as individuals, rather than as a collective. She also deems it crucial to remain up-to-date with regulations, guidelines and training, and to host regular team meetings where new issues are discussed.

Consistent contact with the substance misuse team in the hospital is additionally maintained if Seonaid is aware that one of her patients has been admitted to ensure that there's no gap in treatment.

COMMUNITY PHARMACY PRACTICE OF THE YEAR

Sponsored by
Kent Pharmaceuticals



Jane Rorison and Team
Ogg and Company Pharmacy, Ayr

Established in 1836, the pharmacy is one of the oldest businesses in Ayr, and was purchased by Lime Tree Healthcare six-and-a-half years ago, with Jane adopting the role of manager since the acquisition.

The pharmacy had not experienced any significant investment since the 1970s, however, in 2014, a year after acquiring it, a mammoth enhancement was carried out and the setting was entirely refitted.

One of the key priorities for change included modernising the retail sales area, yet choosing a style which was in sympathy with the heritage of the business and its location in Newmarket Street, one of the oldest streets in Ayr. The work also included doubling the size of the dispensary and propelling it further forward in the layout of the shop. This had the simultaneous effect – and benefit – of moving the location of the pharmacist and the dispensary staff closer to the front shop counter and to the patients. A modern consultation room was also added and is used on a daily basis for clinics and patient consultations.

In the last 12 months a common clinical conditions clinic has been initiated which has advanced the pharmacy's provision of patient care by covering a variety of conditions that Jane has been trained to assess, diagnose and treat. Individuals with sore throats, chest infections, ear problems and a variety of skin issues are examples of those who present regularly to the clinic, as well as patients who can't be treated via the Pharmacy First service.



Bernadette Colford and Team
Cadham Pharmacy Health Centre, Glenrothes

Underscored by a commitment to encompassing as many elements of high-quality

patient care as possible, the pharmacy's array of services continue to go from strength-to-strength. The team's openness to innovation has particularly contributed to their success, in which Bernadette was approached by a pharmacist who thought that she might be interested in a 24 / 7 collection robot. The pharmacy now has two machines installed due to its soaring popularity across the community and the merits which it brings, not just for patients, but for the staff too, by way of adding functionality and saving time collecting repeat packages already assembled and ready to collect.

The introduction of an asthma clinic is in line with Bernadette and the team's aim to see whether a pharmacist utilising all of their expert knowledge of medicines – combined with motivational consultation skills and assessment skills – could support people to change their approach to their asthma management. In the path to its implementation, the workforce were up-skilled to deliver care at the top of their skillset, while it was determined that included in every consultation would be a detailed history and assessment, and an independent pharmacist practitioner would treat in acute and long-term disease management.



The Well Pharmacy Team
High Street, Alloa

A strategic review of the operational effectiveness of the entire Well Pharmacy estate is conducted annually – and with the Alloa store being identified as a

priority, these plans for improvement came to fruition.

The whole project required input from a variety of stakeholders – from the branch staff to the regional and divisional management teams and the various suppliers involved with the refit itself – and the results have been impressive. The dispensary prior to the refit was an 'old style' one raised up from the rest of the shop floor, however this was subsequently levelled with the objective of bolstering both the access and visibility of the pharmacist to patients. Additionally, a previously large retail space was reduced to provide a greater area for the dispensary, and clever design has more than doubled the floor space in the dispensary without halving the retail area.

A small consultation room has been replaced with a more spacious and fully DDA compliant one, including a hatch where patients can access the recently-installed Methameasure system, which has freed up more time for the team, and also allowed the pharmacy to meet the ever-increasing patient safety demands.

Following the successful completion of this large refit project the working environment for the staff has significantly improved and as a result of the modern appearance of the pharmacy and happier team, the patient experience has also been massively enhanced.

RESPIRATORY PROJECT OF THE YEAR

Sponsored by
Teva UK Respiratory



Cian Lombard
Willis Pharmacy, Troon

Willis Pharmacy is a family-run pharmacy, providing patients with support, advice and medication to optimise health and wellbeing. The open plan pharmacy is completely accessible and there is a consultation room where patients can talk privately and confidentially about any healthcare matter.

In order to achieve improved patient outcomes,

the pharmacy's initiative has included the introduction of a pharmacist clinical review of prescribed medication, in addition to the assessment of the patient's inhaler technique. The team have also been diligent in delivering targeted information about relevant services available to patients with asthma and COPD (e.g. pulmonary rehab, smoking cessation and flu vaccination), and promoting the use of the MCN's Asthma Action Plan (where appropriate). As pharmacy is so accessible, the team have utilised the platform to interact with patients and conduct respiratory reviews on an ad-hoc basis, increasing patient engagement.

The enthusiastic pharmacy team, a definitive model of care, appropriate resources, and staff training have been key drivers to the success of the project. Although it's still on-going, it has already made a difference. The pharmacist has reviewed several patients, identified compliance and concordance issues, and initiated patient interventions to improve symptom control and overall disease management.



Libby Kennedy
Newcastleton Medical Practice, NHS Borders

Serving a remote and rural population in the most Southerly health centre in NHS Borders, Newcastleton Surgery's isolation promotes unique challenges and opportunities. For example, the current staff shortage within the respiratory service has meant that the team have been managing their respiratory patients themselves while

they're waiting for clinic appointments.

The underlying motivation of the project has been to deliver the best care possible to all patients registered at the practice who have a respiratory condition. Their approach is multi-faceted – including a comprehensive consultation and discussion at the patient's initial presentation; prescribing according to current formulary and current guidance; counseling on optimal use of inhalers; and providing personal action plans.

Raising awareness of respiratory conditions across the wider community has proven to be vitally important to the team, leading to Libby conducting visits to the local primary school and educating teachers on MDI / Spacer use, as well as offering Asthma UK 'school cards' which the staff have found useful to help monitor children and quantify SABA use. She also recognises the necessity of educating carers regarding how to supervise / administer inhalers, and often carries out home visits to house-bound patients.

Maintaining open lines of communication has helped to foster the team's success, so that information is passed quickly and accurately to the appropriate person or place.



Elaine Hancock
Prescribing Support Pharmacist and Lead Respiratory Pharmacist, NHS Borders

In addition to effectively fulfilling her role as an NHS Borders pharmacist and working in three GP practices in the Scottish Borders, since 2016 Elaine has been developing her position as lead respiratory pharmacist for

NHS Borders.

The respiratory project started to take shape in 2016 – an exciting year in that lessons were still being garnered from the NRAD 2014 report, and in November 2016 SIGN 153 Asthma launched, followed by GOLD COPD guidelines; both of which would change the way in which patients are managed. Having organised a respiratory study day, and identified it as a key platform to talk about the new asthma and COPD guidance, Elaine was driven to apply the new guidance in order to give her patients better and safer care.

Actioning her objective, throughout 2016-to-2018, Elaine visited all 23 Borders GP practices either once or twice in order to deliver a respiratory update session to GPs and practice nurses. The update included an insight into when to prescribe, what to prescribe, the importance of non-pharmacological management, a look at the 'new' inhaler chart, and a hands-on session with the actual inhalers. Following the update either Elaine or the GPs / practice nurses would spend time – often many weeks – reviewing all patients prescribed high-dose ICS.

COMMUNITY PHARMACIST OF THE YEAR (INDEPENDENT)

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Alison Hair
Parkhead Health Centre Pharmacy, NHS Greater Glasgow & Clyde

Each day Alison and the team do their best to deliver the most effective health outcomes possible for all of the patients who present.

Notably, the four IP clinics within the pharmacy have contributed to the setting being recognised as a reliable source of

assistance for the local population. 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 works closely with the GP and nurse colleagues in delivering this care, only referring to secondary care where necessary.

Working in collaboration with the clinicians and other affiliated healthcare workers, the pharmacy also runs a clinic for homeless patients who are registered with their homeless GP practice. Its establishment aligns with Alison's aim to minimise the negative health impact of homelessness by helping patients access healthcare, and to support attendance at other relevant services.

Within the pharmacy setting the team are further participating in a project to increase public awareness of alcohol consumption by way of co-operating with staff from the Glasgow Council on Alcohol to facilitate alcohol brief interventions.



James Higgins
Dalneigh Pharmacy, NHS Highland

Working in a very demographically diverse area, James and the team have been steadfast in their determination to meet the challenge and ensure that the pharmacy is flexible enough to meet the wide range of needs which they're presented with.

Inverness itself adds to this mix in that historically people are not geographically bound and may be registered with any practice in the city regardless of where they are domiciled. The pharmacy have thus sought to lessen the potential for error and frustration this creates by making themselves as accessible as possible to each practice and getting to know their preferred methods of communication, prescription request, triage and the services which they may or may not offer. This has produced excellent interprofessional links which have greatly enhanced the team's growth, as well as improved the patient journey.

The pharmacy were also directly involved with two local practices in the pilot for the expansion of the Chronic Medication Service (CMS) through a 'Test of Change' which resulted in very high rates of CMS registration and of serial prescribing.



Mark Feeney
Bannerman's Pharmacy, NHS Greater Glasgow & Clyde

Supporting their patients to live healthy lives is an important incentive for the team's pharmacy services, particularly because they practice in an area of Glasgow with numerous social and health challenges, and encounter numerous individuals suffering from addiction problems coupled

with other areas of ill health.

Channeling their expertise into strands of support, Mark and the team have worked with NHS Greater Glasgow & Clyde to provide opiate replacement therapy and alcohol dependence services for their patients. This year the team have been involved in delivering holistic services, such as dry blood spot testing for hepatitis C and community pharmacist initiation of antiviral therapies through a PGD.

Always seeking to integrate innovation into the pharmacy, this year they invested in a new consultation room to improve the clinical setting of the pharmacy and help provide confidential advice and support to patients. Bar code scanning technology is also being phased in to implement an accuracy check when dispensing medicines; which thus frees up the pharmacists to spend more time with patients.

WOMEN'S HEALTH

PAUSE FOR THOUGHT

Despite recent increased levels of discussion around the subject of the menopause, due to a previous paucity of information and poor education, there's a high chance that many women will still not understand the changes they're going through; in which half have reported not consulting a healthcare professional about their symptoms. This can be a particular cause for concern in cases where women are going through early or surgical menopause, explains Dr Shahzadi Harper, as she sheds light on the transition, and the importance of it becoming on-trend.



WOMEN'S HEALTH



Dr Shahzadi Harper

Speaking about vaginal health has become mainstream! More recently, campaigns like the Me. No. Pause. posters on Transport for London sites, plus celebrity attention, have even brought the menopause to the foreground. This is, for the most part, fantastic news for women's health and healthcare professionals. With more discussion around the menopause transition, hopefully less women will suffer from its symptoms in silence, which, according to the British Menopause Society (BMS), many do.

It has been labelled a 'taboo subject'. The menopause is poorly covered by the national curriculum and at medical schools, and then, forgotten for the 30-odd years until it manifests as a reality in every woman's life.

Typically, the transition is retrospectively diagnosed after menstruation has ceased for a full year; menopause is not a singular event, but a gradual process that can take between three-and-four years. The actual symptoms, however, can endure for a further 10 years.

It's estimated that 13 million women in this country are current, peri- or post-menopausal. That's one-third of British women, usually between the ages of 45-and-65, who are experiencing some symptoms. A study by the BMS stated that, of these 13 million, 51 per cent found their sex lives to have been affected, 47 per cent had had to take time off work, and a third stated that their mental health and confidence have been compromised.

As with all internet trends – the menopause being no exception – it's easy to find vast swathes of online opinion. But, when it comes to treating menopausal symptoms, or any health issue for that matter, this can be problematic. Celebrity bloggers and lifestyle gurus often have no medical background, yet

despite this they frequently promote radical healthcare choices that may not be suitable to everyone. This can be dangerous and damage women's health further.

SYMPTOMS

Embarrassment around sex, libido, and ageing is one of the biggest hurdles for women and their GPs to overcome. This is obviously an endemic cultural issue that can't be solved overnight, however, it's still important to endeavour to make patients feel comfortable in these kinds of discussions, in any way possible.

Listen and be sympathetic. Many of the menopausal symptoms are deeply personal. Physical issues like vaginal dryness can be almost impossible to broach with a pharmacist or GP, and yet without treatment can be extremely painful for many women. The deeper psychological issues around body image and self-worth will often need to be treated with therapy.

Each case is individual. Reduced oestrogen production affects the brain, which in turn affects mood. It affects the hypothalamus, causing hot flushes and night sweats, which in turn can cause poor sleep, leading women to suffer problems with memory and 'feel like they are going mad'. And it affects the skin, which can lead to problems with elasticity, and in many women, vaginal dryness, and vulvodynia. In total, 34 different menopausal symptoms have been reported.

While some of these can be mitigated through lifestyle choices, such as increased exercise, reduced alcohol intake, and changing diet, others may require diagnosis through sensitive discussion with healthcare professionals. I only use blood tests to measure levels of the reproductive hormone, FSH (follicle-stimulating hormone), in instances of early menopause or if a woman is using a progesterone-only contraception, like the Mirena coil.

Care should be taken to prescribe the correct treatment for symptoms as, again, early menopausal signs are often missed or misinterpreted, especially when they take the form of migraines, insomnia, or anxiety. Every healthcare professional should have access to a menopause doctor, and while this isn't always possible, taking the time to diagnose menopausal symptoms correctly can reduce the number of subsequent appointments. As a rule, if a pharmacist suspects symptoms of being demonstrative of menopausal transition, they should advise that patient to contact their GP or to see a menopause doctor.

TREATMENT OPTIONS

Dependent of whether a woman's menopause has begun naturally, or triggered surgically,

treatment will need to be tailored to suit. In cases where a woman has suffered oestrogen-receptor-positive breast or ovarian cancer, hormonal treatments are not appropriate and natural remedies need to be sourced.

These can take the form of certified-organic, hormone-free lubricants and vaginal laser treatment, used to reverse the effects of vaginal atrophy. Sourcing gentle and effective brands is important as many contain chemicals dangerous to a woman's health.

Cognitive Behavioural Therapy can be recommended to handle anxiety, insomnia, and hot flushes, and some herbal supplements can also be used, although emphasise caution as they can interfere with other medication.

