



Autumn 2019
Issue 18

Primary Care Respiratory Update



Edition Highlights

- FeNO testing for asthma diagnosis: PCRS consensus
- PCRS guide to poorly controlled and severe asthma triggers for referral
- Role of e-cigarettes as a tool to support smoking cessation
- 10 top tips for achieving the respiratory element of the long term plan



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¹ Friedrich P, Ledermüller R, Perera A, Novel hot-wire based spirometry is highly accurate at low flow rates, Current Directions in Biomedical Engineering 2018; 4(1): 513-515

² Dormeyer C et al 2014, Allergologie, 37(4), 1613

³ NICE Guideline Asthma: diagnosis, monitoring and chronic asthma management (2017)

⁴ SIGN 158: British guideline on the management of asthma (2019)

Primary Care Respiratory Update

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Method of Administration: Dissolve NACSYS 600mg, effervescent tablets in half a glass of water to produce a solution that can be consumed immediately. Patients with a reduced cough reflex (elderly and weakened patients) are advised to take the tablet in the mornings.

Contraindications: Hypersensitivity to acetylcysteine or to any of the excipients. The tablets should not be used by children under two years of age.

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Interactions: Antitussive drugs and acetylcysteine should not be administered concomitantly; activated charcoal may reduce the effect of acetylcysteine; it is precautionary to advise the administration of oral antibiotics at least two hours before or after acetylcysteine; concurrent administration of acetylcysteine with nitro glycerine may enhance its vasodilatory effect. Acetylcysteine can interfere with the colorimetric assay for the determination of salicylates.

Pregnancy & Lactation: If necessary NACSYS 600mg may be used during pregnancy and lactation although there are limited data about its use.

Undesirable effects: Common (>1/100) undesirable effects have not been reported. Uncommon (≥1/1000, <1/100) Hypersensitivity headache; tinnitus; tachycardia; hypotension, gastrointestinal reaction (vomiting, diarrhoea, stomatitis, abdominal pain, nausea); fever. Rare (> 1/10000 < 1/1000): dyspepsia; Very rare (<1/100000): anaphylactic shock, anaphylactic reaction, haemorrhage; Serious skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome have very rarely been reported in temporal connection with the use of acetylcysteine. Prescribers should consult the Summary of Product Characteristics in relation to other adverse effects.

Reporting adverse effects: Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Atlantic Pharma at safety@atlanticpharma.co.uk and 0845 5191 609

NHS price: £5.50 for a pack of thirty effervescent tablets.

Legal classification: POM

Distributor: Atlantic Pharma, 25a Becher Close, Renhold, MK41 0LP

MA number: PL 31388/0006

Date of revision of the text: 01/09/2017 AL0001

Ref:

1. MIMS. Accessed on 1st October 2018 at <https://www.mims.co.uk>
2. GOLD guidelines 2018. Accessed on 1st October 2018 at <http://goldcopd.org/>
3. SmPC NACSYS. Accessed at <http://mhra.gov.uk/spc-pil/>



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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 expected 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 medicalinformation@napp.co.uk. FLUTIFORM is a registered trademark of Jagotec AG, and is used under licence. K-HALER is a registered trademark of Mundipharma AG. © 2018 Napp Pharmaceuticals Limited. UK/FLUT-K-18011 Date of Preparation: May 2018

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

References: 1. Mundipharma International Limited. flutiform k-haler. Summary of Product Characteristics. Available from: <https://www.medicines.org.uk/emc/product/9483/smpc>. Last accessed August 2019. 2. MIMS. Available from: www.mims.co.uk/search/drugs?keywords=Beta 2 agonists, long-acting/corticosteroids. Last accessed August 2019. 3. Bell D et al. J Aerosol Med Pulm Drug Deliv 2017; 30:425-34. 4. <https://www.medicines.org.uk/emc/product/9412/pii> UK/FLUT-K-19022 Date of preparation: August 2019

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NAPP
RESPIRATORY

Editor's Round-Up

Dr Iain Small, *Editor Primary Care Respiratory Update*



All of us here at *PCRU* hope you've had a great summer and are ready to come back refreshed and ready to treat, teach and learn. A special mention must go to PCRS Executive former chair, Stephen Gaduzo of Whaley Bridge for (almost literally) allowing an RAF Chinook to land in his front garden in early August. Not everyone has a lake at the bottom of their garden, and neither (now sadly) does Stephen. Praise must be given to residents and emergency services alike for their efforts and endurance.

This edition of *PCRU* has a flavour of 'out with the old and in with the new', as it is the last one in which we will feature Noel Baxter's thoughts and reflections from the Chair.

His successor is fast off the mark though with her superb and clinically invaluable consensus article on the use of fractional exhaled nitric oxide (FeNO) in clinical practice.

As Noel heads off to the Policy wing of PCRS, it's sad to say goodbye to Bronwen Thompson, who has been a respected and valued colleague in the policy team for more years than either of us would care to remember. We will miss her, but welcome to the policy team Tracey Lonergan, who has pitched in for this edition's policy update.

I would encourage you to pay close attention to Darush Attar Zedah's paper on e-cigarettes. If you are looking for something sensible to say to enquiring patients or colleagues on this thorny issue, then look no further.

We also have a very topical piece on difficult asthma, a hard-hitting and thought-provoking contribution from a patient talking to Fran Robinson about why they hate asthma reviews, as well as our usual staples of round-ups from around the Society's portfolio and our pick of the journals in Journal Watch.

Finally, as September knocks on the door as ever, it's time to look forward to the best conference of the year, so pack your clever clogs and your dancing shoes and head off to Telford. We will see you there.



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Fostair® NEXThaler 100/6 now licensed for MART¹

Fostair® — the only extrafine formulation for adult
asthma patients requiring an ICS/LABA combination²

MART = Maintenance and Reliever Therapy

Fostair® maintenance and reliever therapy should especially
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- not fully controlled asthma and in need of reliever medication
- asthma exacerbations in the past requiring medical intervention

ICS = Inhaled corticosteroid

LABA = Long-acting β_2 -agonist

Full indication can be found within the Prescribing Information

Fostair 100/6 and 200/6 Prescribing Information

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

Presentation: Each Fostair pressurised metered dose inhaler (pMDI) 100/6 dose contains 100 micrograms (mcg) of beclometasone dipropionate (BDP) and 6mcg of formoterol fumarate dihydrate (formoterol). Each Fostair pMDI 200/6 dose contains 200mcg of BDP and 6mcg of formoterol. Each Fostair NEXThaler 100/6 dry powder inhaler (DPI) dose contains 100mcg of BDP anhydrous and 6mcg of formoterol. Each Fostair NEXThaler 200/6 DPI dose contains 200mcg of BDP anhydrous and 6mcg of formoterol. **Indications: Asthma:** Regular treatment of asthma where use of an inhaled corticosteroid/long-acting beta₂-agonist (ICS/LABA) combination is appropriate: patients not adequately controlled on ICS and as needed short-acting beta₂-agonist, or patients already adequately controlled on both ICS and LABA. **COPD (Fostair 100/6 only):** Symptomatic treatment of patients with severe COPD (FEV₁ <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. **Dosage and administration:** For inhalation in adult patients (≥ 18 years). **Asthma: Maintenance And Reliever Therapy (Fostair 100/6 only)** can be taken as a regular maintenance treatment and as needed in response to asthma symptoms: 1 inhalation twice daily plus 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation is recommended. The maximum daily dose is 8 inhalations. Fostair 100/6 may also be used as maintenance therapy (with a separate short-acting bronchodilator as needed). Fostair 200/6 should be used as maintenance therapy only. **Maintenance therapy:** Fostair 100/6: 1–2 inhalations twice daily. Fostair 200/6: 2 inhalations twice daily. The maximum daily dose is 4 inhalations. Patients should receive the lowest dose that effectively controls their symptoms. **COPD (Fostair 100/6 only):** 2 inhalations twice daily. Fostair pMDI can be used with the AeroChamber Plus[®] spacer device. BDP in Fostair is characterised by an extrafine particle size distribution which results in a more potent effect than formulations of BDP with a non-extrafine particle size distribution (100mcg of BDP extrafine in Fostair are equivalent to 250mcg of BDP in a non-extrafine formulation). When switching patients from previous treatments, it should be considered that the recommended total daily dose of BDP for Fostair is lower than that for non-extrafine BDP containing products and should be adjusted to the needs of the individual patient. However, patients who are transferred between Fostair NEXThaler and Fostair pMDI do not need dose adjustment. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Warnings and precautions:** Use with caution in patients with cardiac arrhythmias, aortic stenosis, hypertrophic obstructive cardiomyopathy, ischaemic heart disease, severe heart failure, congestive heart failure, occlusive vascular diseases, arterial hypertension, severe arterial hypertension, aneurysm, thyrotoxicosis, diabetes mellitus, phaeochromocytoma

and untreated hypokalaemia. Caution should also be used when treating patients with known or suspected prolongation of the QTc interval (QTc > 0.44 seconds). Formoterol itself may induce QTc prolongation. Potentially serious hypokalaemia may result from beta₂-agonist therapy and may also be potentiated by concomitant treatments (e.g. xanthine derivatives, steroids and diuretics). Formoterol may cause a rise in blood glucose levels. Fostair should not be administered for at least 12 hours before the start of anaesthesia, if halogenated anaesthetics are planned as there is risk of arrhythmias. Use with caution in patients with pulmonary tuberculosis or fungal/viral airway infections. Increase in pneumonia and pneumonia hospitalisation in COPD patients receiving ICS. Clinical features of pneumonia may overlap with symptoms of COPD exacerbations. Fostair treatment should not be stopped abruptly. Medical attention should be sought if treatment ineffective. Treatment should not be initiated during exacerbations or acutely deteriorating asthma. Fostair treatment should be discontinued immediately if the patient experiences a paradoxical bronchospasm. Fostair is not intended for initial management of asthma. Systemic effects of ICS may occur, particularly at high doses for long periods, but are less likely than with oral steroids. These include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression and aggression. Consider referral of patients reporting blurred vision or visual disturbances to an ophthalmologist as causes may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy. Prolonged treatment with high doses of ICS may result in adrenal suppression and acute adrenal crisis. Lactose in Fostair NEXThaler contains small amounts of milk proteins, which may cause allergic reactions. **Interactions:** Possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded and therefore caution and appropriate monitoring is advised. Beta-blockers should be avoided in asthma patients. Concomitant administration of other beta₂-adrenergic drugs may have potentially additive effects. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines, monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants can prolong the QTc interval and increase the risk of ventricular arrhythmias. L-dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance towards beta₂-sympathomimetics. Hypertensive reactions may occur following co-administration with MAOIs including agents with similar properties (e.g. furazolidone, procarbazine). Concomitant treatment with xanthine derivatives, steroids or diuretics may potentiate a possible hypokalaemic effect of beta₂-agonists. Hypokalaemia may increase the likelihood of arrhythmias in patients receiving digitalis glycosides. Presence of ethanol in Fostair pMDI may cause potential interaction in sensitive patients taking metronidazole or disulfiram. **Fertility, pregnancy and lactation:** Fostair should only be used during pregnancy or lactation if the expected benefits

outweigh the potential risks. A risk/benefit decision should be taken to discontinue/abstain from therapy in the mother or discontinue breastfeeding. **Effects on driving and operating machinery:** Fostair is unlikely to have any effect on the ability to drive and use machines. **Side effects: Common:** pneumonia (in COPD patients), pharyngitis, oral candidiasis, headache, dysphonia, tremor. **Uncommon:** influenza, oral fungal infection, oropharyngeal candidiasis, nasopharyngitis, oesophageal candidiasis, vulvovaginal candidiasis, gastroenteritis, sinusitis, rhinitis, granulocytopenia, allergic dermatitis, hypokalaemia, hyperglycaemia, hypertriglyceridaemia, restlessness, dizziness, otosalginitis, palpitations, prolongation of QTc interval, ECG change, tachycardia, tachyarrhythmia, atrial fibrillation, sinus bradycardia, angina pectoris, myocardial ischaemia, blood pressure increased, hyperaemia, flushing, cough, productive cough, throat irritation, asthmatic crisis, exacerbation of asthma, dyspnoea, pharyngeal erythema, diarrhoea, dry mouth, dyspepsia, dysphagia, burning sensation of the lips, nausea, dysgeusia, pruritus, rash, hyperhidrosis, urticaria, muscle spasms, myalgia, C-reactive protein increased, platelet count increased, free fatty acids increased, blood insulin increased, blood ketone body increased, blood cortisol decreased, oropharyngeal pain, fatigue, irritability, cortisol free urine decreased, blood potassium increased, blood glucose increased, ECG poor r-wave progression. **Rare:** ventricular extrasystoles, paradoxical bronchospasm, angioedema, nephritis, blood pressure decreased. **Very rare:** thrombocytopenia, hypersensitivity reactions, including erythema, lips, face, eyes and pharyngeal oedema, adrenal suppression, glaucoma, cataract, peripheral oedema, bone density decreased. **Unknown frequency:** psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes, blurred vision. (Refer to SPC for full list of side effects). **Legal category:** POM **Price and Pack:** £29.32 1x120 actuations **Marketing authorisation (MA) No(s):** PL 08829/0156, PL 08829/0175, PL 08829/0173, PL 08829/0174 **MA holder:** Chiesi Ltd, 333 Styal Road, Manchester, M22 5LG. **Date of Preparation:** Aug 2018. AeroChamber Plus[®] is a registered trademark of Trudell Medical International.

Adverse events should be reported.

Reporting forms and information can be found at
www.mhra.gov.uk/yellowcard or search for MHRA
Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Chiesi Ltd
on 0800 0092329 (UK), 1800 817459 (IE)
or PV.UK@Chiesi.com.

References

1. Fostair® NEXThaler 100/6 Summary of Product Characteristics. Chiesi Limited. 2. MIMS Online. 2018. Available at www.mims.co.uk Accessed October 2018.

CHNEX20181764. Oct 18.

Outgoing Chair's Perspective

Noel Baxter, *PCRS Executive Chair*



This is my last Chair's Perspective for *PCRU* and a good time to reflect on the last 3 years and to welcome Carol Stonham to the privileged position of Chair of PCRS Executive for the next 3 years, when I expect the Society to go from strength to strength under her leadership.

You will see from the Policy Update and PCRS News in this print edition of the publication that I will now be working as the Executive Policy Lead for PCRS, working very closely with Tracey Lonergan as policy co-ordinator. We are taking over the reins from Duncan Keeley, GP in Oxfordshire, and Bronwen Thompson, and hope to maintain and strengthen the impact on national respiratory policy at which they have both been so successful. Duncan has been supported over many years by Kevin Gruffydd Jones, GP in Wiltshire, who remains active in the Society, and both Duncan and Kevin will continue to support us as members of our wider policy forum. I also welcome Amanda Roberts and Graham Ryott from our Lay Reference Group (LRG) to the policy forum. Working with the LRG to develop its role and position within our Society has, for me, been one of the highlights of my term. Graham has recently joined along with Shakeela Riaz, strengthening our LRG further. The LRG will have a stand at this autumn's conference, so do check in with them.

In the last year we have also had unprecedented levels of people applying to be members of our committees. To me, this is a sign of how relevant we now are to a broad range of health professionals from across all disciplines of those involved in respiratory care, including commissioners and from across the UK.

Looking at this edition I can see a lot of the work we have been doing over recent years

coming to fruition, and the content also reflects the changing environment to which the Society must respond. The management of severe asthma has been a key campaign of our partner patient charity, Asthma UK. As a Society, we have seen the increasing need to help colleagues in our primary and community care system to recognise this asthma type and act appropriately to help them get the right care. Whilst we look to our BTS and ARNS colleagues and specialists to manage this problem, it is a key improvement area for general practice to learn to take a broader view of its asthma register and think about who needs a different approach.