Hormone-Replacement Treatment (HRT) has received a lot of negative press, although it is the most effective way to treat menopausal symptoms; 95 per cent of women say that they would prefer to seek natural options before trying the drug. It is, as the name would suggest, a way of replacing the hormones that have ceased to be produced naturally. Studies in 2000 and 2001 raised concerns that HRT may increase the risk of breast and ovarian cancer, even heart disease, which is why its long-term use has been questioned. This evidence has gone on to be dismissed as inaccurate.

In my clinic, I offer women an in-depth consultation to assess their needs as an individual. Usually my advice takes the form of a combined approach, including lifestyle modification, natural remedies, and HRT.

Most women will spend a third, to half their lives in menopause. It is important to identify menopausal coping strategies early to maintain quality of life and wellbeing. Life-coaching and emotional support is also a big part of what I do as often women need a little boost into their third act.

ABOUT THE AUTHOR

Shahzadi Harper is a London-based menopause doctor. She is interested in optimising women's wellbeing and empowering them to look and feel their best. She looks after women of all backgrounds and ethnicities, enabling them to make informed choices for their optimal health and longevity by balancing their hormones from turbulent teens through the menopause transition and beyond.

Dr Harper can be contacted on 07881 364 644, or emailed at info@theharperclinic.com.

ATRIAL FIBRILLATION

THE HEART OF THE MATTER

As one of the most common forms of abnormal heart rhythm, and a major cause of stroke, atrial fibrillation must be propelled to the frontlines of public concern. Help empower patients and provide them with a multi-faceted approach for both the management and prevention of the condition.

WHAT IS ATRIAL FIBRILLATION?

Atrial fibrillation, or AF, is the most common type of irregular heart rhythm. It causes an irregular and often abnormally fast heart rate.

SCOTLAND IN THE SPOTLIGHT

Nearly 100,000 people in Scotland have been diagnosed with AF and it's estimated that as many as 50,000 people with the condition remain undiagnosed.

WHAT ARE THE SYMPTOMS OF AF?

As outlined by Northern Ireland Chest Heart and Stroke, sometimes people with AF have no symptoms and their condition is only detectable during a medical examination.

Some people may experience one or more of the following symptoms:

- Feeling very tired
- Feeling faint at times
- Being breathless
- Palpitations or fluttering or 'thumping' in the chest

HOW CAN AF INCREASE YOUR PATIENT'S CHANCE OF A STROKE?

If the individual's heart doesn't have a regular heartbeat, it may not empty its chambers of blood at each beat. A clot could form in the blood left behind, which can then travel to the brain and cause a stroke.

People with AF are likely to have a much more severe stroke with:

- Almost double the death rate from stroke
- Increased disability from a stroke
- Longer hospital stays
- Increased risk of a stroke happening again

HOW WILL AF AFFECT THEIR DAILY LIFE?

AF is the most common abnormal heart rhythm, but with the right treatment plan for AF, your patient can live a long and healthy life. Treatment plans for AF have two aims – to reduce the risk of a stroke

and to manage the day-to-day symptoms and effects of AF.

In addition to taking their medication, you should discuss with the patient the importance of – and how they must aim to have – a healthy lifestyle.

AF AND TREATMENT

For patients diagnosed with AF, a treatment plan should be devised for them with two aims – to reduce their risk of a stroke, and to bring the rate and rhythm of their heart under control.

PREVENTING A STROKE

Patients should be advised of the importance of working with their doctor to reduce stroke risk, and to make sure that they have a good prognosis with AF. They may be prescribed anti-coagulant medicines to reduce the risk of blood clot formation. It is important that they take the medication exactly as prescribed in order to reduce their risk of a stroke.

CONTROLLING THE PATIENT'S HEART RATE AND HEARTBEAT

There are three potential treatments which may be carried out for the symptoms of AF, to try to restore the patient's heart to a normal rhythm:

1. Prescribe medication – this will aim to control the rate and rhythm of the heartbeat
2. Cardio-version – this is a treatment where electrical signals are sent to the heart through electrodes placed on the chest
3. Ablation – this treatment uses heat or freezing on the area of the individual's heart that is causing the abnormal heart rhythm

AF AND PREVENTION

The cause of AF is not fully understood but there are certain factors that can increase the risk of developing it. For example, certain health conditions including heart failure, high blood pressure or other cardiovascular diseases, diabetes or thyroid disorders can increase an individual's risk. Also, a family history of AF may play a role; and as people get older, the development of the condition may be more likely.

However, while the risk of developing AF increases with the above-mentioned factors, many people develop AF for no explainable reason. However, there are lifestyle changes that can be suggested to the public to help prevent AF and these include the following:

- Moderate their alcohol intake
- Eat a balanced diet
- Keep physically active
- Watch their weight
- Manage their stress levels
- Get enough sleep

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STOMACH DISEASES

TAKING A STAND AGAINST STOMACH DISEASES

PROFESSOR TAMARA MATYSIAK-BUDNIK, HÉPATO-GASTROENTÉROLOGIE & ONCOLOGIE DIGESTIVE, INSTITUT DES MALADIES DE L'APPAREIL DIGESTIF, HIGHLIGHTS THE IMPORTANCE OF WIELDING AWARENESS OF THE GLOBAL BURDEN OF GASTRIC DISEASES, AND THE NEED FOR FURTHER RESEARCH IN THE FIELD, AS WELL AS IMPROVED PREVENTION AND TREATMENT STRATEGIES.

On 2nd October, the United European Gastroenterology, the European Association for Gastroenterology, Endoscopy and Nutrition, and the Healthy Stomach Initiative (HSI), recognised World Stomach Day, which was originally initiated by the HSI.

THE ROLE OF THE STOMACH WITHIN THE DIGESTIVE SYSTEM

The stomach is a vital organ within the digestive system; it's responsible for the chemical breakdown of ingested food before it continues its journey into the small intestine. The stomach is also involved in the absorption of a number of crucial compounds and vitamins, such as vitamin B12, necessary for the production of red blood cells and the functioning of the nervous system. Additionally, the stomach's acidic environment protects against potentially harmful microbes that may enter the body with food and liquids.

GASTRIC DISEASES

Gastric diseases range in prevalence and severity, from common short-term occurrences of dyspepsia (indigestion), to more harmful and severe chronic disorders.

These include a variety of widespread functional disorders, such as irritable bowel syndrome (IBS), which can have a devastating and life-altering impact on the lives of sufferers. Gastric diseases also affect society as a whole, placing significant pressures on over-burdened healthcare systems. IBS, which currently affects one-in-10 people globally, is estimated to cost €3.2 billion per year in Germany alone.

GASTRIC CANCER

As one of the most life-threatening forms of gastric disease, gastric cancer is estimated to be the fifth most frequently diagnosed cancer and third most common cause of cancer-related death in the world. In 2018, there were 80,000 new diagnoses of stomach cancer and nearly 60,000 attributable deaths in Europe. Due to the generalised nature of the symptoms, gastric cancer is often only detected at a later stage, leading to comparatively lower survival rates than many other cancers.

Despite the general decline in gastric cancer cases globally, recent studies have uncovered a concerning link between patients with chronic autoimmune gastritis (AIG) and the development of gastric cancer. In two studies carried in America and Sweden, results showed that individuals with AIG had a three-fold increased risk of developing stomach carcinoid tumours and adenocarcinomas. Like other autoimmune diseases, AIG predominately affects females (3:1 ratio), potentially providing a link between AIG and the increasing incidence of gastric adenocarcinoma among young white females in America. The recent detection of gastric cancer among younger sectors of the population may indicate that declining levels of gastric cancer could reverse in the future.

Identifying and treating gastric cancer at an early stage can dramatically increase survival rates and treatment options. The five-year survival rate for gastric cancer is currently 31 per cent; reflecting the often late diagnosis of the condition. In comparison, the five-year survival rate for gastric cancer more than doubles (68



STOMACH DISEASES

per cent) if the cancer is detected before spreading outside the stomach. Earlier detection of gastric cancer can also lead to a reduced need for aggressive treatment options and invasive surgery. Although not a certainty, precancerous lesions can be an indicator of future cancer progression and should be followed carefully. Recognising precancerous lesions in patients and subsequently monitoring them is an essential measure in reducing the incidence of and mortality rates associated with gastric cancer. The recent publication 'Management of Epithelial Precancerous Conditions and Lesions in the Stomach' clearly characterises the various lesions and management methods, encouraging a standardisation of treatment strategies across Europe for precancerous conditions and lesions in the stomach.

RECENT ADVANCEMENTS IN ENDOSCOPIC IMAGING

Decreasing global mortality relies primarily on the early detection and accurate diagnosis of gastric cancer through endoscopy.

Over the last few decades, there have been a number of critical technological advancements in endoscopic imaging, improving mucosal visualisation and diagnosis. High-definition endoscopy with chromoendoscopy is currently one of the most effective diagnostic methods for identifying gastric adenocarcinoma, potentially allowing for the visualisation of gastric atrophy and intestinal metaplasia.

Despite these advances, continual improvements in endoscopic imaging are still necessary to significantly improve the prognosis of gastric cancer.

HELICOBACTER PYLORI (H. PYLORI)

Helicobacter pylori (*H. pylori*) is one of the greatest risk factors for gastric cancer. Often contracted during childhood, approximately two-thirds of the world's population harbours *H. pylori* bacteria within the stomach. Although an important factor in the development of gastric cancer, evidence has shown that the successful eradication of *H. pylori* does not completely prevent the development of gastric cancer. A 2018 study suggested that *H. pylori* infection may only be an early event in the development of gastric cancer, preparing the gastric mucosa for further changes. Further research on the gastric microbiome is required to identify the precise role of *H. pylori* in the

development of gastric cancer, potentially opening up pathways to novel prevention and treatment strategies.

Important strides are continually being made in the treatment of *H. pylori* infection. Quadruple therapy is becoming increasingly common in areas with growing levels of resistance to standard triple therapy and impressive eradication rates are being achieved. More recently, vonoprazan, a potassium-competitive acid blocker, has been explored as a novel treatment strategy. A large Japanese study comparing vonoprazan to proton-pump inhibitors demonstrated a higher eradication rate with vonoprazan. Noticeably, the eradication rates of vonoprazan combined with amoxicillin and clarithromycin in clarithromycin-resistant patients was over 80 per cent. With a general rise in antibiotic resistance rates globally, evolving treatment options are necessary to combat *H. pylori* infections and associated gastric conditions.

Despite major advancements in the field, gastric diseases remain prominent across the globe. Concerning evidence has also suggested that a variety of gastric diseases may be increasing among the younger population. With the pathogenesis of many gastric conditions still being debated, further research is urgently required to improve patient outcomes and reduce the societal impact caused by these often burdensome and disruptive diseases.

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INTESTINAL FAILURE

INTESTINAL FAILURE: AN EXPLORATION

Intestinal failure is the clinical syndrome in which a patient is unable to digest and absorb food owing to there being insufficient gut length, significant gut disease, or an obstructed or non-functioning gut. As such, patients with intestinal failure can present in a number of different ways and require disparate strategies to manage it. Here, Dr JAD Stewart, Consultant Gastroenterologist and Clinical Lead for Intestinal Failure, Leicester Royal Infirmary, University Hospitals of Leicester, provides an introduction and overview of the condition.



Dr JAD Stewart

WHAT ARE THE CAUSES OF INTESTINAL FAILURE?

1. INSUFFICIENT SMALL BOWEL LENGTH

Small bowel length can be reduced by surgical resection. This may be a result of surgery to treat an underlying disease or following mesenteric infarction. Remaining lengths of small bowel under two metres can cause problems, especially when there is a jejunostomy present.

If the remaining small bowel is connected to the colon, patients can often manage without developing intestinal failure (IF).

However, this depends on the amount of remaining small bowel attached to the colon.

2. GUT DISEASE

Small bowel disease can affect the digestion and absorption of nutrients.

	Jejunostomy Patients	Short Small Bowel Attached to Colon
>2m SB	Drugs to control output Supplements	Normal diet
1-2m SB	IV fluids Drugs to control output Supplements	Low fat, low oxalate, high carbohydrate diet +/- supplements
50-100cm	Drugs to control output Parenteral nutrition	IV fluids Low fat, low oxalate, high carbohydrate diet +/- supplements
<50cm	As above	PN

Residual Anatomy and Nutritional Requirements

This essentially gives a 'functional short bowel'. A condition which may affect the small bowel in such a way is Crohn's disease, through widespread inflammation of entero-enteric fistulation causing a 'functional short bowel'.

3. OBSTRUCTED AND NON-FUNCTIONING GUT

Should the bowel be obstructed from pathology, such as adhesions or extensive intra-abdominal malignancy, then it will seriously impair its ability to function, leading to IF. Occasionally autonomic conditions can lead to a non-functioning gut and this is another cause of IF.

WHAT IS THE EFFECT OF IF?

IF can result in reduced absorption of energy, macro- and micronutrients, fluid, electrolytes and trace elements. This can result in dramatic weight loss, dehydration, vitamin deficiency syndromes and diseases related to lack of trace elements. Coupled with this, there can be huge losses of fluids and electrolytes from the bowel (depending on the remaining anatomy). This is a particular problem with high output jejunostomy.

The gastrointestinal tract produces a high volume of secretions daily, in the region of eight litres per day. These secretions are slowly reabsorbed through the small bowel and colon.

INTESTINAL FAILURE

Causes of IF

Short Bowel	Bowel Disease	Obstructed	Non-Functioning	Functional
Surgical resection Infarction	Crohn's Amyloid Lymphoma Radiation enteritis	Chronic adhesion obstruction Disseminated abdominal malignancy Stricture disease	Autonomic disease Visceral myopathy	Entero-enteric fistula

If the colon is removed and only a small amount of small bowel remains then the effect will be a net secretion of GI contents leading to a net fluid loss. This results in dehydration.

Furthermore, excessive electrolytes will be lost, in particular, sodium, potassium and magnesium, leading to the possibility of dangerous electrolyte imbalances.

In patients with high output jejunostomy the situation is exacerbated if hypotonic fluids (fluids with lower osmolality than the intestinal secretions within the bowel lumen) are drunk in excess. This has the effect of flushing electrolytes out of the bowel lumen which in turn causes fluid to be drawn out of the bowel wall into the lumen, thus increasing fluid and electrolyte losses. This makes the restriction of hypotonic fluids absolutely vital to the effective management of high output stoma patients.

The old adage of 'drink the same volume that your stoma produces' is profoundly wrong and patients should not be advised as such.

The provision of WHO oral rehydration solution is a keystone of treatment as it is isotonic, thus reducing fluid sodium loss.

The colon plays an important role in water reabsorption, thus in contrast to the high output stoma patients described above, patients with a short bowel to colon are less prone to dehydration.

Clearly with a reduced small bowel length there will be limited surface area to enable adequate nutrient absorption leading to malnutrition.

HOW IS IF TREATED?

THE TREATMENT DEPENDS LARGELY ON THE ANATOMY:

Short bowel to colon: This should be treated with a low fat, low oxalate, high carbohydrate diet. A specialist dietician should be involved in care to ensure that nutrition requirements can be met. If the remaining small bowel is small (see table) these patients may require additional fluids or parenteral nutrition.

High output jejunostomy: This is a complex area that can't be adequately covered in a short article.

However, the principles are:

- Reduce intestinal secretions – high dose proton pump inhibitor therapy, e.g. lansoprazole 30mg bd
- Reduce gut motility – high dose loperamide +/- codeine phosphate, e.g. loperamide 12mg qds + codeine phosphate 60mg qds
- Reduce hypotonic fluids – less than 500mls / day
- Oral rehydration solution – WHO solution or double-strength diaoralyte (1-1.5 litres)
- Low fibre diet (fibre will draw water into the bowel)

IF can sometimes be treated with the above measures alone. The more common situation however is to supply parenteral nutrition or parenteral fluids and electrolytes to support the patient.

PARENTERAL NUTRITION

WHAT IS PARENTERAL NUTRITION?

Parenteral Nutrition (PN) is an admixture of fluid, fat, amino acids, glucose, trace elements and vitamins. It is highly metabolically active.

As such, it has to be prescribed only when necessary and with great care. The role of an experienced senior dietician and pharmacist are essential in ensuring that the prescription is appropriate, stable and correct. Bags of parenteral nutrition are usually covered with an opaque plastic bag to protect the contents from light. This is because both the fats and vitamins in PN are prone to peroxidation and photo degradation.

HOW DO YOU GIVE PN?

PN is delivered via either a Hickman line or a peripherally inserted central catheter (PICC). A Hickman line is a venous device which is inserted into the subclavian vein. It is often tunnelled under the skin and has a subcutaneous cuff, both of which reduce the risk of infection.

A PICC line is inserted into a vein in the arm (often in anterior cubital fossa) and threaded up the vein until the tip is in the ideal position. The tip of the delivery device must be situated at the junction of the superior vena cava and right atrium. This is to reduce the risk of

thrombosis and mechanical trauma caused by the PN and delivery devices respectfully.

WHAT ARE THE COMPLICATIONS OF PN?

The complications can be divided into those related to the central venous catheter (CVC) and those related to the PN per se.

Problems with the CVC include fracture, infection, thrombosis and blockage. The risk of these can be significantly reduced with aseptic technique when accessing the line, good line care and flushing the line when not in use.

Problems with the PN are largely related to inappropriate prescriptions and / or inadequate monitoring of electrolytes.

HOME PARENTERAL NUTRITION

Many patients with IF require medium or long-term nutritional support at home; known as Home Parenteral Nutrition (HPN). Patients are trained to administer their PN overnight at home and taught how to aseptically connect / disconnect the feed and look after their venous access device. They also require regular blood testing to ensure that they are not developing biochemical abnormalities. This requires the support of a dedicated hospital-based intestinal failure team whom the patient can contact if problems arise and who they can visit in dedicated IF clinics.

ABOUT THE AUTHOR

Jim Stewart trained in Leicester and was appointed as a Consultant Gastroenterologist at the University Hospitals of Leicester in 2000. He has had a career-long interest in nutrition and has been the Clinical Lead for Nutrition since 2006. Since that time he has expanded and developed the Leicester Intestinal Failure Team into a large multidisciplinary service. He was co-author of the NCEPOD report, 'A Mixed Bag' – a national review of PN. He is a faculty member of the Coventry-Leicester Intestinal Failure Network.

For more information, email James.stewart@uhl-tr.nhs.uk, tweet @Leicnut, or visit www.clifnet.org.

HYPOGLYCAEMIA

HYPOGLYCAEMIA: THE LOWDOWN

Sharpen your knowledge of hypoglycaemia and diabetes – tackling the causes, impact, and avenues of treatment along the way – through the expert analysis of Gabriela da Silva Xavier, Senior Lecturer in Cellular Metabolism at the University of Birmingham.



Gabriela da Silva Xavier

WHAT IS HYPOGLYCAEMIA?

Hypoglycaemia literally means low blood sugar and is clinically defined as a blood sugar level at or below 3 mM. In adults, severe hypoglycaemia is an episode of hypoglycaemia with cognitive impairment and requiring third-party assistance.

(1) For the paediatric population, this would be an episode with severe neuroglycopenic symptoms (e.g. coma and convulsions) that requires third-party assistance. (2) It's a condition that is frequently associated with the treatment of diabetes, although it also occurs in a variety of other less common conditions

e.g. Addison's disease, insulinomas, congenital hyperinsulinism.

Hypoglycaemia is like the quiet relative to hyperinsulinaemia in the treatment of diabetes, in that the lowering of high blood glucose is usually more of the focus topic, even though hypoglycaemia is the most common complication of insulin therapy in people with diabetes and contributes to the adverse health outcomes in diabetes. For example, a recent systematic review and meta-analysis showed an association between hypoglycaemia and longer length of stay and greater in-hospital mortality. (3)

During hypoglycaemia, patients may experience palpitations, pallor, shakiness, dizziness, headaches, and feelings of fatigue, anxiety, hunger, irritability, and a tingling sensation round the mouth. As hypoglycaemia progresses, patients may also experience confusion, visual disturbances, seizures, and loss of consciousness. It's not uncommon for patients experiencing extreme hypoglycaemia to be described as if they were intoxicated. Hypoglycaemia can occur while sleeping. But what gives rise to these symptoms?

WHAT CAUSES HYPOGLYCAEMIA?

In people with diabetes, the main cause of hypoglycaemia is taking too much glucose-lowering medication, such as insulin, sulphonylureas or glinides; delaying / skipping meals; intense exercise or activity; and excessive intake of alcohol. Other possible causes of hypoglycaemia include reactive hypoglycaemia (which may be caused when there had been an excessive intake of carbohydrates and / or alcohol, surgical procedures for gastric bypass or ulcer, inherited metabolic disorders), binge drinking, and fasting / malnutrition.

Hypoglycaemia could also be induced by the intake of certain medication (e.g. quinine).

SO WHAT DOES EXCESSIVE LOWERING OF GLUCOSE DO?

Glucose is essential for brain metabolism and, therefore, brain function. Under normal circumstances, numerous physiological mechanisms ensure that blood glucose levels do not fall dangerously low.



HYPOGLYCAEMIA

Glucagon is a hormone that is secreted by the pancreatic alpha cells (one of the cell types that make up the pancreatic islet) in response to low blood glucose, i.e. glucagon is the counter-hormone to insulin. Like insulin, glucagon signals to peripheral tissues. Unlike insulin, the sum total of glucagon signalling is the mobilisation of glucose stores (primarily in the liver) and de novo synthesis of glucose via gluconeogenesis to restore normal blood glucose.

Insulin secretion is suppressed when blood glucose concentrations fall below 4.4 mM (4), and glucagon secretion is activated when blood glucose is at 3.9 mM (4, 5), followed by elevation of epinephrine, growth hormone and cortisol (the sympathoadrenal response) as blood glucose continues to fall. (4 – 7) The fall in blood glucose is thus accompanied by the activation of counter-regulatory mechanisms to mobilise glucose stores and gluconeogenesis, restriction of peripheral glucose utilisation and autonomic symptoms which may result in food-seeking behaviour (excellently reviewed in (8)).

Glucagon release is suppressed in the presence of high insulin. (9) When excessive insulin is present in the blood stream due to e.g. excessive administration of insulin in type 1 diabetes or congenital hyperinsulinism, the alpha cells do not secrete glucagon, leading to a decrease in the counter-regulatory response. (9, 10) Loss of alpha cell function is observed in patients with type 1 diabetes. (11, 12) This loss of glucagon signalling, accompanied by a blunting of the sympathoadrenal response (caused by repeated exposure to hypoglycaemia) (13), over time, leads to hypoglycaemia unawareness, and the occurrence of persistent episodes of low blood glucose.

Postprandial hypoglycaemia has been reported in c. 75 per cent of patients that have undergone gastric bypass surgery. (14) This may be due to the exaggerated insulin and glucagon-peptide like one response from altered nutrient transit following the bypass surgery (15, 16), followed by subsequent blunting of the sympathoadrenal responses to hypoglycaemia. (8)

HOW IS HYPOGLYCAEMIA TREATED?

Treatment usually involves attempting to restore blood glucose levels to the normal range through the intake of high sugar foods / drinks, or with medication, depending on the cause and severity of the hypoglycaemia. The ability of glucagon to induce elevations of blood glucose means that exogenous glucagon lends itself to counter insulin-induced hypoglycaemia in patients with type 1 diabetes or insulinomas, and reactive hypoglycaemia.

A patient that is unconscious due to severe hypoglycaemia can be treated with an injection of glucagon as an emergency measure.

Various formulations of glucagon are available for use either by intramuscular, subcutaneous, intravenous, intranasal, or insulin pump administration (reviewed in (8)), many with increased stability and ease of administration. Continuous blood glucose monitoring allows the tracking of blood glucose in diabetic individuals requiring insulin and have been shown to help reduce hypoglycaemia incidence, particularly in patients with hypoglycaemia unawareness and nocturnal hypoglycaemia (reviewed in (17) and (18)). The use of glucagon and insulin in combination in a dual-hormone artificial pancreas, mimicking the function of the two hormones in vivo, may help to maintain blood glucose concentration within a target range. (19)

Glucagon acts on multiple tissue systems and the short-term side-effects of glucagon administration – nausea, vomiting, headaches – are well-known, but the long-term consequences of chronic use are still unclear. The preparation and administration of injectable

glucagon can be problematic, leading to errors in the delivery of the drug, and under-prescription and use of injectable glucagon. (20, 21) Thus, there is a requirement for better formulations for glucagon and a better understanding of the long-term effects of chronic use for the treatment of hypoglycaemia.

Severe hypoglycaemia can be life-threatening. Due attention to hypoglycaemia risk is important for good treatment outcomes and avoidance of diabetes-related complications.

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BIOSIMILARS

LEARNING A THING OR TWO

As we enter the final chapter of 2019, Warwick Smith, Director General of the British Biosimilars Association, reflects on how the lessons garnered from adalimumab have the potential to drive future launches.



Warwick Smith

Undoubtedly one of the major developments in recent UK biosimilar history was the end of the adalimumab patent at the end of 2018 which allowed competition into the market. Not only was it a seminal moment due to the sheer scale and cost of the product, it also saw NHS England adopt a new approach to procurement: one which prioritised competition, and therefore savings to the NHS, but also crucially focused on ensuring that there were multiple suppliers, avoiding a 'winner takes all' approach. This assists sustainability for the industry and security of supply for patients.

Nearly a year on from competition entering the market, it's a natural point to reflect on the success and challenges so far in light of real-world activity and experience. Our view, supported by data from the NHS, suggests that overall uptake of the biosimilars has been good, albeit there is variability between different regions. There is also now a significant amount of switching data which shows that the vast majority of existing and new patients have responded well to use of biosimilars, with low levels of re-switches taking place.

At the British Biosimilars Association, we have also undertaken our own analysis on the procurement process based

on feedback from manufacturers. The overall sentiment is that the introduction of competition is demonstrably treating more patients, releasing cost savings and supporting sustainability in the NHS.

From a procurement perspective, we fully supported the NHS in piloting this new approach, given the size of opportunity and need to ensure a multi-player market. We have previously expressed reservations about the inflexibility of some aspects of medicines tendering which often places too much risk on a single manufacturer. The new approach, which centred on plurality of sustainable supply, was right and effective.

The adalimumab system, which in summary delivered greater guaranteed opportunity to secure a share of regional markets, meant that all suppliers were able to participate. Hospital tenders elsewhere have seen the winner get access with others shut out which doesn't deliver market resilience and can lead to shortages.

Other plus points included NHS England oversight and co-ordination of contracts which has been a good mechanism to manage variability in prices offered in each region.

Elsewhere, the communications and engagement from NHS England's Commercial Medicines Unit was excellent in the lead-up to the original tender. We have also had a good sense that NHS England officials are willing to work with suppliers and learn from the experience of adalimumab which will help inform future similar tenders.

Another positive is that trusts are keeping some of the savings achieved so far with the rest going to CCGs. This is an important point as trusts need to see the direct value as part of the uptake process.

But there are areas where all can learn from this process to improve future tenders. Companies feel that the process was not consistent from start to finish, and that the good communication in the early stages did not carry forward to the end. We need to ensure in all cases that the right factors are taken into account in the procurement from the perspective of saving scarce NHS resources and ensuring that patients are appropriately involved, and their access to medicines enhanced.

The balance on health service gains from competition needs to be carefully monitored as well. If individual trusts aren't seeing enough of the benefits then they won't be incentivised to carry out patient switches.

Finally, award criteria based solely on price creates an unsustainable market. We believe that elements such as supply chain excellence – including managing shortages – should be given due consideration.

So, lots to look at and to consider the lessons for future launches. Adalimumab had many unique features but there is also much which can be translated into future biosimilar launches.

Fine-tuning and re-shaping future processes is important in order to deliver the right level of incentives and benefits across the system, which in turn will drive uptake and savings, benefitting NHS budgets and patient access.

IN THE COLD LIGHT OF DAY

Winter can be a worrisome time for individuals with asthma – fuelled by fears of intensified symptoms and insufficient preparation. Dr Peter Kewin, Consultant in Respiratory and General Medicine, Queen Elizabeth University Hospital, investigates the factors which come into play, and how you can help patients cope in the colder months.