I am also delighted to see an article by Stuart Shields providing top ten tips for the new clinical directors of primary care networks in England and looking at how to deliver on the respiratory element of the long-term plan. We now have a very strong service development committee led by Daryl Freeman, who will be driving forward key projects such as the Respiratory Service Framework.

Our respiratory leadership programme goes from strength to strength and I see people who have come through this programme making a real difference locally and more widely, with Jackie Dale and Siobhan Hollier featuring in this edition.

In my time as Chair, the diversification of the workforce has accelerated with pharmacists now embedded not only in clinical practice in primary care but also featuring as key leaders within our organisation, with new appointments to our executive and primary committees over the last 3 years. In response to this change in workforce, some years ago Ren Lawlor from our Education Committee wrote the 'Fit to Care' document that has now become the

go-to resource for system leaders and health professionals wanting to describe and plan for respiratory education, something Carol Stonham discusses in this edition.

The three core areas of interest for this Society have been and continue to be asthma, COPD and tobacco dependency. During the last 3 years we have worked hard to make sense of multiple guidelines and sometimes confusing messages for our health professional audience and delivered pragmatic guidance in all three areas that we continue to keep up to date. One of our policy campaigns has been to persuade BTS, SIGN and NICE to come together to help support people on the ground with clear advice about diagnosing and managing asthma. We were therefore delighted at the announcement this summer that a project between them to design an asthma pathway has been agreed and we expect to hear more on this at the Winter BTS meeting.

The outgoing Chair of Trustees Patrick White challenged me as incoming Chair of the Executive 3 years ago about the relative strength of research within the Society. I hope and am sure that many will recognise how we have encouraged and recruited some really excellent leaders in research to our society and re-energised this important element of our work, and I would like to thank Helen Ashdown who has driven this forward for us. It is pleasing that in recent months we have seen the PACE trial published in the *NEJM*, which will be a game changer for prescribing antibiotics in people with worsening symptoms in COPD. People attending the 2018 Conference will have seen an early abstract related to this work that won the research prize, demonstrating that the PCRS Conference is now a place to come and share quality research.

It has been a privilege to be chair of PCRS Executive and we have exciting times ahead, now that respiratory care is a focus

on a national agenda in a way that has never been seen before.

As many of you know, Carol will achieve two firsts when she takes over the reins at conference this year. She will be the first woman to chair the PCRS Executive and also the first nurse to take the role of Chair of the PCRS Executive, serving to highlight not only the increasing diversity of professions within PCRS but also the trail-blazing passion she holds for respiratory care. I am delighted that Carol, an innovator and positive force for respiratory care, can look forward to more successes during her term of office and to being supported by a talented and hardworking team with a clear mission. Find out more about Carol at <https://bit.ly/2YPLhhD>.

Incoming Chair's Perspective

Carol Stonham



As I anticipate my role as Executive Chair, I have been asked many times what I intend to concentrate on, and what I will change during my term as Chair, especially being the first non-doctor to become Chair, and the first woman. This is an organisation in good shape with an eye on the present, the horizon and the future, so there is little to change. My professional background or gender should not and will not be the dominating factor in leading PCRS, although I am proud and excited; it is an honour.

That said, change is inevitable as healthcare evolves and adapts to suit the future, the changing demographics of the population and

the political landscape. The secret, I have discovered, is to move with it in a proactive way, but also to have the ability to be reactive. PCRS continues to develop in just that way.

Having come into PCRS at a time, not too long ago, when the membership was open to GPs only, we have emerged as a multidisciplinary, non-hierarchical professional society. We still have a way to go in encouraging healthcare professionals newer to the primary, community and integrated care environment – paramedics, pharmacists working in practice or community, physiotherapists and the broader therapy team. I would like to see an even greater diversity of our member-

ship representing the patient journey from all touch points, and from all of the UK.

PCRS has become a driving force for change. We are represented on guideline committees, delivery boards and national respiratory work streams. We have a voice that is important, considered and listened to. Strong leadership has given us national standing – this is something that needs to be continued and increased. Although our policy team is changing, I have confidence that going forward we will continue our involvement where it matters. Working more closely with organisations that share our passion for optimal respiratory health for all will strengthen our voice further – together we will be stronger. As services integrate, the divide between care delivered by specialist teams and that delivered in primary care is less defined – the patient is the same person regardless of the setting in which care is received.

One area I am passionate about is delivering healthcare that is greener and kinder to the environment. I live in an area where we work hard to protect the environment, yet healthcare often sits outside of this agenda.

Recycling inhalers is a part of the greener healthcare agenda, but it is so much bigger than that. The whole patient journey has the potential to impact on environmental issues. Inaccurate diagnosis will potentially result in repeated unnecessary healthcare appointments as symptoms remain unresolved. Repeated appointments for tests, usually all done at different times. Prescribing for an inaccurate diagnosis causes unnecessary transportation

of medication, side effects for patients, and waste from used inhalers that were never necessary.

Introducing a #nowaste campaign will include education of healthcare professionals, patients and the public, influencing guidelines and policy, working with suppliers of medication and recycling schemes. It is something I know we can do better, but change in a busy environment is never easy. It is a campaign that is bigger than caring for people with respiratory symptoms and conditions. It applies to all areas of healthcare and can easily be applied to other disease areas, and more broadly to the way we approach the care we deliver on an individual and organisational basis. The RCP report. 'Outpatients: the Future – adding value through sustainability'¹ considered how we add value through sustainability. It proposed that "a value-based approach to delivery of care takes into account the impact of service delivery on patients and their lives, ensuring their needs are met more efficiently".

With healthcare accounting for 5% of all road traffic in England,² the collateral damage beyond pollution, effect on working lives, childcare exists. A 2017 report from the Royal Colleges of Physicians and Paediatrics and Child Health estimated that UK-wide travel and transport impact on mortality is equivalent to 40,000 deaths a year, in addition to numerous effects on respiratory and cardiovascular health.³ So the campaign certainly goes beyond recycling.

Part of the #nowaste campaign – but a part that stands on its own – is access to

education for healthcare professionals delivering care. Focus has been on the introduction and implementation of the spirometry accreditation programme, but this is just a small part of the jigsaw. If we are to have clinicians delivering optimal respiratory health for all, we need a workforce that is trained, competent and confident in their roles. We produced 'Fit To Care'⁴ in 2017 as a document that advised clinicians and commissioners of the key knowledge, skills and training for clinicians providing respiratory care at standard, advanced and expert level, so that training can be commissioned and accessed at the required level. Time is a precious commodity and one that is in short supply, but the need for appropriate education and training cannot be overlooked for all professional groups delivering care.

My 3-year term will, I am sure, see challenges and opportunities along with the ever shifting sands of the NHS. I am ready for the challenge in the knowledge of leading an organisation that is adaptable, and a membership with a shared vision of delivering high value care in a changing environment.

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The role of e-cigarettes in treating tobacco dependence



Darush Attar-Zadeh *PCRS member and Respiratory Lead Pharmacist at Barnet CCG*

E-cigarettes have become increasingly popular in recent years. An estimated 3.2 million adults in Great Britain currently 'vape', up from 700,000 in 2012.¹

The main reason given by current vapers for using e-cigarettes is to help them stop smoking tobacco. The Smoking Toolkit Study estimates that in 2014 electronic cigarettes resulted in 20,000 more people quitting smoking who otherwise would not have done so.²

This statistic must be considered alongside the fact that smoking tobacco is one of the biggest preventable causes of premature death, disability, and health inequality in the UK and is a significant cause of hospital admissions.³ In 2015/16, an estimated 474,000 NHS hospital admissions in England were linked to smoking-related conditions. An estimated 16% (79,000) of all deaths in 2015 were attributed to smoking tobacco.⁴

The popularity of e-cigarettes across all social classes mean they may be important as a quit tool for disadvantaged groups, who are more likely to use tobacco and generally find it harder to quit. Once a user has purchased their starter kit the e-liquid costs approximately £3 for a 10ml vial of e-liquid which is cheaper than cigarettes.^{5,6}

Safety

But how safe are e-cigarettes? According to NICE e-cigarettes are substantially less harmful to health than smoking but are not risk free. Evidence about e-cigarettes is still developing, including the evidence on their long-term health impact.⁷

When discussing e-cigarettes with patients NICE says they should be advised that while nicotine inhaled from smoking tobacco is highly addictive, it is primarily the toxins and carcino-

gens in tobacco smoke – not the nicotine – that cause illness and death.⁸

In 1976 Professor Michael Russell (one of the developers of NHS evidence-based stop smoking services) wrote: "People smoke for nicotine, but they die from the tar."⁹

A review of the evidence commissioned by Public Health England (PHE) in 2014 found that the hazard associated with electronic cigarette products currently on the market "is likely to be extremely low, but certainly much lower than smoking".¹⁰ Other reviews have drawn similar conclusions with one putting the risks of vaping at less than 5% of the risks of smoking.²

Alongside publication of the review, PHE issued a statement in 2015 noting that while not risk free, electronic cigarettes carry a fraction of the risk of smoking cigarettes and have the potential to help smokers quit smoking.¹¹

NICE says smokers should be advised that if they want to use e-cigarettes to quit they should stop smoking tobacco completely, because any smoking is harmful.⁷

Current use of e-cigarettes by never smokers remains very rare and similar to use of licensed nicotine products with as little as 0.5% of the never smokers taking up vaping, which is similar to NRT. But use in never smokers needs continual monitoring.¹² The use of e-cigarettes among long-term ex-smokers appears to be increasing.¹³

Long term use of e-cigarettes will undoubtedly cause some harms in comparison to licensed NRT, and users should be encouraged to quit vaping too, though not at the expense of relapsing to smoking tobacco.¹⁴ A recent study showed that long-term e-cigarette users (who had been using their product for 17 months on average) had significantly lower levels of key



toxicants in their urine than those that still smoked – with levels in e-cigarette users similar to exclusive nicotine replacement therapy (NRT) users.¹⁵ Further research will provide the best data to answer questions concerning the safety and efficacy of e-cigarettes to support smoking cessation though such studies are time and resource intensive. Vaping should of course be avoided by non-smokers and e-cigarettes should not be sold to young people under the age of 18.¹⁶ E-cigarette uptake and regular use among children is also extremely low and there is currently no evidence to support concerns about a gateway effect to tobacco smoking.¹³ and use of e-cigarettes remains very low among young people (11-18 year olds) in Great Britain.¹⁷

Popcorn Lung (bronchiolitis obliterans)

Concerns around e-cigarettes causing the disease known as popcorn lung are not based on evidence, and the chemical (diacetyl) thought to be responsible for this disease has been banned from use in e-liquids in Europe.¹⁸

Effectiveness of e-cigarettes as stop smoking aid

Stop smoking interventions recommended by NICE are:

- Behavioural support (individual and group)
- Bupropion
- NRT – short and long acting
- Varenicline
- Very Brief Advice.⁵

NHS stop smoking data suggests that e-cigarettes, alongside behavioural support, are commonly and effectively used in combination with prescribed treatments.¹⁹

A recent study in the *NEJM* reported that e-cigarettes are almost twice as effective as NRT treatments at helping smokers to quit tobacco smoking. Led by Queen Mary University of London, and funded by the National Institute for Health Research and supported by Cancer Research UK, this study, a multi-centred randomised controlled trial is the first to test the efficacy of e-cigarettes in helping smokers to quit. It involved almost 900 smokers who also received additional behavioural support for up to four weeks.

The study reported that 18% of e-cigarette users were smoke-free after a year compared to 9.9% of participants who were using other NRT therapies, including patches, gum, lozenges, sprays, inhalators, or a combination of products.²⁰ Overall, throat or mouth irritation was reported more frequently

in the e-cigarette group compared with NRT with no increase in other respiratory adverse effects. Further focused studies are recommended.

The Smoking Toolkit Study is an ongoing national surveillance programme that involves surveys of nationally representative samples of adults in England every month. A study in 'addiction', surveyed a population comprised 18,929 who reported a quit attempt in the last 12 months.²¹

Use of e-cigarettes and varenicline are associated with higher abstinence rates following a quit attempt in England (OR=1.95, 95%CI:1.69-2.24), (OR=1.82, 95%CI:1.51-2.21). Higher abstinence rates were seen with use of prescription of nicotine replacement therapy but only in older smokers (OR=1.58, 95%CI:1.25-2.00) and interestingly use of websites only in smokers from lower socioeconomic status (OR=2.20, 95%CI:1.22-3.98).

Conclusion

PCRS believes that healthcare professionals should be prepared to help their patients to quit tobacco smoking and should be knowledgeable about e-cigarettes so they can answer questions if asked.

However a recent survey presented at the World Conference on Lung Cancer 2018, highlighted that English healthcare professionals are less likely to give advice to quit smoking than other leading tobacco control nations.²²

Of those clinicians that do raise the subject of smoking, only 6.2% mention e-cigarettes, and nearly two thirds either don't recommend them, or have no opinion on them.²³ In addition there are a lot of misconceptions among patients about e-cigarettes. Many smokers (44%) either believe that vaping is as harmful as smoking (22%) or don't know that vaping poses much lower risks to health than smoking (22%).²⁴

With the evidence we have to date on their efficacy and safety, it's appropriate that we are positive about e-cigarettes as an option to add to our existing array of evidence-based treatments and express an interest when a patient raises the subject.

Although these products are not licensed medicines, they are regulated by the Tobacco and Related Products Regulations 2016.

The BMA says that with appropriate regulation, e-cigarettes have the potential to make an important contribution towards achieving a tobacco-free society, leading to substantially reduced mortality from tobacco-related disease.²⁵

The PCRS position on e-cigarettes²⁶

Based on the current evidence PCRS supports e-cigarettes as a positive option available to support people to quit tobacco smoking.

- E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes.
- The hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco.
- The available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.
- The use of e-cigarettes as an option to help patients quit tobacco smoking is supported by Public Health England, the RCP and RCGP

PCRS guidance on treating tobacco dependence

PCRS believes that it is the responsibility of every healthcare professional to treat tobacco dependency systematically and effectively. The new PCRS pragmatic guide to treating tobacco dependence produced by a panel of experts, sets out a practical, evidence-based framework which enables healthcare professionals to routinely identify smokers then encourage and support them to quit.²⁷

Fact: Secondhand vape

'Vape clouds' exhaled from a patient's respiratory tract is not the same as smoke seen from combustible products like cigarettes, roll ups, water pipes, cigars etc. As the name suggests, 'vaping' is more like 'evaporation' where the components are heated (boiled) at temperatures far lower than combustible products. The liquid in the vaping device is heated to about 200 degrees Celsius versus 800 degrees Celsius for a cigarette.²⁸

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Commentary: Neil Jackson PCRS Lay Reference Group

Speaking from a patient angle, I am in support of the PCRS policy on e-cigarettes, and crucially, I believe it to be one of the best and most appropriately worded of its type. It contains everything necessary to address the concerns of the wider respiratory-interested community. Obviously I don't know what their questions are, and it may be helpful to know, but I would imagine they would be along the lines of "*should we be seen to be 'promoting' something that is still inherently a danger and 'as-yet-untested' in regards to its long-term effects?*".

I encounter this viewpoint/worry a fair bit in the patient communities that I am a part of, especially since there was talk in the news of 'fungal infections' and 'dirty water/condensate in vape equipment', and suchlike, and I have met with some quite rabidly-strong voices denouncing vaping as another evil that will one day return to bite us on the behind. It's possible there is some truth in that, at the moment, it's a question of proportional risk. Some detractors have even made unhelpful reference to the adverts of the early 20th Century where doctors were used in the promotion of cigarette brands, and attempted to portray current medical community 'backing' of vaping as being a repeat of the same.

All of it I must say I find rather 'hyper-reactive', flawed, unscientific, populist thinking, and largely missing the real point at hand - namely **the need to stop people smoking tobacco**. The way that the PCRS policy is worded makes it **quite clear** - and easily referenced. It makes clear that:-

- The PCRS stance is based on the vital, paramount need to help people cease smoking tobacco;
- it's a 'positive option', not a magic bullet solution;
- it's based on current evidence (the implication being that if evidence changed, so might our stance);
- the evidence shows majority of vapers are those seeking to quit tobacco (the implication being that few people are taking up vaping as a 'new vice' - which is another so far unfounded worry proposed by its detractors);
- and most-importantly, that PCRS accept there is scope for some risk, but compared to smoking tobacco, this risk is negligible and worth taking when considered responsibly and logically.