WINTER IS COMING! While true, this doom-laden phrase lifted from a recent TV epic does not have to signal a hard time for asthma patients. Asthma itself does not change with the seasons, but winter brings with it a specific set of triggers and problems to consider in any patient.

To put this in context, first let me summarise what asthma actually is.

Asthma is a disease of the lower airways characterised by variable levels of inflammation influenced by both intrinsic and extrinsic factors. This leads to variable narrowing of the airways as a result of inflammatory changes in the epithelium (i.e. swelling), mucous production and smooth muscle contraction. This then results in the typical symptoms of exacerbation:

1. Wheeze – air moving through the narrowed tubes
2. Cough – irritated airway nerve endings and extra mucous to clear
3. Breathlessness – a combination of both
4. Chest tightness – increased effort of breathing due to the above

There are a number of different ‘types’ of asthma (phenotypes) depending on the most important factors present in individual patients, so in asthma clinics we make an attempt to measure these to help guide our advice and treatment. Examples of important factors include the presence or not of eosinophils, the co-existence of allergies, and very specific triggers such as drugs (aspirin / non-steroidal anti-inflammatory drugs especially). Regardless of the type of asthma, ‘non-specific’ (i.e. non-allergic) triggers in the environment also play a key role in driving symptoms.

The cornerstones of treating asthma are controlling the inflammation, and dilating the airways as much as possible. This does not change in winter. ‘Reliever’ medication is aimed at opening up the airways rapidly if narrowing occurs due to smooth muscle contraction after a trigger. This is usually in the form of short-acting beta agonists (SABA).

‘Preventer’ treatments are those taken regularly to damp down any inflammation and keep airways as open as possible. They include inhaled corticosteroid (ICS) and long-acting bronchodilators in the form of beta-agonists (LABA) and muscarinic antagonists (LAMA). ICS and LABA are often used in combination inhalers. If these are insufficient, additional treatments include leukotriene receptor antagonists (LTRA), theophyllines, antihistamines if there are allergies, and in the last resort oral prednisolone.

Treatments are escalated as per British Thoracic Society / SIGN guidelines according to levels of symptoms and frequency of exacerbation (ref). There are newer biological therapies targeting immunoglobulin E (IgE) responsible for allergies, and interleukin-5 (IL-5) that drives eosinophil levels, for those patients with these phenotypes and recurrent or persistent need for prednisolone.

An exacerbation of asthma is regarded as any increase in symptoms necessitating an increase in preventer-type treatment. There is considerable variability in severity (usually based on drop in peak flow rate and severity of breathlessness) and speed of on-set (rarely hours, usually days). Milder exacerbations (e.g. exposure to chemical scents, pollution, allergies) usually result in an increase in SABA use and ICS dose, but more severe exacerbations (usually viral) will require a short course of prednisolone. Only occasionally are antibiotics indicated (for bacterial chest infection).

Continued onto next page

ASTHMA

Hospitalisation is required if rapid on-set, or if not responding to initial increase in treatment, and will usually involve the addition of nebulised SABA / SAMA. Very severe exacerbations can lead to intensive care admission or even death. So, exacerbations are inconvenient, debilitating, and the time of most danger to the patient, and expensive for the healthcare system.

The approach to managing asthma during winter then is aimed at ensuring good asthma control in general, and avoiding exacerbation as much as possible.

ENSURING GOOD CONTROL

This is the same all year-round. The better controlled asthma is, the less likely to exacerbate when provoked.

The key features are:

- Education – patients should understand their own disease and triggers and its variable nature, and the need for preventative treatment even when feeling well
- Avoidance of known triggers (e.g. cats if allergic to cats)
- Adherence to treatment – can be challenging in ‘well’ patients but needs to be frequently encouraged and any barriers removed (e.g. access to medication / prescriptions, allay fears of side-effects)
- Inhaler technique – needs constant vigilance, especially when devices are changed as medications are changed, and especially when changing from metered dose inhaler (MDI) to dry powder or vice versa. An MDI and spacer is often the simplest best option
- A written asthma action plan of usual treatment, when and how to escalate treatment, and any specific issues for that patient

AVOIDING EXACERBATIONS IN WINTER

As mentioned, there are some specific issues with winter:

VIRAL INFECTIONS

These are much more common in winter due to crowding together indoors and having more contact with people for longer. Patients with asthma are no more susceptible to viral infection, but tend to have more serious and longer-lasting lower respiratory tract symptoms. They are responsible for 85 per cent of exacerbations in school-age children, with a peak not long after the start of each term, and about 50 per cent of adult exacerbations. The majority are due to rhinoviruses (the common cold) for which there is no treatment.

So, the key is avoiding people who have the cold, and keeping hands scrupulously clean, as most viral spread occurs via droplets on surfaces transferring by hand to the face. Influenza is less common but more severe so the flu vaccine should be considered, especially if other co-morbidities and in older and younger patients.

COLD WEATHER

Cold air tends to be dry air. This can dehydrate the airway epithelium and provokes an inflammatory response and smooth muscle contraction. Simply using a scarf to breathe through, or exclusive nasal breathing, will warm and humidify the air before it reaches the lower airways. An extreme example of this is the very high level of asthma seen in winter athletes – between 15 per cent and 50 per cent depending on the sport. For contrast, about nine-to-10 per cent of the UK population have asthma.

WARM FIRES

They sound like a great idea, but real fires and wood-burning stoves generate lots of fine particles (i.e. pollution) which can trigger asthma as much as diesel particles can. Ensuring that the chimney is well-swept, and good ventilation in the room can help.

Environmental air pollution in general is worse in winter due to overcast weather ‘trapping’ pollution in the cold air nearer the ground, as well as the increase in car journeys and burning fossil fuels.

ALLERGIES

Certain allergies are worse in colder months due to increased exposure to the allergen. Most common of these is house dust-mite allergy. Dust-mite numbers increase during colder months, thought to be due to the increased use of central heating. We also spend more time indoors in contact with them in our soft furnishings (especially beds and bedding).

Antihistamines, and measures to reduce dust-mite load, may help. These include keeping the temperature even and low and wearing more clothes instead (but be aware of taking dusty jumpers out of storage!), steam cleaning soft furnishings, and considering anti-allergy bedding. Mould spores are also higher in colder weather so may necessitate antihistamines in patients with known allergy.

CHRISTMAS

No joking – this is a dangerous time for asthma patients. They are inside with virus-ridden, perfume-soaked relatives. It is a time of stress. There are increased levels of wood smoke, and hot air / cooking fumes. The dust-covered decorations have been recovered from the dust-filled attic. The tree exudes a lovely pine scent guaranteed to irritate. And with all the bank holidays, they’ve run out of medication, and the GP surgeries and pharmacies are shut. The out-of-hours is miles away. The local emergency department has now been moved and isn’t so local anymore. And once there the hospitals are on a skeleton staff and the Christmas dinner is woeful.

So, take care and hopefully you can help prevent your asthma patients having Christmas dinner in hospital – though they may not thank you for it if it gets them away from the kids for a day or two!

Intelligently designed. Simple to use.^{1,2}



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

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

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

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

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

VULVODYNIA: A VERY PRIVATE PROBLEM

Vulvodynia can be challenging to treat effectively; partly because it may require a multidisciplinary approach, but also due to the fact that taboos on discussion have led to a lack of research and awareness of the problem, meaning that in the past, appropriate treatment has not been easy to access. In this edition of SPR, the Vulval Pain Society overview the condition – including its aetiology, the treatments employed, and rationale for their utilisation.

The vulva includes the external female sex organs, plus the urethral opening and anus (see Figure One). Many different conditions affect the vulva, including skin conditions (e.g. lichen sclerosis, dermatitis) and infection.

Vulvodynia is a distressing condition causing persistent unexplained pain in the vulva, which is diagnosed when skin disease and infection have been excluded.

WHAT EXACTLY IS VULVODYNIA?

Vulvodynia is defined as 'vulvar discomfort most often described as a burning pain, occurring in the absence of relevant visible findings or a specific, clinically identifiable, neurologic disorder'. (1) Patients can present with a spectrum of symptoms: in some cases, itching, throbbing, stinging or soreness is described. The pain may be provoked, spontaneous, or mixed. Its location on the vulva can vary: clitorodynia affects just the clitoris, hemivulvodynia affects just one side of the vulva, and vestibulodynia affects just the vulval vestibule, but any or all vulval parts can be involved. The condition may be linked to cognitive, emotional, or behavioural issues that may need to be addressed in management.

DIAGRAM OF THE VULVA

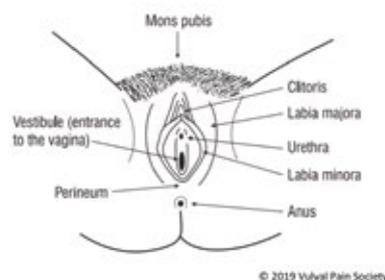


Figure One

HOW COMMON IS IT?

The prevalence of vulvodynia is still unclear: relevant studies have varied in sample size, populations studied, and inclusion criteria used. The inclusion criteria variations are at least partially accounted for by classification and terminology changes which have accompanied progress in our understanding of vulvodynia over the last three decades. To date, there have not been any robust prevalence studies in the UK.

What is clear is that vulvodynia is far

from rare. According to one 2012 study from America, around eight per cent of women have vulvodynia at any one time, and as many as one-in-four may have it during the course of their lifetime. The condition can affect all ages; from little girls to senior citizens. (2)

DEVELOPMENT AND POSSIBLE CAUSES OF VULVODYNIA

Vulvodynia is believed to be a pain syndrome like other pain conditions, such as coccygodynia or scrotodynia, so caused by a chronic rather than acute pain mechanisms.

Physical triggers such as injury; local infection such as thrush; dermatological reactions such as eczema; or the consequences of hormonal changes; can produce acute pain with tissue inflammation which resolves. However, if the acute pain persists for three-to-six months, under certain conditions in susceptible patients, it can lead to central or peripheral nervous system sensitisation.

This chronic pain is not usually inflammatory, so with vulvodynia there is usually no inflammation seen on physical examination.

Vulvodynia could thus be said to be a chronic pain cycle which has one or more triggers and is then perpetuated by physical or emotional factors. Whether or not there is any one specific cause which initiates the cycle is unclear. However, research has shown that vulvodynia may be associated with an overgrowth of dysfunctional nociceptors in the vulval skin.

In one 2011 study, repeated thrush infections in the vulvas of female mice produced allodynia (an abnormal hypersensitivity to touch), and neuronal proliferation. (3) This could support the results of an earlier study from 2003 which showed an overgrowth of dysfunctional nociceptors in the vulval skin of vestibulodynia patients compared to controls. (4)

MAIN TYPES OF VULVODYNIA

The two most common types of vulvodynia are vestibulodynia (formerly known as 'vulval vestibulitis') and unprovoked vulvodynia.

Vestibulodynia, or localised provoked vulvodynia, is pain confined to the vulval vestibule, characterised by tenderness, sometimes severe, when the vestibule is lightly touched.

This hypersensitivity typically causes problems with inserting tampons and also vaginal penetration, leading to psychosexual difficulties and considerable strain on sexual relationships. Jeans, tight trousers, or underwear can be extremely uncomfortable for some sufferers. Gynaecological examinations, including cervical smear tests, can be so painful as to be impossible for women with vestibulodynia, with implications for general health as well as comfort. Vestibulodynia can be diagnosed by gently touching the vulval vestibule with a cotton bud or swab, which will produce pain. Note, however, that with this disorder, the labial skin will not be tender.

Unprovoked vulvodynia can be 'localised', if confined to one part of the vulva (but not the vulval vestibule) or 'generalised', in which case it can affect any part of the vulva, including the mons pubis and even perianal area. Unlike vestibulodynia, unprovoked vulvodynia can produce pain even in the absence of touch and the pain is more constant. Many sufferers experience urethral, perineal or rectal pain or discomfort. Symptoms can vary from a general mild intermittent irritation to constant pain so severe it warrants referral to a pain management clinic. As with vestibulodynia, the condition can cause considerable secondary psychological problems, but with unprovoked vulvodynia these tend to be more due to the chronicity of the pain than to psychosexual issues. However, some women with this type will also have the difficulties with vaginal penetration and clothing we see with vestibulodynia.

TREATMENT

Vulvodynia treatment is aimed at achieving three outcomes: a reduction in pain levels and an improvement in function; an ability of the patient to use education and self-empowerment to manage her own pain; and finally, if desired, a reduction in sexual pain and improved satisfaction and sexual function. (5)

Initially, there are many simple measures which can help with symptoms, such as avoiding tight clothing, scented soaps or lotions which could irritate the vulval skin and maintain the pain cycle, using special cushions for sitting, saddles for cycling, and so on.

The Vulval Pain Society website has a page listing these everyday measures and the physical relief they provide may be enough to break the pain cycle for some women. (6) However, if pain persists, the patient will need a GP referral to a vulval service, where a comprehensive biopsychosocial assessment should be made and individual value-based

needs identified.

In May 2019 the World Health Organisation adopted ICD-11, the first version to include chronic pain based on the current scientific evidence, thus promoting a move away from the biomedical model and towards the biopsychosocial model of treatment. The International Association for the Study of Pain describes vulvodynia as multisystem and multifactorial which calls for a multidisciplinary treatment approach.

The multidisciplinary team may include gynaecologists, physiotherapists, psychosexual therapists, pain management specialists, and sometimes other specialists, such as psychotherapists. Some treatments are more useful for particular vulvodynia types and individuals. For example, pain-modifying drugs, such as amitriptyline and nortriptyline, and / or gabapentin or pregabalin, are better suited for treating moderate-to-severe unprovoked pain (over five / 10 on the subjective pain scale). If the drugs prove unsuitable or the pain is severe or disabling, patients can be referred to pain management, which may offer intralesional injections, TENS machines, nerve blocks or acupuncture. Patients who have sexual pain because of vestibulodynia may find local anaesthetic gels or ointments help to numb the vulva sufficient to allow them to have sex.

Physiotherapy is used to treat pelvic floor muscle dysfunction, shown in studies to contribute to the vulval pain cycle. Treatment can involve pelvic floor exercises, trigger point therapy and desensitisation work with vaginal dilators.