I think PCRS has done everything feasible to couch the policy in terms that make it clear that whilst this is not an entirely risk-free strategy, it's a logical, carefully-considered and sensible one, and is likely to massively reduce the numbers of tobacco smokers, save lives, money and healthcare resources. The alternative is to continue with already-tested strategies that are many orders of magnitude less successful, are just as risky (in different ways) and costly (perhaps more so). To persist in these old strategies makes no logical sense, if there is a markedly better alternative, even if it is not perfect.

Whether it was Einstein or Confucius who actually said it makes no difference, but it's true enough to say that "*repeating the same failing actions in the hope of receiving different results is the very definition of insanity.*" It very much applies here, I think.

E-Cigarettes are - for now at least - something that logic dictates should be fully supported. That does not rule out the opportunity for a future debate when tobacco-smoking is as alien to our culture as sending small children up chimneys to clean them, or making them work in matchstick factories and weaving mills. But we are not there yet, and the first task must be to eradicate tobacco-smoking as a top priority. Not at any cost, but at an appropriate, solidly and ongoingly researched one.

Neil Jackson, PCRS Lay Reference Group Member

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¹For 160/4.5mcg strength only.³

¹³DuoResp Spiromax is licensed for use in adults 18 years of age and older only.³

Please refer to the Summary of Product Characteristics (SmPC) for full details of the Prescribing Information. DuoResp[®] Spiromax[®] (budesonide/formoterol) 160mcg/4.5mcg inhalation powder and DuoResp[®] Spiromax[®] (budesonide/formoterol) 320mcg/9mcg inhalation powder. **Abbreviated Prescribing Information. Presentation:** DuoResp[®] Spiromax[®] 160/4.5. Each delivered dose contains 160mcg of budesonide and 4.5mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 200mcg budesonide and 6mcg of formoterol fumarate dihydrate. DuoResp[®] Spiromax[®] 320/9. Each delivered dose contains 320mcg of budesonide and 9mcg of formoterol fumarate dihydrate. This is equivalent to a metered dose of 400mcg budesonide and 12mcg of formoterol fumarate dihydrate. **Inhalation powder. Indications:** Treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2 -adrenoceptor agonist) is appropriate. COPD: Symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV₁) < 70% predicted normal (post bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. **Dosage and administration:** For use in adults \geq 18 years. Not for use in children < 18 years of age. **Asthma:** Not intended for the initial management. If an individual patient should require a combination of doses other than those available in the combination inhaler, appropriate doses of β_2 -adrenoceptor agonists and/or corticosteroids by individual inhalers should be prescribed. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. When control of symptoms is achieved titrate to the lowest effective dose, which could include once daily dosing. DuoResp[®] Spiromax[®] 160/4.5. **maintenance therapy** – regular maintenance treatment with a separate reliever inhaler. **Adults:** 1-2 inhalations twice daily (maximum of 4 inhalations twice daily). DuoResp[®] Spiromax[®] maintenance and reliever therapy – regular maintenance treatment and as needed in response to symptoms: should be considered for patients with: (i) inadequate asthma control and in frequent need of reliever medication (ii) previous asthma exacerbations requiring medical intervention. **Adults:** The recommended maintenance dose is 2 inhalations per day, given either as one inhalation morning and evening or as 2 inhalations in either the morning or evening. For some patients a maintenance dose of 2 inhalations twice daily may be appropriate. Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. A total daily dose of up to 12 inhalations could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice. DuoResp[®] Spiromax[®] 320/9. Only to be used as maintenance therapy. **Adults:** 1 inhalation twice daily (maximum of 2 inhalations twice daily). **COPD:** **Adults:** 1 inhalation twice daily. **Elderly patients (\geq 65 years old):** No special requirements. **Patients**

with renal or hepatic impairment: No data available. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Precautions and warnings:** If treatment is ineffective, or exceeds the highest recommended dose, medical attention must be sought. Patients with sudden and progressive deterioration in control of asthma or COPD should undergo urgent medical assessment. Patients should have their rescue inhaler available at all times. The reliever inhalations should be taken in response to symptoms and are not intended for regular prophylactic use e.g. before exercise. For such, a separate rapid-acting bronchodilator should be considered. Patients should not be initiated during an exacerbation. Serious asthma-related adverse events and exacerbations may occur. If asthma symptoms remain uncontrolled or worsen, patients should continue treatment and seek medical advice. If paradoxical bronchospasm occurs, treatment should be discontinued immediately. Paradoxical bronchospasm responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. Visual disturbance may be reported with systemic and topical corticosteroid use. Such patients should be considered for referral to an ophthalmologist for evaluation of possible causes. Systemic effects may occur, particularly at high doses prescribed for long periods. Potential effects on bone density should be considered, particularly in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress. Treatment should not be stopped abruptly. Transfer from oral steroid therapy to a budesonide/formoterol fumarate fixed-dose combination may result in the appearance of allergic or arthritic symptoms which will require treatment. In rare cases, tiredness, headache, nausea and vomiting can occur due to insufficient glucocorticosteroid effect and temporary increase in the dose of oral glucocorticosteroids may be necessary. To minimise risk of oropharyngeal Candida infection patients should rinse mouth with water. Administer with caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, or severe cardiovascular disorders. The need for, and dose of inhaled corticosteroids should be re-evaluated in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections in the airways. Additional blood glucose controls should be considered in diabetic patients. Hypokalaemia may occur at high doses. Particular caution is recommended in unstable or acute severe asthma. Serum potassium levels should be monitored in these patients. As with other lactose containing products the small amounts of milk proteins present may cause allergic reactions. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD

exacerbations. **Interactions:** Concomitant treatment with potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration should be as long as possible. Co-treatment with CYP3A inhibitors, including cobicistat-containing products is expected to increase risk of systemic side effects and the use in combination should be avoided. Not recommended with β -adrenergic blockers (including eye drops) unless compelling reasons. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine), and Tricyclic Antidepressants (TCAs) can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance. Concomitant treatment with MAOIs, including agents with similar properties, may precipitate hypertensive reactions. Patients receiving anaesthesia with halogenated hydrocarbons have an elevated risk of arrhythmias. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. **Pregnancy and lactation:** Use only when benefits outweigh potential risks. Budesonide is excreted in breast milk; at therapeutic doses no effects on infants are anticipated. **Effects on ability to drive and use machines:** No or negligible influence. **Adverse reactions:** Since DuoResp[®] Spiromax[®] contains both budesonide and formoterol, the same pattern of adverse reactions as reported for these substances may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds. **Serious:** Immediate and delayed hypersensitivity reactions, e.g. exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction, Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, hypokalaemia, hyperglycaemia, aggression, psychomotor hyperactivity, anxiety, sleep disorders, depression, behavioural changes, cataract and glaucoma, tachycardia, cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystoles, angina pectoris, prolongation of QTc-interval, variations in blood pressure, bronchospasm, pneumonia in COPD patients and paradoxical bronchospasm. **Common:** Candida infections in the oropharynx, headache, tremor, palpitations, mild irritation in the throat, coughing, pneumonia in COPD patients and hoarseness. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** An overdose of formoterol may lead to: tremor, headache, palpitations. Symptoms reported from isolated cases are tachycardia, hyperglycaemia, hypokalaemia, prolonged QTc-interval, arrhythmia, nausea and vomiting. Supportive and symptomatic treatment may be indicated. **Price per pack:** DuoResp[®] Spiromax[®] 160/4.5 and DuoResp[®] Spiromax[®] 320/9: £27.97. **Legal Category:** POM. **Marketing Authorisation Numbers:** DuoResp[®] Spiromax[®] 160/4.5: EU/1/14/920/001. DuoResp[®] Spiromax[®] 320/9: EU/1/14/920/004. **Marketing Authorisation Holder:** Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, The Netherlands. **Date of Preparation:** September 2018. **Job Code:** UK/MED/18/0194.

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References: 1. Chrystyn H et al. *Int J Pharm* 2015; 491: 268–276. 2. Canonica G et al. *J Aerosol Med Pulm Drug Deliv* 2015; 28(5): 309–319. 3. DuoResp Spiromax Summary of Product Characteristics. 4. Sandler N et al. *BMJ Open Res* 2016; 3: e000119.

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FeNO testing for asthma diagnosis: a PCRS consensus

FeNO Testing For Asthma Diagnosis - A PCRS Consensus was commissioned to set out the PCRS position on the role of FeNO testing within the context of asthma diagnosis.



Carol Stonham Vice-Chair, Primary Care Respiratory Society and NHS Gloucestershire CCG and **Noel Baxter** Chair PCRS Executive



PCRS position on FeNO testing for asthma diagnosis

The fractional exhaled nitric oxide (FeNO) test measures the level of NO in the exhaled breath and provides an indication of eosinophilic inflammation in the lungs. For the diagnosis of asthma, the British Thoracic Society (BTS) and the Scottish Intercollegiate Guidelines (SIGN) position FeNO testing after the objective evaluation of airways obstruction and alongside other potential tests for inflammation such as determination of blood eosinophil levels, IgE skin-prick test to detect atopy, and tests for variability (reversibility, peak expiratory flow [PEF] charting and challenge tests).¹ Patients with a history and clinical characteristics that support a high probability of asthma and who have had an objective measure of reversible airways obstruction do not need FeNO before progressing to a trial of treatment.¹ Additional objective evidence including FeNO is recommended as an optional investigation as a test for eosinophilic asthma for those considered to have an intermediate probability of asthma.¹ The current PCRS position aligns with the guidance issued by BTS/SIGN. This article reviews the evidence base and clinical guidelines upon which the PCRS position is based.

Background

Asthma is a heterogeneous condition characterized by respiratory symptoms (wheeze, cough, breathlessness, chest tightness and pain) associated with variable airflow obstruction, hyper-responsiveness and often an underlying inflammation. There is no single defining feature or symptom of asthma, however variability is at its

core, so diagnosis is achieved through a holistic evaluation of patient symptoms over time alongside repeated physiologic evaluation of lung function, and assessment of response to trials of treatment. Pathologic evaluations including tests for eosinophilic airway inflammation, and other investigations, may sometimes be needed.

Nitric oxide (NO) is produced in the lungs and so can be detected in the exhaled breath and elevated exhaled NO levels are thought to be related to eosinophilic lung inflammation.² Fractional exhaled NO (FeNO) testing is quantitative, noninvasive, simple and safe and elevated FeNO may be supportive of a diagnosis of asthma in untreated individuals presenting with respiratory symptoms.³ However, while suggestive, a positive FeNO test is not conclusive evidence of asthma. Indeed, eosinophilic lung inflammation has been suggested to be a contributing factor to asthma in approximately 50% of cases, with the remaining 50% of cases not showing evidence of eosinophilic lung inflammation.^{4,5}

There has been considerable discussion in recent years regarding the relevance of FeNO testing in the diagnostic workup of patients presenting with respiratory symptoms for whom a diagnosis of asthma is suspected. Here we review the current recommendations for the role of FeNO testing in the diagnosis of asthma and explore the benefits, limitations and challenges of utilising this test in the primary care setting.

How is FeNO testing conducted?

The FeNO test measures the level of NO in the exhaled breath. FeNO testing is conducted using a handheld device into which the patient blows



for 10 seconds at 60 litres a minute. A shorter test is available for children. The result is provided within approximately 1 minute with a FeNO level ≥ 35 ppb as a positive test in children and a level ≥ 40 ppb as a positive test in adults.⁶

What are the current recommendations for FeNO testing for asthma diagnosis?

NICE

In November 2017 the National Institute for Health and Care Excellence (NICE) issued guidance for the diagnosis, monitoring and management of asthma.⁶ The guidance focuses on objective testing for the diagnosis of asthma and suggests FeNO evaluation be considered as an objective test alongside spirometry and peak expiratory flow (PEF) at initial presentation if equipment is available, and as part of the diagnostic algorithm for both children over 5 and adults with respiratory symptoms suggestive of asthma (Box 1).

BTS/SIGN

The 2016 BTS/SIGN guidance takes a pragmatic approach to asthma diagnosis and recommends that for patients with a high probability of asthma, a trial of treatment is appropriate.¹ The guideline incorporates FeNO testing as part of the diagnostic algorithm only for patients with an intermediate probability of asthma where further evidence is required (Box 2). Unlike the current NICE guidance, the principle investigation is to test for airway obstruction and bronchodilator reversibility on spirometry. FeNO testing is positioned after spirometric evaluation as an optional investigation to test for eosinophilic inflammation along side determination of blood eosinophil level, IgE skin-prick test for detection of atopy, and tests for variability (reversibility, PEF charting and challenge tests)¹ if the results of spirometric evaluation are not clear. **A positive FeNO increases the probability of asthma but a negative test does not exclude a diagnosis of asthma.**

Box 1: NICE guidance for the role of FeNO is the evaluation and diagnosis of asthma in children over 5 and adults⁶

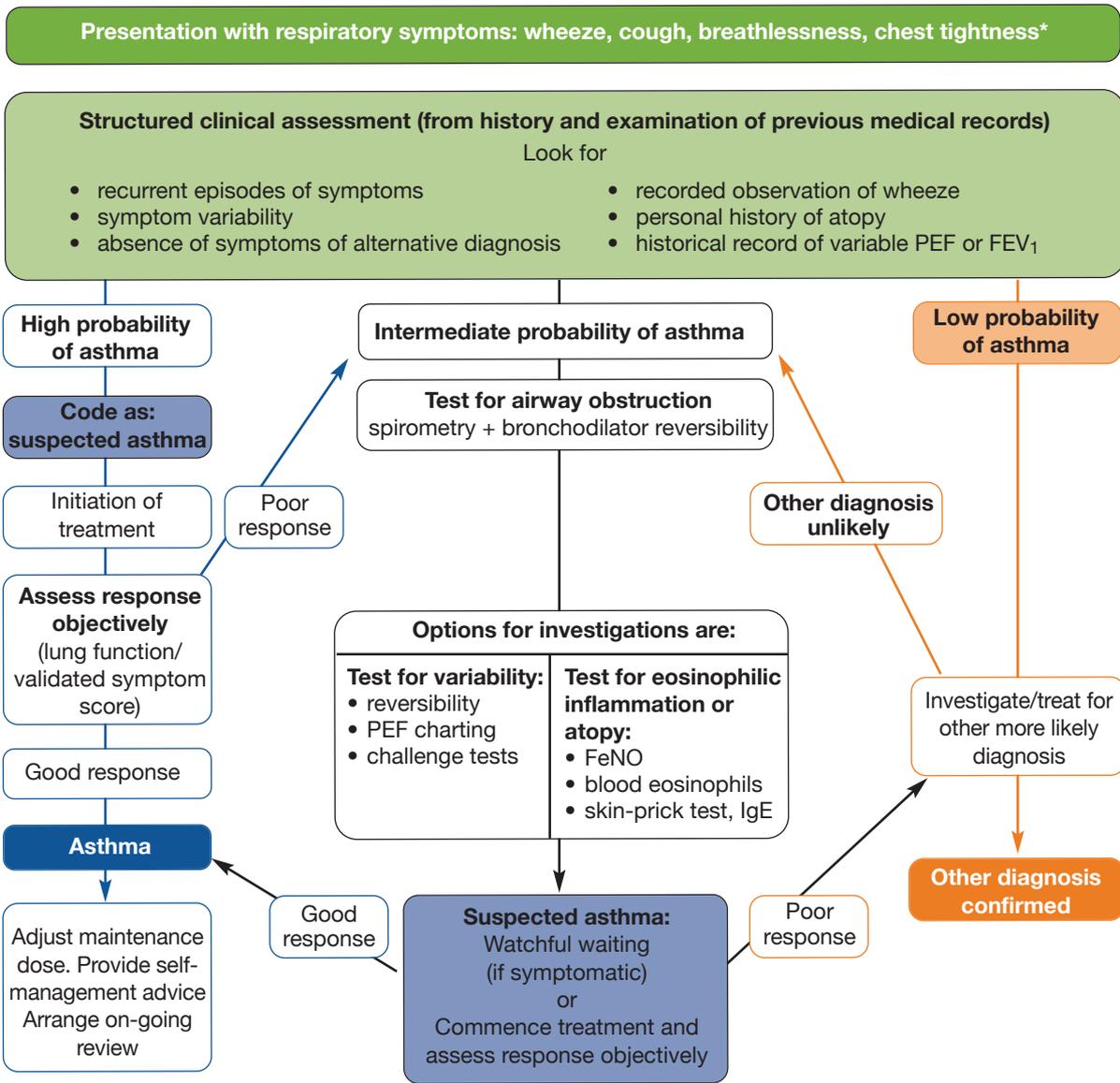
FeNO in the diagnosis of asthma in children

- Consider a FeNO test in children and young people (aged 5-16 years) if there is diagnostic uncertainty after initial assessment and they have either:
 - Normal spirometry or
 - Obstructive spirometry with a negative bronchodilator reversibility test. **Regard a FeNO level of ≥ 35 ppb as a positive test**
- Suspect asthma in children and young people (aged 5-16 years) if they have **symptoms suggestive of asthma** and:
 - A FeNO level ≥ 35 ppb with normal spirometry and negative peak flow variability or
 - A FeNO level ≥ 35 ppb with obstructive spirometry but negative bronchodilator reversibility and no variability in peak flow or
 - Normal spirometry, a FeNO level ≤ 34 ppb and a positive peak flow variability
- Diagnose asthma in children and young people (aged 5-16 years) if they have **symptoms suggestive of asthma** and:
 - A FeNO ≥ 35 ppb with normal spirometry and negative peak flow variability or
 - Obstructive spirometry and positive bronchodilator reversibility

FeNO in the diagnosis of asthma in adults

- Offer a FeNO test to adults (aged >17 years) if a diagnosis of asthma is being considered. **Regard a FeNO level of ≥ 40 ppb as a positive test**
- Suspect asthma in adults (aged >17) with **symptoms suggestive of asthma**, obstructive spirometry and:
 - Negative bronchodilator reversibility, and either a FeNO level ≥ 40 ppb, or a FeNO levels between 25 and 39 ppb and positive peak flow variability, or
 - Positive bronchodilator reversibility, a FeNO level between 25 and 39 ppb and negative peak flow variability
- Diagnose asthma in adults (>17 years) if they have symptoms suggestive of asthma and:
 - A FeNO ≥ 40 ppb with either positive bronchodilator reversibility or positive peak flow variability or bronchial hyperreactivity or
 - A FeNO between 25 and 39 ppb and a positive bronchial challenge test or
 - Positive bronchodilator reversibility and positive peak flow variability irrespective of FeNO level

Box 2: The BTS/SIGN diagnostic algorithm for patients presenting with respiratory symptoms¹



* In children under 5 years and others unable to undertake spirometry in whom there is a high or intermediate probability of asthma, the options are monitored initiation of treatment or watchful waiting according to the assessed probability of asthma

Benefits of FeNO testing as part of the diagnostic workup for asthma

Reliance on physiologic measures of lung function is a point-in-time measure and as such if patients are asymptomatic on the day they attend for testing the results may be negative. A negative result may also be delivered if the test did not achieve optimal quality due to operational or patient factors. FeNO is an objective measure of eosinophilic lung inflammation which is likely to persist even in the absence of overt respiratory symptoms on a given day.⁷⁻⁹

At present, data on the cost-effectiveness of FeNO testing in the primary care setting is limited but early indications suggest this may be favourable.¹⁰ Although an initial investment in equipment and training is required with ongoing consumable costs, there may be cost savings associated with correct diagnosis, reduced referrals to secondary care and reductions in emergency primary care and accident and emergency visits.¹¹⁻¹⁴

While not currently recommended in clinical practice guidelines, evidence suggests FeNO testing may also be informative for the ongoing monitoring of patients with asthma with poor

Box 3: Confounding factors that may result in an increased or decreased FeNO level¹

Confounding factors that may INCREASE FeNO levels

FeNO levels may be higher than population norms in:

- Men, tall individuals and those consuming a diet high in nitrates

FeNO levels may be elevated in:

- Patients with allergic rhinitis exposed to an allergen even in the absence of respiratory symptoms
- Patients with active rhinovirus infection

Confounding factors that may DECREASE FeNO levels

FeNO levels may be lower than population norms in:

- Children (a lower reference range must be used)

FeNO levels may be reduced in:

- Cigarette smokers
- Patients recently treated with inhaled or oral corticosteroids

control, providing an objective measure of steroid responsiveness and providing an alert of persistent lung inflammation even in the absence of evidence of airway obstruction.^{9,15} Changes in FeNO levels may be useful to guide step up and step down of anti-inflammatory medication and may prompt an evaluation of adherence and inhaler technique. Having an objective test result may facilitate opening up a conversation about adherence and inhaler technique that may be otherwise difficult to approach or forgotten.

Challenges and limitations of FeNO testing

There is some overlap between FeNO levels among individuals with and without asthma.³ An evaluation of the results of eight studies among adults within the secondary care setting suggested that around 1 in 5 individuals with a positive FeNO test will not have asthma (false positive) and around 1 in 5 people with a negative FeNO test will have asthma (false negatives).¹ Data are lacking for primary care populations. However, as a general rule, a FeNO level ≥ 40 ppb is regarded as positive in adults with a level of ≥ 35 ppb regarded as positive in children.¹

A variety of factors not related to the pathology of asthma can result in increased and decreased levels of FeNO, confounding the utility of this test in supporting a diagnosis of asthma (Box 3).

Understanding these potentially confounding factors and the potential for false positive and false negative results is essential to the proper utilization of FeNO testing as part of the diagnostic workup of patients presenting with respiratory symptoms.

In the general practice setting cost may be a barrier to the routine use of FeNO testing as part of the work up of patients presenting with respiratory symptoms suggestive of asthma. The introduction of Primary Care Networks and new ways of working with larger populations offers opportunity in primary care beyond practice level. FeNO is not currently widely available in the UK and if this test is to be a required component of the diagnostic workup primary care networks will be required to invest in the

necessary equipment, training (usually provided by the manufacturer of the equipment required) and consumables or rely on referrals to secondary care. Routine FeNO testing for all patients with asthma may not be a practical approach for all primary care practices at this time. The NICE 2017 guideline recommends a FeNO test for all adults presenting with acute respiratory symptoms suggestive of asthma if equipment is available and if testing will not compromise treatment of the acute episode. However, treatment can be initiated for patients who are acutely unwell at presentation if waiting for objective tests may compromise treatment of the acute episode. Objective tests should then be carried out once the acute symptoms have been controlled. Referral to secondary care may be made in cases of diagnostic uncertainty. An alternative to investment in FeNO testing by individual primary care practices may be a locality-based approach whereby primary care practices in a given locality or Primary Care Network pool resources to invest in a FeNO testing service. This approach is currently being trialled in the UK.^{6,16}

Conclusions

FeNO testing is a quantitative, non-invasive, simple and safe test making it suitable for use in the primary care setting with appropriate training of health care professional with responsibility for delivering and interpreting the results.³ The benefits to patients are that they do not need to be referred to secondary care for additional testing as a positive FeNO test alongside respiratory symptoms and lung function tests suggestive of asthma supports a diagnosis. However, concerns remain over the necessity for FeNO testing in every asthma diagnosis and its cost-effectiveness, and it has been suggested the FeNO testing is more appropriately placed in diagnostic centres within the community, intermediate or secondary care setting. Given the current limitations of extending FeNO testing to all patients presenting with symptoms suggestive of asthma, the current PCRS position aligns with the guidance issued by BTS/SIGN namely the use of

FeNO testing as an optional investigation to test for eosinophilic inflammation where there is diagnostic uncertainty.

Acknowledgements

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Poorly controlled and severe asthma: triggers for referral for adult or paediatric specialist care – a PCRS pragmatic guide

This pragmatic guide has been developed by an expert group led by **Dr Steve Holmes** a GP based in *Shepton Mallet, Somerset* and including: **Binita Kane**, Manchester University Foundation Trust, Manchester; **Angela Pugh** and **Alison Whittaker**, *University Hospital of Llandough Cardiff & Vale University Health Board*; **Ruth McArthur**, *Macintosh Practice, East Kilbride, Glasgow*; and **Will Carroll** *University Hospital of the North Midlands, Stoke-on-Trent*

Key facts:

- Asthma UK suggests that an estimated 5.4 million individuals are living with asthma in the UK.¹
- Someone has a potentially life-threatening asthma attack in the UK every 10 seconds and 185 people are admitted to hospital every day.¹
- The number of asthma-related deaths in England and Wales has barely changed in the last 20 years from 1,268 in 2001 to 1,320 in 2017.² The picture is similar in Scotland with 101 deaths in 2001 and 126 in 2017.³
- The cost of caring for individuals with asthma now exceeds £1.1 billion each year, the majority of these being spent on prescription medications and primary care consultations.⁴

Asthma is a chronic respiratory disease that can range from mild to severe in severity. The severity of the condition can change during the year and throughout a person's life, and all patients are at risk for periodic exacerbations that can themselves range from mild to severe and even life-threatening events. Consequently, asthma management is an ongoing and dynamic intervention, and treatment needs to be continually reviewed and tailored to the patient's current level of asthma severity.

It is important to make the distinction between patients with poorly controlled asthma and those with severe asthma, as patients with severe asthma not responding to optimal therapy available in the primary care setting require a different management approach. Poorly controlled asthma (sometimes also referred to as difficult asthma) may be the result of poor adherence to prescribed medication, poor inhaler technique for inhaled medications, the presence of other comorbid conditions (eg, rhinitis) or, indeed, to an incorrect diagnosis. Adherence to prescribed medication can be challenging to measure in clinical practice and involves collecting a prescription, filling the prescription at the pharmacy, attempting to use the medication as prescribed (dose and frequency) and, finally, in the case of an inhaled medication, using the inhaler correctly. A cut-off of 80% adherence for

requesting and filling prescriptions may be a relevant and useful way of deciding on a patient's level of adherence in practice. Patients should be supported to achieve at least 80% adherence to their prescribed medication. Those patients with poorly controlled asthma despite >80% adherence may require further evaluation and medication review.

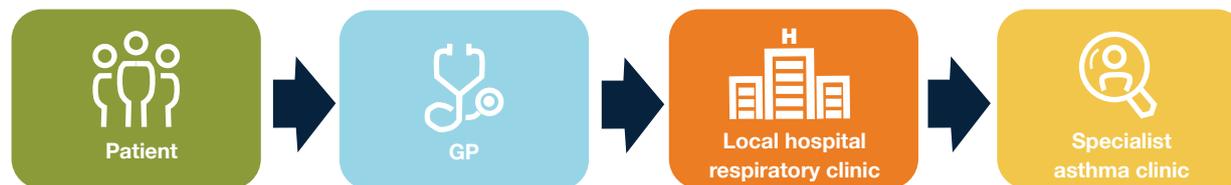
The National Institute for Health and Care Excellence (NICE) defines uncontrolled asthma as:⁵

- 3 or more days a week with symptoms; or
- 2 or more days a week with required use of a short-acting beta agonist (SABA) for symptomatic relief; or
- 1 or more nights a week with awakening due to asthma

The European Respiratory Society (ERS) and American Thoracic Society (ATS) joint guidelines define uncontrolled asthma as:⁶

- Poor symptom control: eg, Asthma Control Questionnaire (ACQ) score that is consistently >1.5 or an Asthma Control Test (ACT) score <20
- Frequent exacerbations defined as ≥ 2 courses of oral corticosteroids (OCS) of more than 3 days' duration in the previous year
- Serious asthma exacerbation requiring hospitalisation
- Airflow limitation (forced expiratory

Figure 1 The Asthma UK ideal pathway to specialist care for patients with difficult or severe asthma.⁹



volume in 1 second (FEV₁) <80% predicted following a withhold of both SABA and LABA)

Severe asthma is increasingly regarded as a distinct disease entity and may be driven by different inflammatory pathways from those driving asthma in the majority of patients. For these patients, alternative treatments are needed that target different inflammatory pathways to those targeted by inhaled and OCS. The British Thoracic Society (BTS) and the Scottish Intercollegiate Guidelines Network (SIGN) define severe asthma as >2 asthma attacks a year or persistent symptoms with SABA use more than twice a week despite specialist-level therapy of asthma and comorbidities.⁷ The ERS/ATS joint guidelines define severe asthma as requiring medications suggested for Global Initiative for Asthma (GINA) steps 4 and 5 (high dose ICS + LABA or LTRA/theophylline) for the previous year or systemic corticosteroids for at least 6 of the previous 12 months to prevent asthma becoming uncontrolled, or which remains uncontrolled despite this therapy.⁶ Where available, these patients should be referred to specialist asthma centres as they may require biologics, bronchial thermoplasty or immunosuppressant therapy.⁷

Patients with severe asthma are estimated to account for around 3.6% of all asthma patients,⁸ equating to around 200,000 individuals in the UK. The proportion of patients whose asthma is poorly controlled is less apparent, not least because patients themselves may not recognise that their level of symptom control is

not as good as it could be. Asthma UK estimates that there are around 1 million individuals in the UK with difficult asthma (17% of the total asthma population).⁹ Both groups of patients are at increased risk for severe, potentially life-threatening asthma attacks, making it imperative to identify them, optimise their treatment and refer them for specialist review as appropriate.

When should we refer our asthma patients for specialist review?

When asthma control is not achieved, a review of the patient's medication, their inhaler technique, exposure to triggers and their general health (to identify any comorbid conditions or aggravating problems such as smoking) is warranted. When treatment with readily available medications has been optimised in terms of both

dose and adherence, the diagnosis confirmed, and other confounding conditions ruled out or managed effectively, and the patient remains symptomatic, the patient should be considered for specialist review (Figure 1).

BTS/SIGN recommend referral for specialist evaluation for patients whose diagnosis is unclear, who have suspected occupational asthma, or who have a poor response to treatment (Table 1).⁷

The UK National Review of Asthma Deaths (NRAD), following a detailed review of 195 asthma-related deaths, recommends that patients who require ≥3 courses of OCS for exacerbations in the past year or those on the level of treatment where three asthma medications have not obtained control or in people who are on regular oral steroid treatment must be referred for specialist review.¹⁰ NRAD also

Table 1: BTS/SIGN recommendations for referral of patients with asthma to specialist services⁷

Adults	Children
Diagnosis is unclear	Diagnosis is unclear
Poor response to asthma treatment	Poor response to monitored initiation of asthma treatment
Suspected occupational asthma (symptoms that improve when the patient is not at work, adult-onset asthma and workers in high-risk occupations)	
Severe/life-threatening asthma attack requiring hospitalisation	
Patient or parental anxiety or need for reassurance	

recommends referral for specialist review following hospitalisation for asthma and for any patient attending the emergency room ≥ 2 times for asthma exacerbation.¹⁰

All patients requiring OCS for an asthma exacerbation should undergo a clinical assessment and, in line with the ERS/ATS recommendation, we support referral for specialist review for patients requiring ≥ 2 courses of OCS for asthma exacerbations in the previous 12 months. It should be remembered that, in a study of >430,000 people with asthma in the USA and UK, the average annual number of asthma exacerbations was 0.16 and 0.11, respectively – equating to one exacerbation every 6–9 years.¹¹

In addition, all patients with asthma who attend A&E or are hospitalised with a severe/life-threatening asthma attack should be referred for specialist evaluation by their treating hospital clinician.^{7,10}

How can we determine when our asthma patient needs specialist referral?