Psychological and psychosexual therapies can be helpful in treating vulvodynia, as psychological dysfunction, which can accompany chronic pain, can exacerbate and maintain the pain cycle. Stress, anxiety and catastrophic thinking are known to amplify our perception of pain, so all measures which can 'turn down the volume' on the pain are useful here, including, among others, psychological approaches, such as



Figure Two

mindfulness and cognitive behavioural therapy. Emotions, thoughts, behaviours and physical sensations can form a vicious cycle (see Figure Two).

Psychosexual therapy is aimed at patients experiencing sexual and relationship problems due to their vulvodynia. Techniques used by the counsellor may include, for example, working on sexual contact beyond vaginal penetration, sensate focus therapy, and therapy for low libido and anorgasmia.

Rarely, surgery is used to treat provoked vulvodynia. Vestibulectomy involves excising a horseshoe-shaped area of the skin of the vulval vestibule, following which the posterior vaginal wall is dissected to cover the resulting skin defect. The aim of the surgery is to physically remove the layer of dysfunctional nerves in the vulval vestibule, thought to cause the pain. Despite some promising results, with one study in 2008 demonstrating pain-free sex in 59 per cent of patients studied, clinicians disagree about the value of surgery, perhaps because it implies a direct physical correspondence between pain and a localised area of the vulva, downplaying any role played by central sensitisation. (7)

CONCLUSION

Vulvodynia, a chronic pain syndrome of the genital skin, should be considered in women when skin conditions and infections have been excluded. All health professionals involved in women's health should be aware of vulvodynia and support patients by making a diagnosis, starting basic treatment and referring patients on to other members of the multidisciplinary team if necessary.

For more information, visit www.vulvalpainsociety.org.

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PSORIATIC ARTHRITIS

A SORE SUBJECT

Explore psoriatic arthritis through the expert eyes of Philip Helliwell, Professor of Clinical Rheumatology at the University of Leeds, and Honorary Consultant Rheumatologist for the Bradford Hospitals NHS Trust, who talks to SPR about the condition's life-impacting potential for patients and why treatment must not be delayed.

WHAT FRACTION OF THE POPULATION ARE MOST LIKELY TO DEVELOP PSORIATIC ARTHRITIS?

Three per cent of the population have psoriasis, and a third of those have psoriatic arthritis – males and females equally, and young and old. In the population at large, it's about one per cent probably.

ARE THERE ANY PATTERNS IN THE NATURE OF THE CONDITION'S FLARE-UPS AND FREQUENCY FOR PATIENTS?

A lot of people say that stress is a trigger, and so is any form of trauma – whether it's psychological or physical. Each individual varies and differs in terms of their flare-ups so we can't give an accurate figure but flare-ups are certainly a characteristic of the disease.

HOW DOES PSORIATIC ARTHRITIS AFFECT THE INDIVIDUAL'S MENTAL HEALTH?

Psoriatic arthritis impacts the patient's physical and mental health in many ways. In fact, one of the comorbidities of this condition is depression and self-harm, but I don't think there's enough awareness of these effects.

WHAT SHOULD THE PSORIATIC ARTHRITIS CARE PATHWAY LOOK LIKE?

Basically, there has to be an awareness of the association between arthritis and psoriasis – that's the first hurdle to overcome, for both the physician and the patient. Very few people know of the link.

There is a frequent delay in diagnosis and referrals for psoriatic arthritis and patients should be seeing their GP a lot earlier. But a lot of patients are put off seeing their GP because they've had treatment in the past which hasn't worked – they're not turning to them when they should be to get an on-ward referral.

The condition should be treated with a multidisciplinary approach across specialties. Skin, joints, mental health, cardiac, gastroenterology, for example, should all be involved in the patient's health.

WHAT TREATMENT STRATEGIES SHOULD BE CONSIDERED BY THE HEALTHCARE PROFESSIONAL?

The treatment for psoriatic arthritis is complex and guidelines and recommendations have been produced as a result. The treatment should be tailored to the sort of disease which the patient presents with. There is not a single pathway, but numerous, depending on how the patient is.

As far as the individual's self-help goes, we advise healthy living, weight-loss, alcohol abstinence, no smoking, and exercise. It's the generic advice that patients attending to their GP receive, but funnily enough those factors have specific relevance to this condition.

WHAT DANGER LIES IN DELAYED TREATMENT – OR THE ABSENCE OF IT?

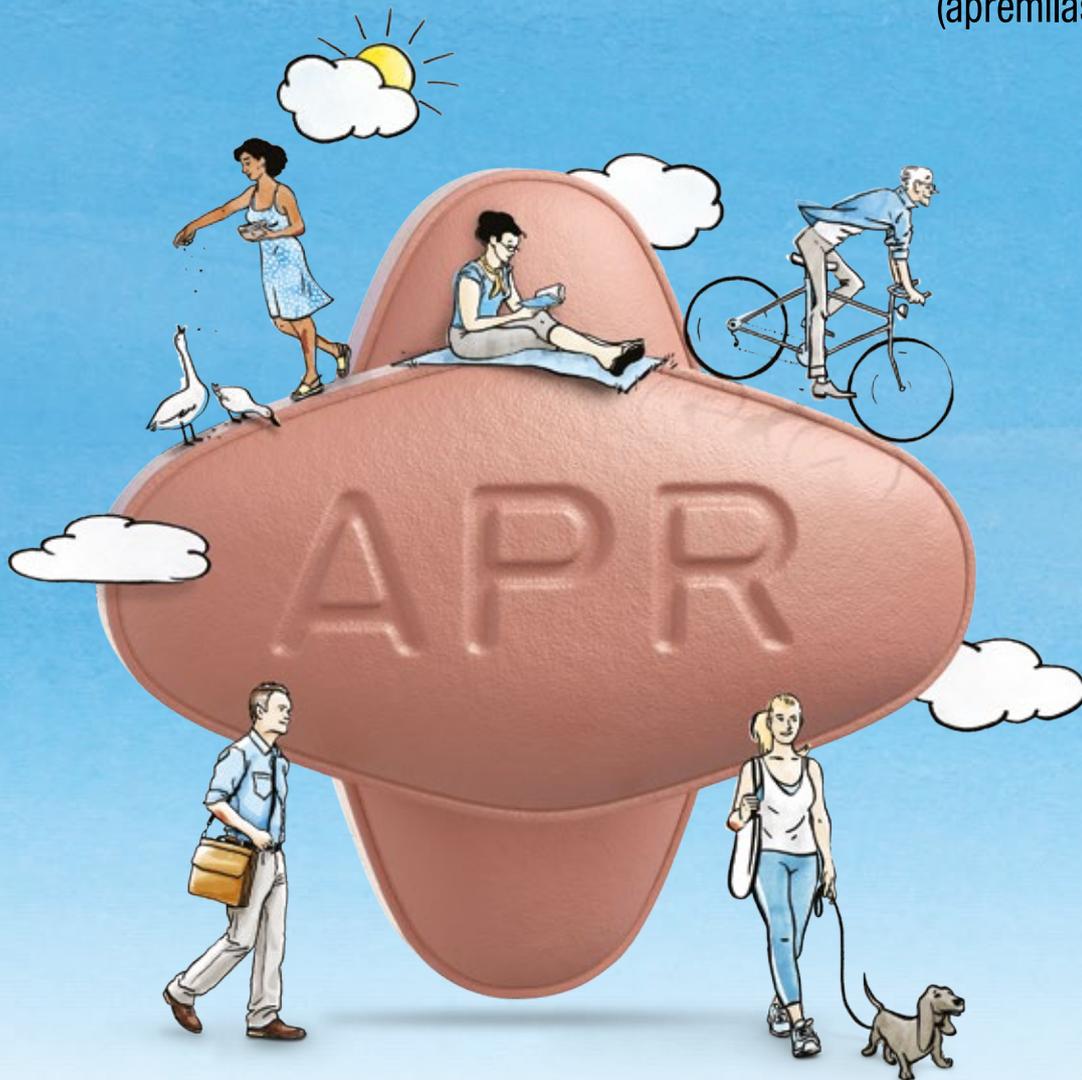
The psoriatic arthritis patient will experience more damage if treatment is delayed. In fact, a study from Dublin showed that a six-month delay in treatment causes severe damage, so that six-month cut-off is crucial.

It's 95 per cent true that patients who adhere to the treatments can live a happy and healthy life – nowadays, the majority of the patients are successful with treatment – but there's a small group that we struggle with.

HOW HAS THE SECTOR'S APPROACH TO PSORIATIC ARTHRITIS – AS WELL AS THE AVENUES OF TREATMENT – EVOLVED OVER THE YEARS?

There's no doubt that we're not seeing the problems which we saw in the past. That's true of all arthritis, not just psoriatic arthritis. Rheumatology, as well, has developed and we have better treatment and awareness now. However, even though there has been improvement, there's still room for a lot more to come, particularly in getting patients in to see a specialist earlier. From my point of view, if we could improve that referral time by just a few months for our patients, it would make a huge difference. We're actually currently conducting a national study which will be published in the next year or two to prove that earlier referral improves outcome.





RESULTS

————— *the way* —————

PATIENTS WANT THEM¹⁻⁶

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

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

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

Prescribing information can be found overleaf.

August 2019 PM-UK-OTZ-0298

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

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

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

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

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

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

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

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

glucose-galactose malabsorption should not take this medicinal product. Severe diarrhoea, nausea, and vomiting associated with the use of Otezla has been reported. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older may be at a higher risk of complications. Discontinuation of treatment may be necessary. OTEZLA® is associated with an increased risk of psychiatric disorders such as insomnia and depression. Instances of suicidal ideation and behaviour, including suicide, have been observed in patients with or without history of depression. The risks and benefits of starting or continuing treatment with OTEZLA® should be carefully assessed if patients report previous or existing psychiatric symptoms or if concomitant treatment with other medicinal products likely to cause psychiatric events is intended. Patients and caregivers should be instructed to notify the prescriber of any changes in behavior or mood and of any suicidal ideation. If patients suffered from new or worsening psychiatric symptoms, or suicidal ideation or suicidal attempt is identified, it is recommended to discontinue treatment with OTEZLA®. OTEZLA® should be dose reduced to 30mg once daily in patients with severe renal impairment. OTEZLA® may cause weight loss. Patients who are underweight at the start of treatment should have their body weight monitored regularly. In the event of unexplained and clinically significant weight loss, these patients should be evaluated by a medical practitioner and discontinuation of treatment should be considered. Women of childbearing potential should use an effective method of contraception to prevent pregnancy during treatment. OTEZLA® should not be used during breast-feeding. No fertility data is available in humans. **Interactions:** Co-administration of strong cytochrome P450 3A4 (CYP3A4) enzyme inducer, rifampicin, resulted in a reduction of systemic exposure of OTEZLA®, which may result in a loss of efficacy of OTEZLA®. Therefore, the use of strong CYP3A4 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin and St. John's Wort) with OTEZLA® is not recommended. In clinical studies, OTEZLA® has been administered concomitantly with topical therapy (including corticosteroids, coal tar shampoo and salicylic acid scalp preparations) and UVB phototherapy. There was no clinically meaningful drug-drug interaction between ketoconazole and OTEZLA®. OTEZLA® can be co-administered with a potent CYP3A4 inhibitor such as ketoconazole. There was no pharmacokinetic drug-drug interaction between OTEZLA® and methotrexate in psoriatic arthritis patients. OTEZLA® can be co-administered with methotrexate. There was no pharmacokinetic drug-drug interaction between OTEZLA® and oral contraceptives containing ethinyl estradiol and norgestimate. OTEZLA® can be co-administered with oral contraceptives. **Side effects:** The most commonly reported adverse reactions in Phase III clinical studies have been gastrointestinal disorders including diarrhoea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache, and tension headache. The most common adverse reactions leading to discontinuation during the first

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

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

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

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

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

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Date of preparation: August 2019
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#PAINNOFILTER

A bold campaign has been sparked to expose the painful reality faced by millions of people every day.

Tying in with World Arthritis Day's recent arrival on 12th October, the UK's leading arthritis charity, Versus Arthritis, has launched a striking social media campaign to expose the true reality for the millions of people in the UK living with conditions that cause persistent pain. It has been designed to challenge attitudes and break down the societal stigma that is currently preventing people in persistent pain getting the support and care they need and deserve.

Currently 18 million people are living with arthritis or related conditions in the UK, making it one of the biggest causes of incessant pain. As many as half of those individuals experience pain every day, and eight-in-10 (78 per cent) have stated that they experience pain 'most days'.

Despite its scale and impact, arthritis remains hidden. Research commissioned by the charity has revealed that as many as two-in-five people with arthritis (43 per cent) actively keep their condition from their loved ones. It has identified reasons as to why those living in pain often feel unable to speak openly about the impact it has on them:

- Society's dismissal: two-thirds (66 per cent) of people with arthritis don't tell people about their condition because they worry that they could be seen as 'whinging'
- Lack of understanding: half (50 per cent) of people with arthritis feel that those without the condition don't understand what it's like to live with
- Social media pressure: because of its 'filtered' nature, almost a third (30 per cent) of people with arthritis actively avoid going on social media

Liam O'Toole, CEO of Versus Arthritis, further explained, 'Millions of people with arthritis are living with pain every single day; the simplest of movements like standing, holding, walking or hugging are exhausting and excruciating. Yet we know as many as half of people with the condition hide their pain. That's not okay.'

'With #PainNoFilter we want to show people with arthritis they are not alone and they do not have to suffer in silence. And we want the public to recognise what it's like to live with persistent pain, so that more people get the help and support they desperately need and deserve.'

Donna Roberts, 50, was diagnosed with psoriatic arthritis aged 33. Delving into her everyday experience, she said, 'My energy levels are rarely high due to the fatigue that comes with my condition, but every day I get up, dress up, and am reminded how chronic pain can change lives. I don't let it stop me though, it might slow me down a bit but that's what planning is for. I practice self-care every day and adhere to my pain relief and treatment plans in order to have my life how I want.'

Commenting on the campaign, Donna added, 'Campaigns such as #PainNoFilter bring previously hidden, and misunderstood, illnesses into the mainstream. This is a wonderful thing! Since speaking out about my condition, my friends and colleagues now ask me how I am. Living with pain is much more common than we think and everyone is carrying something, so by speaking up about arthritis we not only lighten the load for ourselves, we do it for others.'