Identifying patients at increased risk for a severe/potentially life-threatening asthma attack before they experience a severe event and referring these patients for specialist review has the potential to reduce the number of asthma-related deaths each year. Proactively identifying patients with poorly controlled asthma also has the potential to improve symptom control and quality of life for the estimated 200,000 individuals with difficult or severe asthma in the UK.⁹

A major challenge is that, while these patients are likely to be experiencing daily symptoms, their symptom burden may have become normalised for them and they might consider that they are managing those symptoms effectively with what is in fact overuse of their rescue SABA therapy.¹²

The patient who comes to clinic

Generally, asthma is most appropriately managed in the primary care setting with regular structured clinical review at least

Table 2: NICE recommendations for monitoring asthma control⁵

Monitor asthma control at every review. If control is suboptimal:

- Confirm the person's adherence to prescribed treatment in line with the recommendations on assessing adherence in the NICE guideline on medicines adherence
- Review the person's inhaler technique
- Consider if treatment needs to be changed
- Ask (if relevant) about smoking status, potential occupational triggers and other triggers

Consider using a validated questionnaire (eg, the Asthma Control Questionnaire or Asthma Control Test) to monitor asthma control in adults (aged 17 and over)

Monitor asthma control at each review in adults, young people and children aged 5 and over using either spirometry or peak flow

Do not routinely use fractional exhaled nitric oxide (FeNO) to monitor asthma control. Consider FeNO measurement as an option to support asthma management in people who are symptomatic despite using inhaled corticosteroids

Do not use challenge testing to monitor asthma control

Observe and give advice on the person's inhaler technique:

- At every consultation relating to an asthma attack, in all care settings
- When there is deterioration in asthma control
- When the inhaler device is changed
- At every annual review
- If the person asks for it to be checked

once a year, using a validated tool to assess symptom burden (eg, Asthma Control Test (ACT), Control of Allergic Rhinitis and Asthma Test [CARAT], CARAT KIDS), along with assessment of medication use and inhaler technique, among other areas.

NICE guidance on monitoring asthma

NICE recommendations for monitoring asthma control are shown in Table 2.⁵

The patient who does not come to clinic

More challenging is the patient who does not attend clinic for their annual review or when they experience symptom worsening. This may be because they fail to recognise that their symptoms are not well controlled, that they are overusing their

rescue SABA inhaler and that this overuse is a sign of poor asthma control.¹³

A Europe-wide survey of 8,000 patients with asthma conducted in 2012 revealed that almost half (45%) of those questioned had uncontrolled asthma at the time of the survey and 44% had required oral OCS for asthma in the previous 12 months.¹³ Of concern was the observation that 75% of those who had required OCS for their asthma in the previous 12 months did not regard their asthma as serious.¹³ In practical terms, if a patient does not attend a clinic in general practice where it is often much closer than a local hospital and often has wider hours of variability, it is unlikely they would attend a tertiary specialist asthma clinic.

The prescriber is responsible for any prescriptions, so it should be incumbent

Table 3: Metrics to evaluate short-acting beta agonist (SABA) use and define overuse

Number of rescue SABA inhalers prescribed per year	Available reliever doses per inhaler	Average reliever dose per day over 365 days
1	200	0.6 reliever doses every day (1 reliever dose every 2 days)
6	1200	3.3 reliever doses every day
12	2400	6.6 reliever doses every day

upon the practice to make (and document) every attempt to engage these patients constructively and encourage them to attend. Practical and escalating steps may include:

- A written communication (letter, email, text message) with each prescription and a further communication within 7–14 days of a prescription fill.
- Follow-up telephone calls – one from reception and a further call from a clinician if needed.
- An alert/s to the dispensing pharmacist who can also be asked to encourage the patient to make an appointment with the GP.

Rescue SABA overuse as an indicator of poor control

An objective factor that could be assessed to measure the level of symptoms is a review of prescription refill frequency for rescue SABA medication. Overuse of rescue SABA inhalers is known to be associated with poor asthma control as well as an increased risk for exacerbations, hospitalisation and death.^{10,14} This may provide an indication of poor adherence to prophylactic treatment if prescriptions are requested less frequently than expected, but may also reveal an over-reliance on rescue SABA medication if prescriptions are requested more frequently than expected.

A recent study of 10 GP practices in North Glasgow found that 5% of patients who received at least one prescription for a reliever or prevention inhaler in the previous 12 months could be defined as SABA overusers (≥ 13 SABA inhalers in the

past 12 months).¹⁰ There are currently no formal guidelines on which to define a threshold for rescue SABA overuse based on prescription frequency. Indeed, a recent survey of a panel of GPs and hospital physicians found that the threshold for acceptable SABA use varied between 0.5 (100 doses) and 12 SABA inhalers (2,400 doses) per year.¹⁵ If we consider this in terms of daily SABA doses, this would range from 0.3 reliever doses per day to 6.6 reliever doses per day (Table 3).

Collection of medical records data including reliever use, healthcare utilisation, lung function and smoking status, among other risk factors, can effectively identify patients at risk of recurrent asthma attacks.¹⁶ While routine collation of all such data may be beyond the capacity of an individual general practice when such data are available, they can be particularly helpful in identifying ‘at-risk’ individuals. For those at risk, written communication can be useful.

An example of a letter that could be sent to a patient identified as filling prescriptions for ≥ 6 rescue SABA in-

halers over a 12-month period is shown in Box 1.

For patients identified as potentially poorly controlled through filling prescriptions for more than a predefined number of rescue SABA inhalers, as outlined above, a review of prescription fill rates for ICS or ICS/LABA should also be undertaken.

Educating patients to monitor their symptoms and recognise poor control

Educating patients on what is poorly controlled asthma may encourage them to attend clinical with worsening symptoms. Not all patients with worsening symptoms will require specialist referral, but all should have their current medication reviewed and their inhaler technique and their medication adherence and symptoms assessed.

An example of a simple algorithm that may be useful to empower patients to recognise poor asthma control in the context of rescue SABA inhaler use is shown in Figure 2. This could be used as a visual

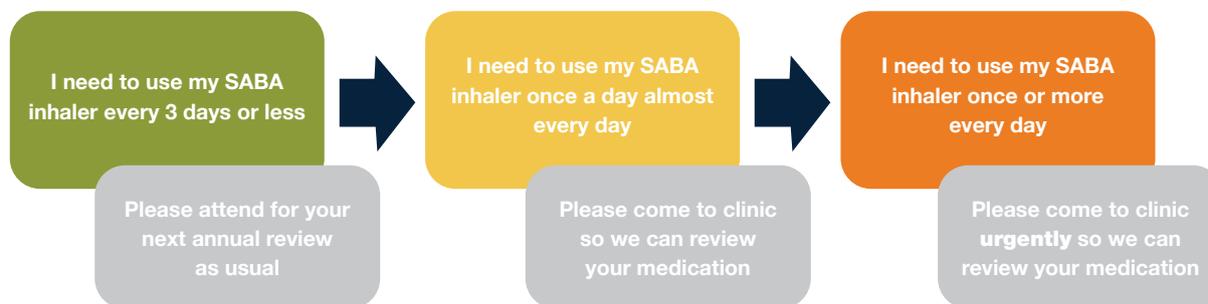
Box 1 Example letter that could be sent to a patient filling prescriptions for ≥ 6 rescue SABA inhalers over a 12-month period

Dear [Patient Name]

You have asked for a repeat prescription for your asthma ‘blue’ reliever inhaler. As your use of reliever medication is in the high-risk category, we would like to offer you an appointment to discuss your use of medication. Please could you arrange an appointment to see your usual GP or nurse who helps you to manage your asthma. You can also speak to one of the reception team to help you make an appointment.

With kind regards

Figure 2 Example of a simple algorithm that may be useful to empower patients to recognise poor asthma control in the context of rescue short-acting beta agonist (SABA) inhaler use.



Pragmatic guidance

All patients with asthma should undergo a clinical review at least every 12 months.

There is some evidence that telephone review for people who are well controlled is acceptable^{17,18} and, if not controlled, a clinician telephoning may be sufficient to encourage the patient to attend.

For patients who do not attend for their scheduled clinical review, a review of prescription requests for rescue SABA and OCS prescriptions should be undertaken followed by a significant and escalating effort to try to engage these patients constructively. Each prescription should be accompanied by an attempt to get the patient to attend with written communications, follow-up telephone calls (one from reception and a further call from a clinician if needed). The dispensing pharmacists should also be alerted that the patient has been asked to attend for review and can also be asked to encourage the patient to make an appointment with their GP.

- Indicator for rescue SABA overuse may be ≥ 6 inhalers prescribed in the previous 12 months as a trigger for an invitation for a clinical review
- Trigger for an urgent invitation for a clinical review may be an OCS prescription for asthma exacerbation in the previous 12 months

All patients should receive a personal action plan that provides specific guidance on how to recognise poor asthma control and what to do if asthma control is worsening. Poor control would be:

- 3 or more days a week with symptoms; or
- 2 or more days a week with required use of a rescue SABA inhaler for symptomatic relief; or
- 1 or more nights a week with awakening due to asthma

Include graphical or written guidance on the level of SABA inhaler use that should prompt a patient to attend for a medication review in the patient's personal action plan.

A patient should be referred for specialist review when:

- The diagnosis of asthma is unclear
- Their asthma remains poorly controlled despite optimal treatment with, and adherence to, medications readily available in primary care
- Occupational asthma is suspected
- The patient has received ≥ 2 courses of OCS for exacerbations in the past year
- The patient has received more than 12 reliever inhalers in a year (and the amount does not look like reducing)^{7,19}
- The patient has experienced a severe/life-threatening asthma attack, attended the Emergency Department or been hospitalised with asthma in the last year^{7,19}

A clinician should be prepared to refer for a more specialist opinion (tertiary level) if, despite secondary care specialist review, the patient and clinician agree that care and improvement does not match their expectations.

guide during a consultation or included as part of a personal action plan.

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Date of Preparation: August 2019 Version 1



FeNO aids the accurate diagnosis and improves symptom management through medicine optimisation for asthma patients

Diagnosing and managing asthma is still a challenge today

Asthma is a heterogeneous clinical disorder with varying presentations. Objective tests currently in use such as spirometry and peak flow, focus solely on lung function, but cannot assess the degree of airway inflammation. Knowledge of airway inflammation facilitates and aids asthma diagnosis and management through medicine optimisation, which can lead to clinical benefits including fewer exacerbations.

Why use FeNO monitoring for accurate asthma diagnosis?

Eosinophilic inflammation is a major underlying cause of asthma whereby nitric oxide is produced by epithelial cells as part of the inflammatory response. Fractional exhaled nitric oxide (FeNO) is a biomarker of this airway inflammation and monitoring FeNO is becoming an increasingly common, quick and highly accurate way of diagnosing asthma. It gives an immediate result compared to blood or sputum eosinophils. It's quick, easy and non-invasive for both adults and children from the age of five years.

Medicine optimisation in asthma

FeNO monitoring can also be used for patients who already have an asthma diagnosis - through tracking airway inflammation over time and ensuring their medication is working properly. It complements existing asthma monitoring tools for a complete picture to diagnose, treat and manage asthma.

FeNO monitoring:

- Aids the diagnosis of asthma and identifies patients with Th2 inflammatory phenotype
- Is a predictor of response to Inhaled Corticosteroids (ICS) and optimises ICS dose
- Uncovers non adherence to ICS
- Reduces exacerbations in patients at risk of future events
- Helps to identify patients for treatment with a biologic

Benefits for the patients

By seeing a FeNO reading themselves on a screen, patients automatically have greater knowledge around their condition, a faster diagnosis and potential clinical benefits. Preventative measures can also be taken if a reading is higher than usual, providing an early warning system for exacerbations, giving patients a tailored treatment plan, and the assurance that their asthma is being controlled using the latest technologies.

Cost effective asthma diagnosis and management

FeNO monitoring reduces healthcare costs through medicine optimisation and improving clinical management and easily integrates into primary care workflows.

FeNO monitoring and the technology behind it is a means of supporting highly accurate asthma diagnosis and treatment. Already in place in many hospitals and endorsed by a number of CCGs across the UK, it is also likely to be used in increasing numbers of GP surgeries over the coming years.

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Why I hate asthma reviews



Fran Robinson talks to a patient who has had asthma all her life, feels that annual asthma reviews are a waste of time (except when they are conducted by PCRS members). In this article she explains why ...

I absolutely hate the annual asthma check-up because it feels like a tick-box exercise conducted for the practice's financial benefit rather than to improve the patient's management of their condition.¹

I have had lots of annual asthma check-ups and I've never had one that meant anything to me at all.

I think the idea behind the review is a really good one, but the reality is that it is carried out by a generalist practice nurse who often doesn't seem to know much about asthma and is not empowered to change anything which might help the patient.

It's computer-driven and feels like the Little Britain TV programme ("computer says no"). You sit there, the asthma nurse is behind the computer asking questions but with no apparent interest in the answers. There is no eye contact and it's very impersonal.

I'm convinced that if I gave responses that indicated I was technically dead the nurse would not even notice. The nurse never seems to express an opinion about the information he/she is writing down. All they are doing is filling in the answers to the questions on the form. The appointment always seems to be as short as they can make it and often I'm still trying to ask questions as I'm being ushered out of the door.

Neither side wants to be there and it is a burden for the patient. I run my own business and I have to take time off work to attend the appointment. I have to go, even if I have seen the GP recently and had my medication changed, otherwise I will not be allowed to continue receiving my repeat medication.

I am a relatively well patient and one who is fairly capable of managing my condition but I never have my inhaler technique checked. The

nurse always seems to assume I know what I'm doing. But I would like to know if I could be managing my asthma better than I do. As a patient who is relatively well informed, I would like to have a discussion with the nurse about whether there is any new medication available or anything else on the horizon that might improve my condition.

I wonder, does anyone ever look at what is written in the asthma review? If they don't there is very little point in going through the process. It feels like a wasted opportunity for the patient to engage with the surgery about improving the way their condition is managed.

The way I see it is – the only way to make the review of any value is for there to be some give and take on both sides. The deal should be that the patient gives the practice their information so they can claim their QOF points and then they are given some bonus information in return.

It is a sad reflection that the check-up is done because money is involved. I always feel the review is carried out at the lowest possible standard. I'm not blaming the nurses who do the reviews because they are not empowered; it's the system that is wrong.

I'm sure anyone who is a PCRS member would do an excellent asthma review. So my solution would be that there should be a new rule that anyone who is tasked with conducting an asthma review should be a member of the PCRS. This way they would most likely be up to date and have an interest in asthma and patient-centred care because they would have access to all the fantastic PCRS resources.

The money the practice gets for the review could in turn be used to pay for their healthcare professionals to be members of the PCRS.

The patient's name has been withheld to avoid embarrassing her practice.



Ren Lawlor, Senior Lecturer, Advanced Nurse Practitioner, Department of Adult Nursing and Paramedic Science, University of Greenwich reflects on this patient's experiences

Sadly, this experience is not uncommon.

There is often a lot of anxiety around the development of personalised asthma action plans from both the clinician undertaking them and the person living with their own experience of asthma.

Clinicians can feel as though they don't have the right training around how to develop a plan, but actually the key to success is in the title – the plan must be 'personalised'. Asthma is such a variable and individual condition that the use of generic 'templates' are often unhelpful or appear irrelevant to the patient.

A good asthma review essentially needs to be an interaction between the two parties, a conversation that allows both sides to explore how the condition can be managed successfully.

Commonly, the review and support for patients is left to the practice nurse and, as such, it is imperative that that individual has had some formal training in asthma care. The PCRS 'Fit to Care' document sets out clearly what level of training a clinician should have before undertaking certain tasks, be it reviews, spirometry, medicine management and so on.

Throughout the interactions with the patient they should feel empowered to take ownership of their condition and work in collaboration with healthcare professionals for support and to manage their condition. The management of chronic conditions is not solely in the remit of the nurse tasked with performing annual reviews; it should be a collaborative partnership between the patient and all clinicians and allied healthcare professionals involved in the care of the patient.