A FAST WORKER

The Medicspot virtual GP service is attracting record numbers of tourists and business travellers.

Lindsay & Gilmour Pharmacy Group, established in 1826 – making it one of the oldest independents in Scotland – now operates 31 pharmacies across the country.

With some of its pharmacies dominating prime city centre locations, tourists and business travellers are a vital and growing customer base. Philip Galt, Managing Director and Superintendent Pharmacist at the group is the driving force behind the early adoption of a number of innovations and recognises that advances in technology bring much-needed operational and financial efficiencies, as well as improving the patient experience.

Most recently, the chain has implemented a virtual GP service, Medicspot; turning its consulting rooms into in-house private GP surgeries. The Medicspot station holds a stethoscope, close examination camera, pulse oximeter, thermometer, and blood pressure monitor which allows doctors to perform full clinical examinations of patients via a two-way live video link.

Patients are guided by a remote doctor on how to use the diagnostic devices, and pharmacy staff are on-hand as needed. Philip believes

that the unique combination of video appointment with connected diagnostics, along with the simplicity of accessing the service, is the reason why it is attracting record numbers of tourists and business travellers. Patients follow a three-step process; they book appointments online or walk-in to the pharmacy, consult with and get examined by a private GP remotely, and pay for and collect prescriptions on their way out.

The group uses technology in this way to offer a quick, easy, convenient, and alternative way to access high-quality healthcare; attributes which the market value enormously. The virtual GPs in the consulting rooms treat 96 per cent of health conditions; they provide advice, referral notes, and sick letters if required at no additional cost.

Tourists or business travellers who have run out of essential medicine or fallen ill can now bypass the lengthy process of accessing NHS care and indeed the more costly option of traditional private doctor consultations which can run into hundreds of pounds per visit.

The pharmacy group confirms the innovative service has created an

important new revenue stream and it has benefited from a significant increase in footfall, OTC and retail sales.

The Medicspot service will be rolled out across other pharmacies within the group.

For more information, visit www.lindsayandgilmour.co.uk and www.medicspot.co.uk.



Philip Galt



GUIDING THE WAY

The 'Management of Symptoms in Adults with Heart Failure' was recently officially launched.

A significant number of patients are diagnosed with heart failure, and with an ageing population, the number of patients with heart failure is anticipated to continue to rise. However, despite this evidence no specific symptom guidance for end-of-life heart failure patients exists for healthcare professionals.

The Palliative Care Programme Board (Northern Ireland) have highlighted a national aim to improve the quality of life for those with palliative and end-of-life care needs, and to improve the experience of those important to them. The need to improve early patient identification, planning and guidance is furthermore highlighted as the need for palliative care is expected to increase by 26 per cent by 2040.

Due to the trajectory of the condition, patients with advanced heart failure can often have suboptimal palliative care management when compared to their peers suffering from cancer. This can often be equated to the disease itself which can make it more challenging for clinicians to identify

when a patient is approaching the end-of-life. As with many conditions, patients with heart failure will often have specific symptoms, implantable devices, and palliative needs related to their condition.

In light of this evidence, the Regional Heart Failure Forum, clinicians from across all five Health & Social Care Trusts, and British Heart Foundation Northern Ireland have collaborated to develop regional guidance to support symptom management at end-of-life for these patients, including advice for Implantable Cardioverter Device deactivation (ICD) at end-of-life.

For more information, visit www.bhf.org.uk/HFguidance and www.professionalpalliativehub.com/guidelines/northern-ireland-palliative-care-tools-guidance.

NEWS

MAKING THE LIST

A Dundee academic is among BBC's 100 Women 2019.

Dr Sarah Martins da Silva, of the University of Dundee, has been named on BBC's 100 Women 2019 list of inspiring and influential women from around the world.

The BBC list asks, 'What would the future look like if it were driven by women?' and features such globally-recognised names as climate change activist, Greta Thunberg, and footballer Megan Rapinoe among many others.

Dr da Silva, Senior Lecturer in Reproductive Medicine in the School of Medicine at Dundee, runs a translational research programme focussed around male infertility, sperm biology and drug discovery.

She said, 'I hope that we can harness science, technology, investment and innovation in male reproductive health to redress global inequalities and the current burden of fertility on women.'

'I am surprised but delighted to be included on the BBC 100 Women list. It will raise awareness of the leading work we are doing in Dundee in the area of male infertility.'

Dr da Silva is also an NHS Tayside honorary consultant gynaecologist based at Ninewells Hospital, Dundee. Her clinical activities include investigation and management

of fertility problems, including diagnostic ultrasound and all aspects of assisted conception. She runs sperm studies research clinics for couples affected by male factor infertility, azoospermia and unexplained fertilisation problems following IVF / IC



Dr Sarah Martins da Silva

AN AGE-OLD QUESTION

A study has suggested that the body's ageing process is accelerated by DNA changes.

DNA changes throughout a person's life can significantly increase their susceptibility to heart conditions and other age-related diseases, research suggests.

Such alterations – known as somatic mutations – can impact the way blood stem cells work and are associated with blood cancers and other conditions.

A study says that these somatic mutations and the associated diseases they cause may accelerate a person's biological age – how old their body appears – faster than their chronological age – the number of years they have been alive.

A study by scientists from the Universities of Edinburgh and Glasgow examined these changes and their potential effects in more than 1,000 older people from the Lothian Birth Cohorts, born in 1921 and 1936.

The LBCs are a group of people – now in their 80s and 90s – who sat intelligence tests as 11-year olds. They are some of the most-intensively studied research participants in the world.

Scientists studied people where the biological and chronological age was separated by a large gap. They found the participants with somatic mutations – around six per cent – had a biological age almost four years older than those with no alterations.

Experts have said that they will now explore the link between these DNA changes and biological ageing acceleration.

The study, published in Current Biology, was funded by Alzheimer's Research UK.

Dr Tamir Chandra, Group Leader at the University of Edinburgh's MRC Human Genetics Unit, commented, 'Previously, somatic mutations have largely been studied in cancer. Our findings suggest they play a role in other diseases, which will change the way we study disease risk.'

Struggling with a dependency issue?

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SPOTLIGHT ON: NOCTURIA

Mr Roland Morley, Consultant Urologist at Imperial College Healthcare NHS Trust, presents an analysis of nocturia, focussing on its repercussions, associations, and the key elements to the provision of safe and effective treatment.



Roland Morley

Nocturia is a complaint that the individual has to wake at night one or more times to void. In recent years, however, there has been growing recognition that it is a specific symptom in its own right, with wide-ranging pathophysiology. It also is associated with significant negative outcomes in terms of patient health and quality of life. (1)

Nocturia has historically been linked primarily to overactive bladder and benign prostatic obstruction, even though its main cause is nocturnal polyuria. Patients with nocturia are treated by healthcare providers from numerous different disciplines because nocturia is prevalent in many other conditions, such as cardiovascular

disease, diabetes, and OAB. However, the specific condition of nocturia is ignored by most specialities, and only rarely does it improve with treatment of other underlying conditions.

No single treatment can effectively treat nocturia. However, desmopressin is the only evidence-based pharmaceutical therapy for nocturia, but despite this the breadth of use in clinical practice is limited (2, 3) and patients with nocturia have to face delays in diagnosis before being diagnosed properly and treated with desmopressin, instead of other medication. (2) Reasons for this include the limited knowledge of clinicians regarding the drug and how to use it, and anxiety about safety, regardless of the evidence that with the available low-dose formulations, hyponatremia is extremely rare, even in older patients. (4, 5)

WHAT TESTS ARE REQUIRED?

Three-day bladder diaries, including sleep and wake-up time, as well as the next morning's first void, have been recommended as giving the optimal balance between compliance and reliability. (6)

The maximum voided volume, void frequency, and the ratio of nocturnal to 24-hour urine production are the most used diary parameters to study and assess nocturia. (7) A maximum voided volume of 350 mL is generally considered as reduced without real evidence to support this criterion. Causes of reduced voided volumes include an OAB and residual urine (secondary to obstruction or detrusor underactivity). A residual urine measurement is, therefore, part of the initial assessment of nocturia. When reduced voided volumes are seen, imaging, urodynamics, and occasionally cystoscopy are performed, as appropriate.

Excessive nocturnal or 24-hour urine output is diagnosed using a bladder diary. Nocturnal polyuria is diagnosed if more than one-third (>33 per cent) of the 24-hour urine volume is produced during the night in patients over 65 years, and after excluding patients with 24-hour polyuria (>40 mL/kg/d). This has a high sensitivity but low specificity.

Renal causes of polyuria include diseases such as nephrogenic diabetes insipidus and loss of different circadian rhythms of the kidney, for example, through ageing of the kidney. (8, 9) Nephrogenic diabetes insipidus can also be caused by some medications, including lithium. Renal failure can also lead to leg oedema with nocturnal polyuria as a consequence.

When (nocturnal) polyuria is found, it is possible to diagnose the

cause of the excess in urine output using renal function profiles. (8) These renal function profiles help in distinguishing whether the excess in urine production is due to an increase in free water clearance (vasopressin-related), osmotic diuresis (mainly salt, but can be urea (protein), glucose (diabetes), calcium (hypercalciuria), or lithium), or a combination. However, renal function profiles are only advised after the failure of desmopressin therapy, and for research purposes. In clinical practice, elevated free water clearance is the most frequent cause of nocturnal polyuria throughout the lifespan and increases with age. The second most frequent aetiology is an increased sodium clearance (e.g., due to excess intake, leg oedema, heart failure, hypertension, obstructive sleep apnoea and medication), and this also increases with age.

Vasopressin is the main water-regulating hormone in our body. Vasopressin deficiency and vasopressin resistance of nephrogenic (receptor) origin are the main mechanisms leading to a lack of antidiuretic response within the body. The result is 24-hour polyuria and polydipsia, known as diabetes insipidus, which is a rare condition diagnosed via a bladder diary and a low morning (fasting) serum and urine osmolality. An abnormal circadian rhythm of vasopressin is the main mechanism for nocturnal polyuria. (10, 11)

Sleep pathology, insomnia, and sleep disruption are well-known causes of nocturnal polyuria and nocturia (12, 13) and need to be diagnosed, especially as they are associated with morbidity and mortality. (14)

Both Parkinson's disease and restless legs syndrome are associated with nocturnal polyuria and a reduced bladder capacity due to OAB and sphincter dysfunction. (15, 16)

Hypertension is associated with nocturia and nocturnal polyuria (21) and the metabolic syndrome is strongly associated with nocturia and many conditions predisposing to nocturnal polyuria. (17, 18)

Heart failure often coincides with renal failure and correlates with increased mortality. Both conditions coincide with an elevated creatinine, and demand referral before initiation of desmopressin or timed diuretic therapy. (18, 19) In right-sided heart failure, fluid retention and swelling of the abdomen, legs, and feet occur. Oedema causes nocturnal polyuria and nocturia through resorption of fluid when supine (20, 21), resulting in an immediate excess in urine output and a delayed increase in atrial natriuretic polypeptide-related salt diuresis. A high intake of water, salt, or protein results in an increased excretion by the kidney and can result in nocturnal polyuria and nocturia.

Concomitant medication is often difficult to interrupt or change but might have an important impact on nocturia through increasing or decreasing diuresis, changing bladder function, or through interfering with sleep.

Calcium channel blockers increase salt excretion to lower blood pressure, but side-effects include leg oedema, which can potentially worsen nocturia when the oedema fluid is resorbed during the night.

Medications that typically increase diuresis are diuretics, all antihypertensive medication, progesterone, melatonin, lithium, and SGLT-2-inhibitors (antidiabetic patients). Medications that typically cause leg oedema are antidepressants (monoamine oxidase inhibitors, trazodone), antihypertensives (beta-blockers, clonidine, hydralazine, methyldopa, minoxidil and so on), antivirals (acyclovir), hormones (sex hormones), NSAIDs (celecoxib, ibuprofen), and some chemotherapeutics and cytokines.

Continued onto next page

NOCTURIA

TREATMENT

The following conditions are a contraindication for desmopressin:

- Congestive heart failure
- Polydipsia
- Concomitant medication with a high-risk of hyponatremia

Desmopressin for nocturia is contraindicated in patients with mild (class II) to severe (class IV) congestive heart failure or uncontrolled hypertension, and there is ample evidence that treating heart conditions, increasing physical activity, salt restriction, losing weight, and preventing oedema treats nocturia. (2) In people with moderate cardiac failure, this condition should be treated before any attempt to address nocturia.

High-risk medications for hyponatremia are thiazide diuretics, lithium, valproate, and carbamazepine (23) and use of these should be considered as a contraindication for desmopressin therapy. Low-to-moderate risk medications for hyponatremia are loop diuretics, antidepressants, ACE-inhibitors, and angiotensin-II-receptor blockers. These can be used concomitantly with desmopressin after consideration of the other factors and comorbidities.

There is ample evidence that treating heart conditions, increasing physical activity, salt restriction, losing weight, and preventing oedema treats nocturia. (6)

Lifestyle interventions aim to prevent rather than treat renal disorders. Salt, protein, and caloric restriction are advised in patients with renal failure but there is no evidence of its effect on nocturia.

Desmopressin can have some effect in partial nephrogenic diabetes insipidus but is not the primary choice in patients with

severe renal failure as the risk of hyponatremia is much higher. In patients with low-to-moderate renal failure, as is seen in the older population, a loss of circadian rhythms in diuresis is found and these patients are potentially good candidates for desmopressin therapy.

Limiting excess fluid intake and changing the type of fluid is advised and from a theoretical point of view, a protein-rich and fat / carbohydrate-restricted diet might increase urine output as well as reduce it in the longer-term via weight loss. A well-balanced calorie-restricted diet is the most logical approach to avoid high excretion of urea and salt in patients with nocturia.

Patients with nocturnal polyuria due to a blunted increase in atrial polypeptide secretion at night, leading to an increase in free water clearance, are good candidates for desmopressin therapy. (23)

Patients with 24-hour polyuria due to central diabetes insipidus (in which production of the hormone is compromised) are also effectively treated with desmopressin. (24)

In older people with nocturnal polyuria and nocturia, the underlying condition should be treated first including bladder outflow obstruction in men and the overactive bladder with / without detrusor activity.

INITIATING DESMOPRESSIN TREATMENT

Nocturnal polyuria due to reduced nocturnal vasopressin is the primary target for desmopressin. Salt-related nocturnal polyuria is associated with other causes such as sleep apnoea (the primary target for CPAP), oedema, obesity, hypertension, heart failure, and high salt intake. There is level 1a evidence that desmopressin and CPAP treat nocturia. (3)

Table 1: Prescribing Information for Different Desmopressin Formulations Indicated for Nocturia

	Desmopressin 0.2 mg Tablets	Nasal Spray 0.83 – 1.66 mcg/0.1ml	Sublingual 25 - 50 mcg
Contraindications	Congestive heart failure Polydipsia Medication with high-risk of hyponatraemia	Congestive heart failure Polydipsia Medication with high-risk of hyponatraemia	Congestive heart failure Polydipsia Medication with high-risk of hyponatraemia
Indications	Nocturia Nocturnal polyuria	Nocturia Nocturnal polyuria	Nocturia Nocturnal polyuria
Age for Baseline Sodium Checks and Follow-up	65	65	65
Fluid Restriction	Restrict	Moderation advised	Restrict 1 h before to 8 h after administration
GFR (Lower Limit for Prescribing)	60	50	50-60
Sodium Checks After Baseline (≥65 y)	3 days and after up-titration	Within 7 days and after up-titration	4-8 days, 1 month, every 3 to 6 months, depending on clinical need
Cardiovascular Contraindication	Cardiac insufficiency or conditions requiring diuretics	Class II or higher CHF	Heart failure, oedema
Frail Elderly	Contraindicated	Use with caution	Use with caution

Women are more prone to hyponatremia.

With earlier formulations of desmopressin (0.2 mg tablets), hyponatremia was seen mainly in older populations, leading to a restriction in use to those below 65 years of age. Low-dose therapy to provide an antidiuretic effect of six-to-eight hours is beneficial to treat the older (especially female) population. Low-dose therapy is advisable in older (but not frail) patients and serum sodium monitoring is needed; such

monitoring can be individualised depending on patient-specific factors (e.g., age, concomitant medication) and comorbidities. Frail older patients with bothersome nocturia and comorbidities or other risk factors should first be treated for other issues and comorbidities and then, if still required, desmopressin should be initiated with careful monitoring.

Young, healthy patients can be treated with any licensed desmopressin formulation.

FOLLOW-UP OF DESMOPRESSIN THERAPY

There are various approaches to sodium monitoring in the literature. Before starting therapy, baseline sodium levels must be obtained in patients at risk for hyponatremia.

There is some evidence that a sodium monitoring plan should begin with a baseline sodium ≥ 135 mmol/L with additional testing at week one and month one after initiation of desmopressin in patients who are at increased risk (e.g., due to older age, or concomitant medications). Beyond one year, there is no consensus on follow-up required.

If the response to desmopressin is insufficient at a low-dose, there is consensus that the dose should be up-titrated depending upon the frailty of the patient. If the dose is up-titrated and further sodium checks are appropriate, these should be carried out within seven days. (Table One)

If hyponatremia is found after initiating desmopressin therapy, treatment should be discontinued when a serum sodium concentration is below 130 regardless of the presence of symptoms. If a sodium check is between 130 and 135 and the patient is asymptomatic, treatment need not be discontinued but further checks or drug-free intervals or lowering the dose should be performed.

The monitoring of serum sodium in nocturia patients treated with desmopressin lacks sufficient evidence to produce good guidelines. As hyponatremia is rare in well-selected patients with the currently available low-dose formulations, producing strong evidence for a safety protocol will be difficult.

CONCLUSION

Desmopressin is a safe and effective treatment for nocturia and nocturnal polyuria with a safe side-effect profile

ABOUT THE AUTHOR

Roland is a Consultant Urologist at Imperial College Healthcare NHS Trust.

He is a member of the British Association of Urological Surgeons, a member of the International Continence Society, and Chair of the United Kingdom Continence Society. Roland is also a member of the British Association of Paediatric Urologists and has recently completed terms as President of the Urology Section of the Royal Society of Medicine, Chairman of the Specialist Advisory Committee for Urology, and Chairman of the British Association of Urological Surgeons' Section of Female Urology and Reconstruction.

Roland was previously Divisional Director of Surgery and Critical Care at the Kingston Hospital NHS Trust and Director of Medical Education.

His special areas of interest are female urology, paediatric urology and benign reconstruction of the genitourinary tract. Greater than 75 per cent of Roland's practice is now devoted to these aspects.

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DIABETES

THINKING ON THEIR FEET

How can diabetes affect your patients' feet? Emma Howard, Specialist Podiatrist and Team Leader, Oxford Health NHS Foundation Trust – on behalf of the Diabetes Research & Wellness Foundation – investigates, overviews what neuropathy is, and presents tips as to how individuals can keep their feet healthy.

WHAT IS NEUROPATHY?

Diabetic foot complications develop as a result of raised blood glucose levels over time and are of two main types.

Ischaemia happens when small blood vessels in the feet become partially blocked, leading to reduced blood supply to the feet.

Diabetic neuropathy occurs in people with type 1 and type 2 diabetes and is the commonest cause of loss of feeling in the leg.

Damage to the nerves results from erosion of the protective sheath surrounding the nerves. This can result from raised blood glucose levels disrupting the structure and function of the nerve, or reduced flow in small blood vessels supplying nerves in the feet.

Neuropathy can affect nerves throughout the body, but due to the long length of the nerves to the foot, damage occurs there first.

DIFFERENT SYMPTOMS AND TYPES OF NEUROPATHY

SENSORY DIABETIC NEUROPATHY

This neuropathy affects the nerves which carry messages from the skin, bones and muscles to the brain and is the most common. The changes usually happen in both feet at the same time and can progress from your toes to your feet and sometimes the legs, fingers and hands can be affected, although this is less common.

Symptoms can range from feelings of numbness or walking on cotton wool or sponges, to more severe symptoms like pins and needles, tingling, burning or small electric shocks. Symptoms are typically worse at night.

Sensory neuropathy can affect balance, but the main problem is the inability to feel damage to your feet, and sense pain associated with this. You could tread on a sharp object, or even burn your feet in hot water without your feet detecting pain to

tell you your foot is damaged. The lack of sensation can allow further damage to occur which may result in a foot ulcer.

AUTONOMIC NEUROPATHY

Autonomic neuropathy affects the nerves which control involuntary activity in the body. Damaged nerves can lead to more blood flowing to the foot. This results in a reduction of sweating and moisture in the foot. The skin will be warm but very dry. Overtly dry skin can lead to deep cracks in the skin, especially around the heels, and could lead to a foot ulcer (see Figure 2).

MOTOR NEUROPATHY

Small muscles in the foot could lose strength and size due to the loss of nerve function. This means that the toes start to claw and the arch of the foot becomes higher. As the foot changes shape more pressure is loaded on the bones under the foot and calluses can form.



Figure 1: The progress of the neuropathy is dependent on blood glucose control, but factors such as duration of diabetes, age, smoking, high blood pressure and high cholesterol also play a part



Figure 2: Overtly dry skin can lead to deep cracks in the skin and could lead to a foot ulcer

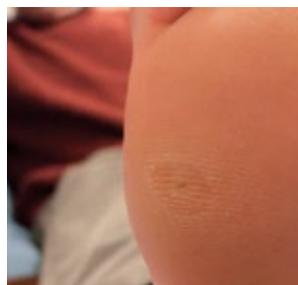


Figure 3: Your patients should never try to treat corns or hard skin themselves. They should see their podiatrist. If not treated, the pressure may lead to ulceration



Figure 4: If your patient has a wound which does not heal, they should see their podiatrist immediately

DIABETES

REDUCED BLOOD FLOW

Reduced blood flow (ischaemia) is caused by a process called atherosclerosis where small blood vessels within the foot develop thickened walls. Thickened walls means less blood flow to the foot. Ischaemia is exacerbated by raised blood glucose, high blood pressure, high cholesterol and smoking.

The absence of foot pulses will indicate that blood flow is reduced to the foot. Other symptoms which suggest ischaemia are cramp in the calves during exercise, which is relieved by rest, or pain in the feet when the feet are elevated. If your patient has neuropathy, symptoms are not always present, but signs such as cold feet or thin / discoloured skin may also indicate ischaemia.

DIAGNOSIS AND TREATMENT

Assessment of the feet for neuropathy should be carried out annually. This may be by a podiatrist or trained health professional. Tests include the use of a monofilament (a graded nylon filament applied to the foot), or using a tuning fork, which tests the perception of vibration.

Tests determine the presence of neuropathy and reduce the risk of foot ulcers developing.

Reduced blood supply to the foot should always be taken seriously.

Carefully managed exercise and stopping smoking are essential.

Medication for raised cholesterol and high blood pressure may also be appropriate.

TOP TIPS FOR HEALTHY FEET**CHECK FEET DAILY**

If your patient has poor sight, they should ask a family member or carer to help. They should look for colour change, swelling, damage to skin, heat, redness, discharge, and pain / discomfort.

HARD SKIN

Your patient should never try to treat corns or hard skin themselves (see Figure 3). A trained podiatrist will remove the callus or corn thereby

reducing pressure on the area. If not treated the pressure may lead to ulceration. Never apply corn plasters or acid preparations. They can burn the skin and cause a wound. Neuropathy or ischaemia makes you especially susceptible.

NAIL CARE

If your patient can easily cut their toenails, do not let diabetes stop them. Trim them straight across and file rough edges. If they suspect a deformity, infection or ingrown nails, they should consult a podiatrist.

FOOTWEAR

Your patient should always wear footwear for protection; feet are easily damaged when bare. They should check shoes and socks for foreign objects which cause skin damage and purchase well-fitting shoes.

HEAT

Your patient should check the temperature of water and avoid hot water bottles. Heat sources can burn the skin if neuropathy is present and a wound can develop.

SKIN CARE

Your patient should wash their feet daily and dry well between the toes to avoid athlete's foot. Skin can get very dry; they should apply moisturising cream daily, except between the toes.

HOLIDAYS

Your patient should apply sun cream to prevent burning and protect their soles of their feet from heat by wearing sandals. They should take a small first aid kit to treat wounds and seek advice if they don't heal (see Figure 4).

REMEMBER

Diabetic foot complications can be prevented, but without care will progress with time. The following measures can be advised to your patients to help prevent complications:

- Control diabetes as effectively as possible
- Attend foot screening
- Seek treatment for foot problems, such as corns and hard skin
- Don't trust the nerves in the foot if

they are damaged; your patient should trust their sight and their instincts

MORE INFORMATION

When looking for a podiatrist, remember that they all should be registered with the Health Care Professions Council.

Patients can search for a local podiatrist at www.cop.org.uk/find-a-podiatrist or ask your diabetes healthcare professional.

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Diabetes Research & Wellness Foundation

ABOUT THE DIABETES RESEARCH & WELLNESS FOUNDATION**STAYING WELL UNTIL A CURE IS FOUND**

Our aim is to raise awareness to all forms of diabetes so that people may take preventative actions where possible to avoid or delay the onset of type 2 diabetes and to access the support and guidance necessary to manage both type 1 and type 2 diabetes effectively.

The series of DRWF diabetes information leaflets can be requested by emailing enquiries@drwf.org.uk (quoting DRWFMEDCOM), or by calling 023 9263 7808.

You can also download the leaflets free of charge in PDF and audio format at www.drwf.org.uk/understanding-diabetes/information-leaflets.

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MENTAL HEALTH

MIND THE APP

For younger generations, embarrassment or social stigma surrounding mental health issues can so easily lead to confusion with what may be normal development, as opposed to the early progression of a mental health issue. As a result, intervention in teenage mental health issues is key – addressing the problems posed at an early stage. Demonstrating an innovative route for doing so, Dr Nihara Krause, Consultant Clinical Psychologist, and Founder and CEO of teenage mental health charity, stem4, depicts the impact of digital help for anxiety and depression in children and young people.

Recent research has confirmed a high prevalence of anxiety disorders and depression in children and young people (CYP). In fact, emotional disorders are the most prevalent psychiatric disorders experienced in childhood and adolescence. (1, 2)

They include a range of anxiety and depressive disorders, including generalised anxiety disorder, obsessive compulsive disorder, phobias, post-traumatic stress disorder, body dysmorphic disorder, and major depressive disorder. Anxiety disorders are more common than depressive disorders, but comorbidity for depression occurs in around 50 per cent of those who have anxiety.

A MULTI-LAYERED IMPACT

Emotional disorders affect self-esteem, interpersonal development, and cause significant distress impacting on a child or adolescent's general functioning (3) and quality of life through to adulthood. (4)

Anxiety disorders that start in childhood and adolescence often continue into adult life. (5) The Adult Psychiatric Morbidity Survey (6) carried out in 2014, and published in 2016, indicates that depression and anxiety disorders are also the most common mental health problems, affecting one-in-six of the adult population, while one-in-12 (8.1 per cent) five-to-19-year-olds have an emotional disorder. (2)

Childhood depression affects family, school, and social functioning (7), impacts on daily life (8), and is often reoccurring, especially in adulthood. (9) The lifetime prevalence of an anxiety disorder is 30 per cent.

There are a number of risk factors that underlie the possibility of developing an emotional disorder. According to NHS Digital (2017) (2), emotional disorders were more commonly found in girls than boys, with the highest rates of 22.4 per cent found among girls aged 17-to-19 years old.

CYP with special educational needs are more than three-times as likely as children without special educational needs to have an emotional disorder; while children whose parents have a mental illness were five-times more likely to be identified with

an emotional disorder. Anxiety disorders and depression are more common in CYP living in households with low income. In addition, emotional disorders have complex etiology comprising of a mixture of 'biopsychosocial' factors, thereby amenable to a range of treatments with 'no one size' fitting all.

WHY THE WAIT?