The patient mentions not being asked about having the inhaler technique checked. This is something that patients should – through the right environment and collaborative partnership with healthcare professionals – feel they could verbally request during their appointment. For example, "Would you just mind checking to see if I am doing this right?" would prompt the clinician who may have unintentionally overlooked this part of the review. Alternatively, the patient should feel able to ask the pharmacist for a demonstration of inhaler use.

Prescribing Information (UK)

SPIRIVA® RESPIMAT® (tiotropium)

Inhalation solution containing 2.5 microgram tiotropium (as bromide monohydrate) per puff.

Indication: COPD: Tiotropium is indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD). Asthma: Spiriva Respimat is indicated as add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year.

Dose and Administration: COPD: Adults only age 18 years or over: 5 microgram Tiotropium given as two puffs from the Respimat inhaler once daily, at the same time of the day. Asthma: Adults and patients 6 to 17 years of age: 5 microgram Tiotropium given as two puffs from the Respimat inhaler once daily, at the same time of the day. In adult patients with severe asthma, tiotropium should be used in addition to inhaled corticosteroids ($\geq 800 \mu\text{g}$ budesonide/day or equivalent) and at least one controller. In adolescents (12 - 17 years) with severe asthma, tiotropium should be used in addition to inhaled corticosteroids ($> 800 - 1600 \mu\text{g}$ budesonide/day or equivalent) and one controller or in addition to inhaled corticosteroids (400 - 800 μg budesonide/day or equivalent) with two controllers. For children (6 - 11 years) with severe asthma, tiotropium should be used in addition to inhaled corticosteroids ($> 400 \mu\text{g}$ budesonide/day or equivalent) and one controller or in addition to inhaled corticosteroids (200 - 400 μg budesonide/day or equivalent) with two controllers. **Contraindications:** Hypersensitivity to tiotropium bromide, atropine or its derivatives, e.g. ipratropium or oxitropium or to any of the excipients; benzalkonium chloride, disodium edetate, purified water, hydrochloric acid 3.6% (for pH adjustment). **Warnings and Precautions:** Not for the initial treatment of acute episodes of bronchospasm or for the relief of acute symptoms. Spiriva Respimat should not be used as monotherapy for asthma. Asthma patients must be advised to continue taking anti-inflammatory therapy, i.e. inhaled corticosteroids, unchanged after the introduction of Spiriva Respimat, even when their symptoms improve. Immediate hypersensitivity reactions may occur after administration of tiotropium bromide inhalation solution. Caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Inhaled medicines may cause inhalation-induced bronchospasm. Tiotropium should be used with caution in patients with recent myocardial infarction < 6 months; any unstable or life threatening cardiac arrhythmia or cardiac arrhythmia requiring intervention or a change in drug therapy in the past year; hospitalisation of heart failure (NYHA Class III or IV) within the past year. These patients were excluded from the clinical trials and these conditions may be affected by the anticholinergic mechanism of action. In patients with moderate to severe renal impairment (creatinine clearance ≤ 50 ml/min) tiotropium bromide should be used only if the expected benefit outweighs the potential risk. Patients should be cautioned to avoid getting the spray into their eyes. They should be advised that this may result in precipitation or worsening of narrow-angle glaucoma, eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes from conjunctival congestion and corneal oedema. Should any combination of these eye symptoms develop, patients should stop using tiotropium bromide and consult a specialist immediately. Tiotropium bromide should not be used more frequently than once a day. **Interactions:** Although no formal drug interaction studies have been performed, tiotropium bromide has been used concomitantly with other drugs commonly used in the treatment of COPD and asthma, including sympathomimetic bronchodilators, methylxanthines, oral and inhaled steroids, antihistamines, mucolytics, leukotriene modifiers, cromones, anti-IgE treatment without clinical evidence of drug interactions. Use of LABA or ICS was not found to alter the exposure to tiotropium. The co-administration of tiotropium bromide with other anticholinergic-containing drugs has not been studied and is therefore not recommended. **Fertility, Pregnancy and Lactation:** Very limited amount of data in pregnant women. Avoid the use of Spiriva Respimat during pregnancy. It is unknown whether tiotropium bromide is excreted in human breast milk. Use of Spiriva Respimat during breast feeding is not recommended. A decision on whether to continue/discontinue breast feeding or therapy with Spiriva Respimat should be made taking into account the benefit of breast feeding to the child and the benefit of Spiriva Respimat therapy to the woman. Clinical data on fertility are not available for tiotropium. **Effects on ability to drive and use machines:** No studies have been performed. The occurrence of dizziness or blurred vision may influence the ability to drive and use machinery. **Undesirable effects:** COPD: Common ($\geq 1/100$ to $< 1/10$) Dry mouth. Uncommon ($\geq 1/1,000$ to $< 1/100$) Dizziness, headache, cough, pharyngitis, dysphonia, constipation, oropharyngeal candidiasis, rash, pruritus, urinary retention, dysuria. Rare ($\geq 1/10,000$ to $< 1/1,000$): Insomnia, glaucoma, intraocular pressure increased, vision blurred, atrial fibrillation, palpitations, supraventricular tachycardia, tachycardia, epistaxis, bronchospasm, laryngitis, dysphagia, gastroesophageal reflux disease, dental caries, gingivitis, glossitis, angioneurotic oedema, urticaria, skin infection/skin ulcer, dry skin, urinary tract infection. Not known (cannot be estimated from the available data): Dehydration, sinusitis, stomatitis, intestinal obstruction including ileus paralytic, nausea, hypersensitivity (including immediate reactions), anaphylactic reaction, joint swelling. Asthma: Uncommon ($\geq 1/1,000$ to $< 1/100$) Dizziness, headache, insomnia, palpitations, cough, pharyngitis, dysphonia, bronchospasm, dry mouth, oropharyngeal candidiasis, rash. Rare ($\geq 1/10,000$ to $< 1/1,000$): Epistaxis, constipation, gingivitis, stomatitis, pruritus, angioneurotic oedema, urticaria, hypersensitivity (including immediate reactions), urinary tract infection. Not known (cannot be estimated from the available data): Dehydration, glaucoma, intraocular pressure increased, vision blurred, atrial fibrillation, supraventricular tachycardia, tachycardia, laryngitis, sinusitis, dysphagia, gastroesophageal reflux disease, dental caries, glossitis, intestinal obstruction including ileus paralytic, nausea, skin infection/skin ulcer, dry skin, anaphylactic reaction, joint swelling, urinary retention, dysuria. Serious undesirable effects consistent with anticholinergic effects: glaucoma, constipation, intestinal obstruction including ileus paralytic and urinary retention. An increase in anticholinergic effects may occur with increasing age. Prescribers should consult the Summary of Product Characteristics for further information on undesirable effects. **Pack sizes and NHS price:** Single pack: 1 Respimat inhaler and 1 cartridge providing 60 puffs (30 medicinal doses) £23.00. **Legal category:** POM. **MA number:** PL 14598/0084. **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in April 2018.**

Adverse events should be reported.
Reporting forms and information can be found at
www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to
Boehringer Ingelheim Drug Safety on
0800 328 1627 (freephone).

References:

1. Mallik, D.A. Peak Inspiratory Flow Rate as a criterion for dry powder inhaler use in COPD. *Ann Am Thorac Soc* 2017; 14: 1103-1107
2. Pohlmann, G. et al. Assessment of the power required for optimal use of current inhalation devices. *J Aerosol Medicine* 2018; 31: 339-346
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▼SPIOLTO® RESPIMAT® (tiotropium and olodaterol)

Inhalation solution containing 2.5 microgram tiotropium (as bromide monohydrate) and 2.5 microgram olodaterol (as hydrochloride) per puff. **Action:** Inhalation solution containing a long acting muscarinic receptor antagonist, tiotropium, and a long acting beta₂-adrenergic agonist, olodaterol. **Indication:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dose and Administration:** Adults only aged 18 years or over: 5 microgram tiotropium and 5 microgram of olodaterol given as two puffs from the Respimat inhaler once daily, at the same time of the day. **Contraindications:** Hypersensitivity to tiotropium or olodaterol or any of the excipients; benzalkonium chloride, disodium edetate, purified water, 1M hydrochloric acid (for pH adjustment); atropine or its derivatives e.g. ipratropium or oxitropium. **Warnings and Precautions:** Not for use in asthma or for the treatment of acute episodes of bronchospasm, i.e. as rescue therapy. Inhaled medicines may cause inhalation induced paradoxical bronchospasm. Caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Patients should be cautioned to avoid getting the spray into their eyes. They should be advised that this may result in precipitation or worsening of narrow-angle glaucoma, eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes from conjunctival congestion and corneal oedema. Should any combination of these eye symptoms develop, patients should stop using Spiolto Respimat and consult a specialist immediately. In patients with moderate to severe renal impairment (creatinine clearance ≤ 50ml/min) use only if the expected benefit outweighs the potential risk. Caution in patients with a history of myocardial infarction during the previous year, unstable or life-threatening cardiac arrhythmia, hospitalised for heart failure during the previous year or with a diagnosis of paroxysmal tachycardia (> 100 beats per minute) as these patients were excluded from the clinical trials. In some patients, like other beta₂-adrenergic agonists, olodaterol may produce a clinically significant cardiovascular effect as measured by increases in pulse rate, blood pressure and/or symptoms. Caution in patients with: cardiovascular disorders, especially ischaemic heart disease, severe cardiac decompensation, cardiac arrhythmias, hypertrophic obstructive cardiomyopathy, hypertension, and aneurysm; convulsive disorders or thyrotoxicosis; known or suspected prolongation of the QT interval (e.g. QTc>0.44 s); patients unusually responsive to sympathomimetic amines; in some patients beta₂-agonists may produce significant hypokalaemia; increases in plasma glucose after inhalation of high doses. Caution in planned operations with halogenated hydrocarbon anaesthetics due to increased susceptibility of adverse cardiac effects. Should not be used in conjunction with any other long-acting beta₂-adrenergic agonists. Immediate hypersensitivity reactions may occur after administration. Should not be used more frequently than once daily. **Interactions:** Although no formal *in vivo* drug interaction studies have been performed, inhaled Spiolto Respimat has been used concomitantly with other COPD medicinal products, including short acting sympathomimetic bronchodilators and inhaled corticosteroids without clinical evidence of drug interactions. The co-administration of the component tiotropium with other anticholinergic containing drugs has not been studied and therefore is not recommended. Concomitant administration of other adrenergic agents (alone or as part of combination therapy) may potentiate the undesirable effects of Spiolto Respimat. Concomitant treatment with xanthine derivatives, steroids, or non-potassium sparing diuretics may potentiate any hypokalaemic effect of adrenergic agonists. Beta-adrenergic blockers may weaken or antagonise the effect of olodaterol. Cardioselective beta-blockers could be considered, although they should be administered with caution. MAO inhibitors, tricyclic antidepressants or other drugs known to prolong the QTc interval may potentiate the action of Spiolto Respimat on the cardiovascular system. **Fertility, pregnancy and lactation:** There is a very limited amount of data from the use of tiotropium in pregnant women. For olodaterol no clinical data on exposed pregnancies are available. As a precautionary measure, avoid the use of Spiolto Respimat during pregnancy. Like other beta₂-adrenergic agonists, olodaterol may inhibit labour due to a relaxant effect on uterine smooth muscle. It is not known whether tiotropium and/or olodaterol pass into human breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Spiolto Respimat should be made taking into account the benefit of breast-feeding to the child and the benefit of therapy for the woman. Clinical data on fertility are not available for tiotropium or olodaterol or the combination of both components. **Effects on ability to drive and use machines:** No studies have been performed. The occurrence of dizziness or blurred vision may influence the ability to drive and use machinery. **Undesirable effects:** Uncommon (≥ 1/1,000 to <1/100): Dizziness, headache, tachycardia, cough, dysphonia, dry mouth. Rare (≥ 1/10,000 to <1/1,000): Insomnia, vision blurred, atrial fibrillation, palpitations, supraventricular tachycardia, hypertension, laryngitis, pharyngitis, epistaxis, bronchospasm, constipation, oropharyngeal candidiasis, gingivitis, nausea, stomatitis, hypersensitivity, angioedema, urticaria, pruritus, rash, arthralgia, back pain, joint swelling, urinary retention, urinary tract infection, dysuria. Not known (cannot be estimated from the available data): Nasopharyngitis, dehydration, glaucoma, intraocular pressure increased, sinusitis, intestinal obstruction ileus/paralytic, dysphagia, gastroesophageal reflux disease, glossitis, dental caries, anaphylactic reaction, skin infection and skin ulcer, dry skin. Serious undesirable effects include anaphylactic reaction, angioedema and consistent with anticholinergic effects: glaucoma, constipation, intestinal obstruction including ileus paralytic and urinary retention. An increase in anticholinergic effects may occur with increasing age. The occurrence of undesirable effects related to beta₂-adrenergic agonist class should be taken into consideration such as, arrhythmia, myocardial ischaemia, angina pectoris, hypotension, tremor, nervousness, muscle spasms, fatigue, malaise, hypokalaemia, hyperglycaemia and metabolic acidosis. Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack sizes and NHS price:** Single pack: 1 Respimat inhaler and 1 cartridge providing 60 puffs (30 medicinal doses) £32.50 **Legal category:** POM **MA numbers:** PL 14598/0101 **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in** January 2019

Date of preparation: July 2019

PC-UK-101634 V1



More COPD patients than you realise need *inhaleability*

Not all patients with COPD have the **ability** to generate enough inspiratory flow to **inhale** their medication correctly.^{1,2}

RESPIMAT® requires a lower inspiratory effort to achieve higher flow rates compared with most commonly used dry powder inhalers*.³

*Breezhaler®, Genuair® and Ellipta® device.

SPIRIVA® Respimat® and SPIOLTO® Respimat® are indicated as maintenance bronchodilator treatments to relieve symptoms of patients with chronic obstructive pulmonary disease.^{4,5}

Prescribing information for SPIRIVA® Respimat® can be found on the adjacent page.

SPIRIVA®
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RESPIMAT®
tiotropium & olodaterol

Countdown to



The PCRS Respiratory Conference 2019
19th-21st September, Telford International Centre



As we finalise our preparations for the PCRS Respiratory Conference 2019, we are looking forward to welcoming delegates to our event which is the highlight of the calendar for healthcare professionals working in primary and community-based respiratory care.

PCRS Chair-Elect Carol Stonham says:

“ This year there are some really interesting speakers who will give you all the latest information about respiratory care, make sure you’re up to date and give you some practical tips to improve what you do every day. ”

The programme offers something for everyone with five streams plus satellite clinical sessions held in conjunction with our pharmaceutical partners.

The clinical stream

Clinical symposia will ensure you are up to date with the latest clinical developments. This year, as well as focusing on the ‘patient with asthma’ or the ‘patient with COPD’, this stream covers broader issues such as managing cough, respiratory-related allergy, how to reduce patients’ over-reliance on short-acting beta agonists (SABA) and respiratory disease in the context of the frail and elderly patient with comorbidities. There will be an update on the latest COPD guidelines and a session

that will bring delegates up to date with recent high quality published respiratory research papers.

Practical skills workshops

Our popular practical skills workshops run in conjunction with Education for Health give you an opportunity to improve your hands-on skills. Topics cover: cognitive behaviour therapy, interpreting spirometry, helping people to change, COPD, smoking cessation techniques, getting your patient moving, supported self-

PCRS member Garry Macdonald, a pharmacist, describes the Conference as a family reunion for respiratory healthcare professionals.

“ We are a round table organisation where no profession is superior to any other. This is a great environment to share and learn from other professions. ”

Clare Cook, co-Chair of the PCRS Respiratory Leadership Programme Board, says what she loves most about coming to the PCRS Conference is not only to hear about the latest innovation in respiratory care but also to touch base with what she calls the 'nuts and bolts' of respiratory care such as smoking cessation, spirometry interpretation, inhaler technique, sarcopenia and nutrition.

“ As we all know, it's getting the basics right that can be the cornerstone of improving a patient's quality of life. Also the conference offers such value for money, especially as dinner and a disco is included. The mix of formal education, debate and dancing make the conference a great place to meet colleagues working in specialist and unique roles across respiratory services. ”

management and nutrition, using the Right Breathe app, sarcopenia and respiratory disease.

The service development stream

If you are interested in improving respiratory services, the service development stream will give you inspiration on providing innovative and sustainable change. Speakers will be discussing topics ranging from how to re-design services for the seldom reached and hardly heard patient, how to make the best use of the skills of allied health professionals in the respiratory pathway and how to run effective group consultations. There will be plenty of new ideas to be gained from delegates presenting their Best Practice abstracts.

Plenaries

The plenaries offer delegates a chance to hear how the NHS Long Term Plan will impact on respiratory care and reshape services, learn how to optimally manage breathlessness and better understand how to diagnose respiratory disease.

The research stream

The PCRS conference is the only UK event in the academic calendar with a stream entirely dedicated to primary care respiratory research, showcasing the cutting edge of respiratory scientific research in primary care.

Dedicated sessions for professions and taster sessions

This year for the first time we are running discipline-

specific sessions for GPs and practice nurses, physiotherapists, pharmacists, respiratory nurse specialists and physicians working in integrated respiratory care services. There will also be a taster session for anyone interested in finding out more about the PCRS Respiratory Clinical Leadership Programme.

Inspiring primary care respiratory research and researchers and PCRS affiliated groups

On the afternoon prior to the Conference we are holding a workshop for early and mid-career academic respiratory researchers and a meeting for local affiliated group leaders and anyone interested in becoming a group leader.

PCRS Executive Chair Dr Noel Baxter says the PCRS Conference always gives him some practical tips to take home and implement in his practice.

“ Last year the fantastic e-cigarette myth buster session really helped me to feel more confident when discussing with patients the recommendations from Public Health England around the use of these tools in supporting quit attempts and harm reduction from tobacco. This story isn't going away and I am sure will be a hot topic of discussion in our PCRS channels. ”



The PCRS Respiratory Conference 2019

19th - 21st September, Telford International Centre



Put the date
in your diary!

The must-attend event of the year for
all healthcare professionals interested
in developing best-practice and
integrated respiratory care.

● **Enhancing** ● **Integrated** ● **Holistic** ● **Life-Learning**

The PCRS Respiratory Conference is the UK's leading respiratory conference.

Its aim is to inspire delegates to discover new ways of working with patients and colleagues, helping them to respond positively to the challenges of primary and community care. Attendees will be able create a brighter future for respiratory patients and a level of greater job satisfaction for themselves.



This is a Conference of benefit to all respiratory care professionals and people involved with multi-morbidities and health disciplines involving respiratory care.

Sessions are designed to be of equal interest regardless of where in the UK you are working. The Telford International Centre is an acclaimed conference venue, within easy reach from anywhere in the UK via road, train and air.

Register Now

To register for this event, please visit www.pcrs-uk.org/annual-conference to book your place. Registration rates are discounted if you are a PCRS Member.



Our 2019 Conference Partners



Our 2019 Conference Sponsors



Service Development

10 top tips for PCN clinical directors: the respiratory long-term condition perspective



The 10 Top Tips for PCN Clinical Directors was written by **Stuart Shields** a GP in Cambridgeshire & Peterborough. He has for several years had a significant role in designing respiratory and other long-term conditions care in his CCG.

The PCRS felt that, in July 2019 when all Primary Care Networks (PCNs) were in place, we (PCRS) had to encourage and enable the Clinical Directors to look at how they were going to improve respiratory care within their PCN.

PCRS recognises the speed at which these posts were developed and implemented, and seeks to ensure that respiratory care does not become lost under a pile of other clinical priorities. The article enables Clinical Directors to focus on respiratory care with real examples and encouragement from a clinician who has worked in a similar field (albeit in commissioning) for years, and who understands the rewards, pitfalls and barriers to providing excellent care.

The PCRS hopes that Clinical Directors when they have read this article will feel inspired, encouraged and enabled to tackle the issue of incorporating respiratory care into their PCN's priorities in line with the respiratory section and priorities of the 10-year Long Term Plan (LTP).

How one long-term condition might be used to fulfil the potential of PCN investment

(1) Vision

A PCN consists of groups of general practices working with a range of local providers across primary, community, social care and the voluntary sector to offer more personalised, coordinated health and social care to their local populations. For information about this, visit <https://www.england.nhs.uk/gp/gpfv/re-design/primary-care-networks/>. Don't lose

sight of this. Your PCN should not try and do anything without help from allies.

(2) Analysis

Primary care has a lot of live data; use it to plan where to make improvements in pockets of poor outcomes. You do not have to do it yourself – you need to ask your health informatics department and you can use the RightCare website (<https://www.england.nhs.uk/rightcare/workstreams/respiratory/>). Your CCG have informatics resources for your use – you just need to ask them.

(3) Scenarios

Discuss what needs to be done to improve respiratory care within your PCN – you all know what needs to be done. Choose the scenario that addresses what you think needs to improve respiratory care in your locality. See www.pcrs-uk.org for examples of best practice.

(4) Options

Who is going to deliver the changes? Will it be a motivated primary care team working across practices? Will it be a collaboration with a community provider? Will secondary care come out and work in your locality? Will any options become slowed down by contracting and commissioning? Choose an option that will deliver most of your expectations rather than one that is too good to ever happen.

(5) Legal implications

You are going to be sharing data, accessing



records, prescribing and treating respiratory patients on behalf of the group. Run your option through a 'what if' table-top exercise and invite critical friends in to try and 'break' it. Learn and adjust.

(6) Policy and strategy

There are national strategies for respiratory care. They are both clinical and environmental. Map them against your population from pre-conception to 'end-of-life care'. These strategies direct other providers and agencies. PCRS has done some of the work for you (see https://www.pcrs-uk.org/sites/pcrs-uk.org/files/Respiratory_services_Framework.pdf).

(7) Resources

You should now have an idea about what resources you need, and what is available for your chosen option. You could make a case for investment if there is a gap. Patient groups are vital – don't plan without them as they will be your data when you demonstrate a reduction in smoking/admission/ED attendance rates.

(8) Planning and doing

The PCN contract does not give you a lot of time. You cannot deliver this alone. Each member practice is already delivering res-

piratory care. Your aim is to assure that it reaches the whole population with consistent fair access to sustainable primary care.

(9) Policy performance

Your respiratory performance data are mostly generated by QOF and this can be collated live. Your patient groups can be involved in reported experiences. Consider delegating patient experience data to your patient groups.

(10) Evaluation

The PCN programme will change year by year. Social prescribing, pharmacists, physiotherapists, paramedics and improved access appointments will all be part of the investment. When the question comes "But what did they actually do?", your respiratory care plan will provide the answer. Start with the end in mind. What matters? Are there already some priorities illustrated by your PCN group? If so, ensure outcomes are aligned with them.

Good quality of life? Minimal emergency admissions? Medication used well with minimal waste? The fewest number of clinical hours to achieve all your aims? These are either being measured or could be measured from the beginning.

Policy Round-Up

A summary of the latest developments in the UK health services, including any major new reports, guidelines and other documents relevant to primary care respiratory medicine



Tracey Lonergan, *PCRS Policy Coordinator* and **Noel Baxter**, *Executive Policy Lead for PCRS*

Respiratory disease on the national agenda

Ensuring that respiratory disease remains high on the National Health agenda is a key focus for all PCRS policy-related activities, and we continue to work closely and partner with other relevant organisations to ensure the general practice and community care voice is both heard and listened to at the national level.

Respiratory disease is a priority area within the NHS Long Term Plan for England and the implementation plan is now in place, with working groups starting to design the recommendations and levers to deliver improvements in respiratory care with a focus on reducing local health inequalities and improving prevention. PCRS continues to ensure it sits at the heart of these initiatives and delivers our members' perspective at every stage.

As reported in the last *PCRU*, in December 2018 the Lung Health Task Force published its 5-year plan to improve outcomes for people with respiratory disease. During the first half of 2019 the LHTF have established working groups to focus on key areas for implementation. These include:

- Early and accurate diagnosis
- Flexible learning – ensuring the workforce is trained to deliver modern respiratory care
- Breathlessness – clear pathways to correct diagnosis and management
- Pulmonary rehabilitation: optimising patient uptake and service provision
- Medicines optimisation for inhaler use: staff training programmes for patient inhaler use

PCRS has worked hard to ensure we have representation across these key working groups and will continue to support and be actively involved in shaping the initiatives that are being developed.

PCRS also continues to work closely with NHS RightCare on their respiratory workstreams including the development of the asthma and pneumonia clinical pathways and case studies. PCRS representation is proving critical in ensuring the primary care voice is heard and that the pathways and other initiatives are balanced between primary and secondary/tertiary care. The first of the clinical pathways – asthma and pneumonia – are expected to be published in October this year.



The overhaul of the NICE Quality and Outcomes Framework (QOF) for respiratory disease continues apace with PCRS contributing and championing the primary and community care perspective. Our focus has been to encourage NICE to develop more outcome-focused indicators and to utilise the valuable work from the National Audit for COPD and Asthma (NACAP), which has provided a wealth of information around appropriate coding in respiratory disease. So far the QOF for asthma and COPD have been reviewed with more changes expected in the QOF for April 2020, and PCRS will continue to contribute to this ongoing and important initiative.



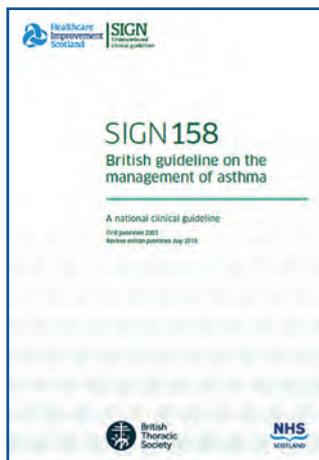
National respiratory guidelines

July saw the publication of the updated British Thoracic Society (BTS)/Scottish InterCollegiate Guidelines Network (SIGN) British

guideline on the management of asthma and an update to the NICE COPD guideline, both of which PCRS have consulted on with members and input a PCRS perspective during development.

The latest update to the BTS/SIGN asthma guideline was developed during 2018, and the key changes were presented at the BTS Winter Meeting in 2018. A consultation was undertaken between December 2018 and January 2019 in which PCRS took part. We welcome this further update to the long established, comprehensive and highly respected BTS/SIGN guideline for asthma and that the final guideline recognises many of the recommendations made by PCRS during the consultation process. We particularly welcome the focus on predicting and assessing future risk including the recognition of high SABA use as a marker of high risk. Evaluating SABA use has been a central part of the Asthma RightCare program, a global initiative led by the International Primary Care Respiratory Group (IPCRG), to encourage conversations between HCPs and between HCPs and patients and to raise awareness of high SABA use as an identifiable risk factor of increased asthma exacerbation risk. The new recommendation to quadruple the dose of inhaled steroid for up to 14 days to reduce the need for oral steroids to abort an asthma attack in recognition of the growing evidence that this intervention can be helpful is also a considerable step forward. There remain a number of areas in which PCRS will continue to campaign for change. These include recognition that smoking is responsible for more than a slight increase in future risk for asthma exacerbation and the value of Very Brief Advice (VBA) to trigger a quit attempt in smokers with asthma. You can read more about the PCRS policy position regarding the updated guidelines in our latest briefing document. To access all the PCRS briefing documents, just select the category 'PCRS position' in the search page under the 'Resources' drop down menu.

A key campaign for PCRS in recent years has been the need for a single guideline for the management of patients with asthma in the UK. The current situation with two separate guidelines – one from NICE and a separate guideline issued jointly by BTS/SIGN – have not always been in alignment and this has posed significant challenges for HCPs in ensuring they deliver optimal care for patients. The announcement at the end of July that future UK-



wide guidance for the diagnosis and management of chronic asthma will be jointly produced by the BTS, SIGN and NICE will be of considerable benefit to HCPs and ultimately improve patient care.

July also saw the publication of an addendum to the NICE COPD guidance focusing on the place of triple therapy in the treatment of patients over 16 years of age (<https://bit.ly/2z8KCcK> paragraphs 1.2.14 to 1.2.18). The addendum supplements the recent guideline issued in December 2018 after PCRS and other organisations advised that this omission would render the publication out of date on publication. The guideline now includes recommendations that, prior to initiating triple therapy with any COPD patients, a clinical review should be undertaken to ensure that non-pharmacological management is optimised, including treating tobacco dependency, and to exclude any non-COPD related causes of acute episodes or day-to-day symptoms. The guideline also now clarifies that the recommended duration of oral corticosteroids during an exacerbation should be for 5 days, in line with GOLD recommendations, although the two guidelines recommend slightly different doses (NICE 30 mg; GOLD 40 mg).

Addressing tobacco dependency in the UK

The publication of the PCRS Pragmatic Guide for Clinicians on the Diagnosis and Management of Tobacco Dependency in January of this year underscored the importance placed on smoking as a threat to respiratory health and a burden on health services in the UK. A new health prevention Green Paper was published by the Government on 24 July, setting out a goal of a 'smoke-free' England by 2030. Proposals to achieve this admittedly ambitious goal include:

- Offering all smokers who are admitted to hospital support to stop smoking
- Requiring tobacco companies to pay towards the cost of tobacco control
- Investigating the possibility of inserts in tobacco products giving quitting advice
- Launching a call for independent evidence to assess how effective heated tobacco products are in helping people quit smoking. The evidence on e-cigarettes will be kept under review
- Plans to discourage young people from starting smoking

These measures were submitted by Bob Blackman MP, the Chair of the APPG on Smoking and Health, supported by ASH and endorsed by 16 other leading health organisations including PCRS. PCRS will continue to contribute to the consultation process and push for action on the proposals including clarity on funding sources and details of how the goals will be achieved.

The PCRS position

An important part of the policy development and influencing work at PCRS is to establish consensus positions on key respiratory topics. A suite of briefing materials is now available and more are being added all the time, setting out the PCRS position on the current situation and our aspirations for the future.

You can find these briefing documents on the PCRS website. To access these, just search under the 'Resources' drop down menu using PCRS Position as the category or use this link <https://bit.ly/2MuwHWW>.

In development:

- BTS bronchiectasis guideline – version for primary care (expected summer 2019)
- NICE lung cancer screening quality standard update (expected December 2019)
- BTS/SIGN/NICE asthma guideline in development (expected 2020)
- NHSE Respiratory Board – development of metrics to track real respiratory improvements



Helping Primary Care Networks Grow and Deliver

The creation of Primary Care Networks (PCNs) is a key focus of the NHS Long Term Plan; as is the role these networks will play in the delivery of services for people with long term conditions.

Yet, setting up PCNs and ensuring they continue to run efficiently is also a huge undertaking for those involved.

At Education for Health, we're offering support across the UK to healthcare professionals to enable you to setup and effectively work within a PCN. These can be tailored to suit your local needs and budgets.

 Know your local population	 Map your patient journeys
 Build effective networks	 Lead the PCN
 Map local services	 Build a tailored package

Find out more about what we can offer at <https://www.educationforhealth.org/pcn>



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Journal Round-Up

Each quarter the Primary Care Respiratory Academy, in partnership with the *Primary Care Respiratory Update* Editorial Board, publishes a series of informative summaries of studies and reviews in areas relevant to respiratory health in a primary or community setting. The summaries can be found online at <http://www.respiratory-academy.co.uk/clinical/journal-club/>. Below is a selection of those published.

** Editor's Choice **

Systematic review of clinical prediction models to support the diagnosis of asthma in primary care

Daines L, McLean S, Buelo A, et al. *npj Primary Care Med* 2019;29
<https://doi.org/10.1038/s41533-019-0132-z>

Asthma is commonly misdiagnosed, with over-diagnosis leading to potentially harmful treatment and unnecessary healthcare cost, and under-diagnosis risking avoidable morbidity and mortality.