Anyone who experiences an anxiety disorder will tell you how acutely disabling it feels. However, even with such high prevalence and impact, anxiety disorders are under-diagnosed and under-treated in the UK. The NHS crisis in the provision of adequate mental healthcare is well-publicised. Years of underfunding have resulted in mental health services being poorly resourced. This creates a bottleneck for treatment; the long wait for treatment is also likely to lead to more complex problems, which in turn necessitates more specialist and longer-term intervention. The NHS is at breaking point, especially so in Child and Adolescent Mental Health Services (CAMHS).

stem4's recent survey (2018) (10) of 1,000 GPs found that most (90 per cent) think that mental health services for young people are inadequate, with nearly all (99 per cent) fearing that children in their care could come to harm while waiting for specialist treatment.

In such circumstances the NHS has had to unofficially perform triage when it comes to crisis-level mental health conditions. As a result, CYP suffering from anxiety disorders 'lose out'. Under current government funding proposals, new services to tackle rising mental ill health among CYP are being developed, but the wait is long in the face of an urgent need for good quality, comprehensive services. Even under these new funding proposals it's unlikely that a robust programme for anxiety disorders will be rolled out in the near future. Anxiety disorders are very responsive to early intervention in the form of evidence-based treatments, such as Cognitive Behaviour Therapy (CBT), but in many local areas services of this kind have been cut, denying young people access to expert treatment.

TAKING DIGITAL STRIDES

stem4 is a London-based, teenage mental health charity I founded seven years ago. It offers early detection through mental health education in secondary schools and early digital intervention.

Based on the requests made by many students, and awareness of need observed in the course of my own clinical practice, I developed Calm Harm for stem4 in 2017 – a mobile phone app to help young people manage their urge to self-harm.

Calm Harm helps by using strategies from evidence-based dialectic behaviour therapy, and aims to teach CYP impulse control, emotional regulation, and tracks underlying triggers to harmful urges. It also helps to self-monitor. Calm Harm has met NHS Clinical Governance standards to be included on the NHS app library.

Incredibly, in the 18 months since its launch, Calm Harm has had close to 900,000 downloads worldwide – promoted by young people for young people. It is mainly used by young people under the age of 19, and 93 per cent of them report that their urge to self-harm passed after each use of the app.

The self-reflection section indicates that the most common reason why CYP self-harm is because they 'feel sad'.

Scoring 4.7-out-of-five on the app store, many users write in with positive comments. One such comment includes, 'I would like to say a humongous thank you to the creators of the Calm Harm app. I've used it many times to avoid hurting myself and have recommended it to friends. It has helped massively and I find the coping strategies extremely helpful and they work very well. I also love how easily accessible everything is! It's all very organised and quick and easy. One of my favourite things about the app is that you do not need to be able to access Wi-Fi to use this so it's a massive help when I'm not at home. Again, a huge thank you to everyone who created and run this app, you've saved my life, literally! And I'm guessing so many more. You are the reason I'm still here guys and I will never ever be able to thank you enough. I love you all guys and once again, thank you.'

In 2018, based again on requests from young people and by the users of Calm Harm, I developed Clear Fear for stem4. This is an app to help CYP manage symptoms of anxiety using the principles of CBT. Clear Fear aims to provide CYP with tools to help them negotiate some of the challenges they may face. It does this by offering them relaxation training, self-monitoring, and ways of challenging negative thoughts and solving problems. It also harnesses the benefits of humour, provides them with inspirational quotes and examples of inspirational people, and endeavours to help them find the 'grit' they need to keep going when the going gets tough. Released in December 2018, it is too early to comment on uptake, but on the first day of release the reach on Facebook was 3,800.

While Calm Harm was initially developed through fundraising and then an NHS Digital grant to meet NHS app store requirements, Clear Fear has been part funded by a Tech for Good grant by Comic Relief and the Paul Hamlyn Foundation, as well as generous fundraisers. stem4 continues to want to offer the app free to CYP and is exploring various

models to monetise updates. In addition, there are plans to extend the stem4 library of self-help apps using the same formula – developed using a clinical framework and with ideas and input from young people.

While digital therapies should not be seen as a substitute for face-to-face engagement, assessment, and treatment, a handful of studies confirm that online CBT is as effective as face-to-face treatment for anxiety and depression. It therefore constitutes a first step in helping young people self-monitor and benefit from simple techniques for anxiety management. Calm Harm and Clear Fear may be of benefit to those CYP who do not reach the threshold for acceptance to CAMHS, for those who are on a waiting list, or to use in conjunction with treatment. stem4 will use app analytics as well as a research study to further confirm effectiveness.

For more information, visit www.stem4.org.uk, www.clearfear.co.uk, and tweet @clearfearapp.

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DIABETES

DIABETES: A STEP IN THE RIGHT DIRECTION

In light of diabetes' widespread incidence, the sector is increasingly motivated to address the associated risks for patients. With one particular landmark diabetes trial investigating renal and cardiovascular outcomes, Anna Strzelecka, SAS Doctor in Diabetes and Endocrinology, Antrim Area Hospital, Northern Health & Social Care Trust, discusses her involvement.

BACKGROUND

If not managed properly, diabetes can lead to serious complications, such as microvascular disease, including retinopathy and nephropathy, and macrovascular disease, including heart disease, stroke and peripheral vascular disease. (1)

It has been proven that patients with type 2 diabetes have a greater risk of cardiovascular (CV) death than patients without diabetes, whether or not they had experienced a previous myocardial infarction. (2, 3)

Atherosclerotic cardiovascular disease occurs 14.6 years earlier in type 2 diabetic patients when compared to the non-diabetic population, with greater severity and with more diffuse distribution. Furthermore, about two-thirds of deaths in people with diabetes mellitus are caused by CV disease: of these, around 40 per cent are from ischaemic heart disease; 15 per cent from other forms of heart disease, principally congestive heart failure; and around 10 per cent from stroke. (4)

Diabetes also remains the single most common cause of kidney failure. Almost four-in-five people with diabetes will develop kidney disease in their lifetime. 11 per cent of deaths in type 2 diabetes are caused by kidney disease. (5) 27.5 per cent of new cases needing dialysis or renal transplant are caused by type 2 diabetes. (6)

In recent years, several clinical trials showed positive effects of SGLT2 inhibitors on CV outcomes. The CANVAS study showed that patients treated with Canagliflozin had significantly lower rates of the primary CV outcome than patients receiving placebo. The results also showed a possible benefit of Canagliflozin in respect to the progression of albuminuria and the composite outcome of a sustained 40 per cent reduction in the eGFR, the need for renal-replacement therapy, or death from renal causes and further evaluation of effects of Canagliflozin on renal disease was advised. (7)



Anna Strzelecka

DISCUSSION

In 2014 the first patient was randomised to take part in the CREDENCE study, and in November 2015 Antrim Area Hospital was accepted as one of the study sites.

The goal of this double-blind, randomised trial was to assess whether Canagliflozin has a renal and vascular protective effect in reducing the progression of renal impairment relative to placebo in participants with type 2 diabetes mellitus (T2DM), stage 2 or 3 chronic kidney disease and macroalbuminuria, who are receiving standard of care, including a maximum tolerated labeled daily dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker.

PRIMARY ENDPOINT

Composite outcome of ESKD, doubling of serum creatinine, or renal or CV death.

SECONDARY ENDPOINTS

- CV death or hospitalisation for heart failure
- Major CV events (three-point MACE: CV death, MI, or stroke)
- Hospitalisation for heart failure
- ESKD, doubling of serum creatinine, or renal death
- CV death
- All-cause mortality
- CV death, MI, stroke, hospitalisation for heart failure, or hospitalisation for unstable angina (8)

INCLUSION CRITERIA

- Age >30 years
- Type 2 diabetes mellitus with a hemoglobin A1c (HbA1c) greater than or equal to (\geq) 6.5 per cent and less than or equal to (\leq) 12.0 per cent with an estimated glomerular filtration rate (eGFR) of \geq 30 milliliter

(mL)/minute (min)/1.73meter (m)² and less than ($<$) 90 mL/min/1.73 m²

- Participants need to be on a stable maximum tolerated labelled daily dose of an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) for at least four weeks prior to randomisation
- Must have a urine albumin to creatinine ratio (UACR) of greater than ($>$) 300 milligram (mg)/gram (g) and \leq 5000 mg/g

EXCLUSION CRITERIA

- History of diabetic ketoacidosis or type 1 diabetes mellitus
- History of hereditary glucose-galactose malabsorption or primary renal glucosuria
- Renal disease that required treatment with immunosuppressive therapy
- Known significant liver disease
- Current or history of New York Heart Association class IV heart failure
- Blood potassium level $>$ 5.5 millimole (mmol)/liter (L) during screening (8)

There were 34 countries involved, with 690 sites that randomised 4,401 participants. 118 participants were randomised in the UK, with eight in Antrim Area Hospital, making it one of the top recruiting sites in the UK. 2,202 were randomised to the Canagliflozin 100mg group, and 2,199 to the placebo group.

The trial was stopped early after a planned interim analysis reviewed by an independent data monitoring committee. Median follow-up was 2.62 years.

The relative risk of the primary outcome was 30 per cent lower in the Canagliflozin group than in the placebo group, with event rates of 43.2 and 61.2 per 1,000 patient-years, respectively (hazard ratio, 0.70; 95 per cent confidence interval, 0.59 to 0.82; $P=0.00001$).

The relative risk of the renal-specific composite of end-stage kidney disease, a doubling of the creatinine level, or death from renal causes, was lower by 34 per cent (hazard ratio, 0.66; 95 per cent CI, 0.53 to 0.81; $P<0.001$), and the relative risk of end-stage kidney disease was lower by 32 per cent (hazard ratio, 0.68; 95 per cent CI, 0.54 to 0.86; $P=0.002$). The Canagliflozin group also had a lower risk of CV death, myocardial infarction, or stroke (hazard ratio, 0.80; 95 per cent CI, 0.67 to 0.95; $P=0.01$) and hospitalisation for heart failure (hazard ratio, 0.61; 95 per cent CI, 0.47 to 0.80; $P<0.001$).

There were no significant differences in rates of amputation or fracture. (9)

CONCLUSION

It is fascinating to see such an advance in the development of oral glycaemic agents. SGLT2 inhibitors not only proved to improve glycaemia, but have the added benefits of blood pressure and weight reduction along with CV benefits. They also reduce the risk of developing end-stage renal disease in patients with significant kidney disease and albuminuria.

In recent time ADA/EASD guidelines have been changed as well as SIGN guidelines. The NICE guideline update is awaited. It is now advised to use agents that showed CV and renal benefits earlier especially in patients with CV and renal disease.

At present SGLT2 inhibitors are licenced to be initiated only if eGFR is over 60 and can be continued at lower dose as long as eGFR remains above 45. Hopefully the licence of Canagliflozin will change in the near future and will allow the use of this agent in patients with more advanced renal disease.

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BEREAVEMENT

AT A LOSS FOR WORDS

When a baby or child dies, or a child is bereaved, lives are shattered, and healthcare professionals often play a pivotal part in helping families through their loss. Child Bereavement UK shed light on how the professionals providing a helping hand need to be supported themselves in order to be effective in what can be emotionally-challenging work.



The feelings of isolation, confusion, helplessness and pain experienced by someone who is bereaved can't be overstated. Having someone who is experienced in supporting bereaved families, who can listen, and help reassure you that your, sometimes, overwhelming response to the death of your child or partner is normal, can be a lifeline. Supporting families when a baby, child, or parent has died can be emotionally very challenging. Yet professionals often feel that they should demonstrate strong emotional control when working with bereaved families and may mistakenly feel that it's a weakness to show their emotions.

Child Bereavement UK support families and educate professionals both when a baby or child of any age dies or is dying, and when a child is facing bereavement. Bereaved families supported by the charity frequently tell us that it's helpful when professionals are able to show their own humanity. They appreciate the acknowledgement of their loss, and professionals who can 'sit with and hold' the distress of the family, and then offer information, support and signposting according to their needs.

The most important thing that a professional can do is to listen. Listening involves much more than just hearing; it involves using all our senses to pick up on what the person is communicating, both verbally and non-verbally, giving our undivided attention to the other person and noticing not only what is being said, but also what is not being said.

Active listening of this kind is important, but it can be hard to do.

Sarah Harris, Director of Bereavement Support and Education at Child Bereavement UK, explained, 'It is important not to underestimate the toll on the practitioner who is working with families who are grieving, and, understandably, many professionals are uncomfortable around the issues of death and bereavement.

'The need for support for yourself is not a sign of professional inadequacy or personal weakness, but rather a sign of maturity, recognising that you need help to do this work well. Most professional carers are very good at caring for others, but far less good at caring for themselves or for each other.'

David Trickey, Consultant Chartered Clinical Psychologist, who works with Child Bereavement UK to deliver training for professionals, added, 'Tea pots need to be refilled if they are to carry on pouring cups of tea. Professionals and volunteers need to be cared for and supported if they are to carry on caring and offering support. Most people know this, but few actually do anything about it. Child Bereavement UK address this crucial aspect of bereavement care through its resources, courses, and helpline.'

Child Bereavement UK's training for professionals encourages reflective practice in which feelings and experiences are shared

with others involved in supporting bereaved families. Reflecting on, and being aware of, our reactions to situations helps professionals to better understand their own strengths and weaknesses. There are no 'set answers' or ways of dealing with situations; professionals are continually learning from bereaved families and discovering new ways to help support them. It advocates that enabling health professionals to access the support they need is an important part of empowering them to support bereaved families, and that professionals working in this field need to feel supported and valued. In recognition of this, Child Bereavement UK have developed a full day workshop, considering the impact on healthcare professionals when a child dies, and the charity also facilitates reflective practice, consultation and debriefing sessions.

In addition, a masterclass 'Eight Pillars of Strength: Supporting Families, Individuals and Ourselves' has been developed by Child Bereavement UK's founder patron, and author of Grief Works, Julia Samuel.

Professionals who attend the charity's training have said that they benefit from the chance to reflect with others on their work and the impact it has on them. A bereavement support professional said, 'It was great to have a study day which acknowledges how our work can, and does, affect us, and also to think about how we can help ourselves and each other.'

For more information about supporting yourself and Child Bereavement UK's training for professionals, visit www.childbereavementuk.org/for-professionals.

For guidance and support for professionals supporting bereaved families, call Child Bereavement UK's helpline on 0800 02 888 40.



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

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