Asthma is a clinical diagnosis, with no definitive reference standard that can confirm or refute the diagnosis. Conflicting recommendations in national and international guidelines are evidence of the uncertainty about the best combinations of clinical features and tests for asthma diagnosis.

Clinical prediction models help healthcare professionals to assess the probability of a diagnosis and enhance shared decision making. Daines and colleagues set out to identify, compare and synthesise existing clinical prediction modules that could support the diagnosis of asthma in children and adults in the primary care setting.

They searched Medline, Embase, CINAHL, TRIP and US National Guidelines Clearinghouse databases from 1 January 1990 to 23 November 2017. They screened titles, abstracts and full texts for eligibility, extracted data and assessed risk of bias. From 13,798 records, they reviewed 53 full-text articles. Seven clinical prediction models to support the diagnosis of asthma in primary care were identified.

This review highlighted the paucity of current criteria to inform diagnostic algorithms. All seven of the selected studies were at high risk of bias and could not be recommended for diagnosing asthma in routine clinical practice. Wheeze, allergy, allergic rhinitis, symptom variability and exercise-induced symptoms were associated with asthma and could be considered as predictors in future prediction models. Cough, respiratory tract infections and nocturnal respiratory symptoms were consistently associated with asthma.

In the future, establishing a data-driven approach to asthma diagnosis could resolve current discrepancies in guidelines and enable the unacceptable level of asthma misdiagnosis to be reduced.

COPD exacerbations: the impact of long versus short courses of oral corticosteroids on mortality and pneumonia: nationwide data on 67000 patients with COPD followed for 12 months

Sivapalan P, Ingebrigtsen T, Rasmussen D, et al. *BMJ Open Resp Res* 2019;6:e000407
<https://doi.org/10.1136/bmjresp-2019-000407>

Patients with COPD are at greater risk of developing pneumonia due to impairment of lung defence mechanisms and use of inhaled corticosteroids. Higher rates of intensive care admission, longer hospital stays and increased mortality rates

are also seen in patients hospitalised with COPD and pneumonia than in patients with pneumonia only.

Recommended treatment duration with oral corticosteroids (OCS) has dropped from 10–14 days in 2001 to 5–7 days currently (GOLD). While OCS have been reported to shorten the length of hospital stays, improve lung function and reduce the risk of early relapse and treatment failure in patients with non-pneumonia exacerbations, they are also associated with a number of adverse side effects including hyperglycaemia, fluid retention, weight gain, hypertension, diabetes mellitus, adrenal

suppression, deep vein thrombosis, osteoporosis and increased fracture risk. However, the risk of severe infections and death following the use of OCS is unknown.

These study authors conducted a nationwide, observational cohort study to determine the association between duration of OCS treatment in outpatients with acute exacerbations of COPD and the risk of pneumonia hospitalisation and all-cause mortality during a one-year study period, and to explore how the timing of the exposure affects risk estimates.

Study participants (n=10,152) were drawn from the Danish Register of Chronic Obstructive Pulmonary Disease, had received a diagnosis between 1 January 2010 and 31 October 2017, and had received prednisolone prescriptions for the treatment of exacerbations. They were set in two groups: those on a short course of OCS (prednisolone \leq 250 mg; n=6,002) and those on a long course (prescriptions >250 mg; n=4,150).

Long courses were associated with an increased 1-year risk of pneumonia hospitalisation or all-cause mortality, pneumonia hospitalisation and all-cause compared with the short course of OCS treatment. Future studies could focus on testing the results reported in this paper and investigating the possible causes of the increased all-cause mortality often associated with long courses of OCS.

COPD patents' experiences, self-reported needs, and needs-driven strategies to cope with self-management

Sigurgeirsdottir J, Halldorsdottir S, Arnardottir RH, et al. *Int J COPD Dis* 2019;14:1033–43

<https://doi.org/10.2147/COPD.S201068>

COPD is characterised by a gradual decline in health and progressive organ failure, with acute exacerbations and decreased chances of survival. In addition to struggling with multiple medications and multimorbidity, a patient with COPD will experience uncertainty, chaos, fluctuations in health and repeated setbacks. It is reasonable to assume that the therapeutic needs of patients with COPD will not be met by therapy alone, but rather by continuous and flexible interdisciplinary treatment.

Self-management refers to an individual's active management of a chronic illness in collaboration with their family members and clinicians, and involves education, physical therapy and monitoring, with the emphasis on patients being in control of their own lives.

Pulmonary rehabilitation (PR) is effective for patients at every stage of COPD, in that it improves quality of life and functional status by reducing symptoms of COPD. However, there is a strong likelihood that patients with COPD receive neither

appropriate self-management education nor timely assessments for PR. The authors proposed that an evaluation of the patient's wellbeing should be conducted in preparation for PR, and that this evaluation should be based on the patient-clinician relationship, with a particular focus on the patient's view of what they need. Such research into patients' needs is lacking in the literature. Therefore, the purpose of this study was to explore COPD patients' experiences, self-reported needs and needs-driven strategies for coping with COPD.

Ten participants with mild-to-severe COPD were each interviewed either once or twice, and a total of 15 in-depth interviews were conducted, recorded, transcribed and analysed. Fourteen needs were identified and eight clusters of needs-driven strategies that patients used for coping with their self-management. Helpful coping strategies included conducting financial arrangements, maintaining hope, fighting tobacco addiction, seeking knowledge about COPD and accepting support. Having a positive mind-set and a willingness to accept professional help were important. Procrastination and avoidance were examples of unhelpful coping strategies. The study also highlighted the cycle of dyspnoea, anxiety and fear of breathlessness experienced by participants.

The study authors call for further studies on the biopsychosocial attributes of dyspnoea and better education for clinicians to help patients improve self-management.

Effectiveness of school-based self-management interventions for asthma among children and adolescents: findings from a Cochrane systematic review and meta-analysis

Kneale D, Harris K, McDonald V, et al. *Thorax* 2019;74:432–8

<https://doi.org/10.1136/thoraxjnl-2018-211909>

In England, one in six children between the ages of 5 and 14 will have experienced asthma at some point, with an estimated 2.8 million school days lost in the UK each year.

It is known that well-controlled asthma is defined by reduced daytime and night-time symptoms and diminished risk of life-threatening asthma attacks. Self-management is a cornerstone of treatment for people with asthma and involves educating and enabling individuals to achieve good control of their asthma symptoms and prevention of future exacerbations.

The impact of providing self-management education and support within schools is unclear, and the aim of this systematic review was to identify and synthesise evidence on school-based interventions for children with asthma, with a focus on effectiveness. There were two key objectives: to identify the key design features and processes associated with successful implementation of school-based asthma self-management in-

interventions; and to understand whether school-based interventions can effectively change asthma self-management behaviour.

Intervention studies were eligible for inclusion in the systematic review if they employed a randomised parallel-group design and were published in English from 1995 onwards. Participants included children aged 5–18 years, who participated within their own school environment. Searches were conducted on the Cochrane Airways Group Specialised Register. The titles and abstracts of 379 outcome evaluation studies were independently screened by two review authors and, following exclusion on title and abstract, 105 full-text records were assessed for eligibility, and 33 outcome evaluation studies were included for further analysis.

School-based interventions were effective in reducing the frequency of emergency department visits and moderately effective in reducing levels of hospitalisations. A meta-analysis of three studies suggest that the approach could reduce the number of days of restricted activity. There is uncertainty as to whether school-based self-management interventions reduce absences from school.

School-based self-management interventions are effective in improving outcomes for children with asthma.

CRP-guided antibiotic treatment in acute exacerbations of COPD admitted to hospital

Prins H, Duikers R, van der Valk P, et al. *Eur Respir J* 2019;53:1802014

<https://doi.org/10.1183/13993003.02014-2018>

A patient with COPD will experience an average of 1.5 exacerbations a year, and co-infection of viruses and bacteria is detected in 25% of exacerbations. Although molecular techniques can detect viral infections as triggers of an acute exacerbation, no infectious agents can be detected in around one-third of instances.

Current GOLD recommendations state that antibiotic treatment should be based on patient-reported sputum purulence, the (controversial) assumptions being that patients' assessment of sputum colour is reliable and that purulence is a good marker of bacterial infection. As a consequence, implementation of the GOLD strategy results in overuse of antibiotics with resulting higher medical costs, side effects and growth in antimicrobial resistance.

A 30% reduction in resistance can be achieved by implementing recommendations that discourage antibiotic treatment, for which a better marker of patients who would benefit is essential. Serum C-reactive protein (CRP) is such an acute-phase protein and marker for systemic inflammation, whose levels

are significantly higher during an acute exacerbation of COPD compared with baseline levels. As previous reports have indicated that patients with an acute exacerbation admitted to hospital with a CRP ≥ 50 mg/L showed a trend to benefit more from antibiotics than patients with low CRP, Prins and colleagues set out to test the hypothesis that, in patients with an acute exacerbation admitted to hospital, CRP-guided antibiotic therapy may lead to a reduction in antibiotic therapy within 24 hours of admission compared with a strategy of patient-reported sputum purulence without increasing the rate of treatment failures or adverse events within 30 days.

The multicentre randomised controlled open intervention clinical trial was performed in two hospitals in the Netherlands between July 2011 and February 2015. Eligible patients were randomly assigned to receive either CRP-directed antibiotic therapy or GOLD-directed antibiotic therapy. The primary endpoint was antibiotic treatment started during the first 24 hours after admission, and secondary endpoints included 30-day treatment failure rate, length of hospital stay, time to next exacerbation, difference in symptoms score, quality of life after 30 days and safety profile.

CRP-guided antibiotic therapy for patients hospitalised with acute exacerbations of COPD resulted in a 14.5% decrease in antibiotic use at admission compared with GOLD-guided antibiotic therapy. It was not associated with either an increase in adverse events or with 30-day treatment failure rates. Similar outcomes between groups were observed with regard to exacerbation recovery and time to next exacerbation.

Cluster-randomised trial of a nurse-led advance care planning session in patients with COPD and their loved ones

Houben C, Spruit M, Luyten H, et al. *Thorax* 2019;74:328–36
<https://doi.org/10.1136/thoraxjnl-2018-211943>

Advance care planning (ACP) enables patients to discuss and determine their priorities for medical care with family and healthcare professionals. There are several studies suggesting that ACP interventions improve patient outcomes and satisfaction, yet it is not a routine implementation among patients with COPD. The key impeding factors reported by physicians for not conducting ACP include a lack of time and concern over triggering psychosocial distress in patients and their family. Above all, the unpredictable disease trajectory of COPD makes it very difficult for healthcare professionals to determine the optimal timing to arrange for an ACP discussion.

In this cluster-randomised trial, the study authors aimed to assess whether introducing a 1.5-hour structured ACP session conducted by nurses could have an impact on the quality of end-of-life care communication in patients with advanced

COPD. Secondary objectives were to assess the prevalence of ACP discussions six months after baseline, changes in mental health conditions and quality of death and dying.

The study participants were individuals with COPD and their loved ones. Patients with COPD were randomised to receive either an ACP intervention (n=89) or usual care (n=76) and were followed up for two years. The patients were assessed to study the prevalence of ACP discussions six months after baseline.

The findings of this study indicated that one session of nurse-led ACP intervention could significantly encourage and facilitate patients' end-of-life care communication with physicians, and was positively correlated with the incidence of ACP discussions with healthcare professionals after six months. In ac-

cordance with previous findings, ACP intervention improved anxiety symptoms within the loved ones at six-month follow-up. However, there was no overall improvement in depression symptoms and quality of death and dying. There were many patients with advanced COPD in this study who did not report an ACP discussion with physicians. It is generally assumed that most patients often remain quiet even when they are concerned about their future and end-of-life care.

ACP is a process and a joint effort between patients, loved ones and healthcare professionals. Moving forward, the study authors opined that patients should be empowered to take the initiative for an ACP discussion with healthcare professionals, and multidisciplinary training was recommended to ensure high-quality palliative care.



The PCRS Respiratory Leadership Programme

Develop your leadership skills and grow your confidence in creating improved health outcomes for more patients



The PCRS Respiratory Leadership Programme is especially for all respiratory health practitioners operating in a primary or a community care setting and led by highly regarded and experienced clinical leaders

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**The programme is free to access for PCRS Members.
Visit www.pcrs-uk.org/clinical-leadership for more details.**

Upcoming Programme Events - Mark Your Diaries

- *Bringing out the best in yourself and others*, 8-9 November 2019
Ramada Birmingham Solihull
- *Influencing: Empowering a culture of change*, 5-6 June 2020
Kents Hill Park, Milton Keynes

PCRS-UK News Round-Up

END OF AN ERA AND NEW BEGINNINGS



As we say farewell to Bronwen Thompson this autumn from her almost two decades long association with PCRS as Policy Advisor, we welcome in Dr Tracey Lonergan. Tracey will be taking up the reins from Bronwen as PCRS Policy Co-ordinator and supporting Noel Baxter as he moves into his new role as Executive Lead for Policy. Tracey has had a long career as a medical and science writer working in multiple therapeutic areas including respiratory and oncology and will be utilising her experience to coordinate all the PCRS policy-related activities as well as supporting the development of a range of PCRS-led activities from pragmatic guides to focus pieces on key topics. Noel will continue to be supported by the Policy Forum, a group of committed PCRS members who will help to

guide and shape PCRS policy activities and priorities moving forward. These changes reflect the increasing volume of policy and influencing work PCRS is undertaking – and, indeed, is being invited to undertake – as PCRS is increasingly viewed as the ‘go-to’ integrated respiratory care organisation in the UK. Noel says: “Our influence on policy has always been important and our commitment to a patient-focused and integrated approach to respiratory health over recent years means we are now in a greater position to have impact through our broad range of committed health professional and lay PCRS members who represent us on the extensive national and regional boards that are being tasked with respiratory improvement.”

SPREAD THE WORD ...

The PCRA Clinical Platform is designed to help primary care clinicians provide best-practice respiratory care to their patients. It offers a wide range of resources including CPD modules, videos and articles – all reflecting best practice.

The CPD modules are free of charge to complete and provide between 1 and 2 CPD points per module.

Current CPD modules (<https://respiratoryacademy.co.uk/clinical/cpd-modules/>) include:-

- Key questions on asthma
- Management of co-morbidities in asthma
- Childhood wheeze
- Supported self-management in asthma
- Acute exacerbations of COPD
- Key questions on COPD
- Management of co-morbidities in COPD
- Pulmonary rehabilitation
- Supported self-management in COPD
- Spirometry
- The value of tests in respiratory disease
- Inhaler devices
- Respiratory allergies
- Symptom management
- Key questions on obstructive sleep apnoea
- Multi-morbidity in respiratory patients
- Say no to antibiotics
- Smoking cessation

OPPORTUNITIES TO JOIN THE CONFERENCE ORGANISING COMMITTEE

As a result of the terms of office of existing committee members being complete, we have vacancies for new members on the Conference Organising Committee.

The Conference Organising Committee is responsible for advising on and developing the charity's annual conference. We recruit new members to the committee each year to ensure we always have fresh thinking and are in touch with our delegates.

Applicants will ideally be regular attenders of the PCRS Conference and must have attended at least one conference.

View the Conference Organising Committee Terms of reference.

Planning for the 2020 conference will start immediately following this year's conference. The Conference Organising Committee will be meeting on Monday 14th October and Friday 29th November 2019, to develop the plans and programme for the forthcoming year's annual conference. Both meetings will be held in London; travel expenses and locum fees (or loss of earnings) are reimbursed. Regular teleconferences (circa 6 weekly) are then held (typically 7.30pm on a Tuesday), supported by email correspondence to fine tune the plans and to see them through to fruition.

If you would like to apply, please log in and complete the committee application form (<https://bit.ly/33N1IL8>) and submit with a CV, by midnight on Sunday 29th September 2019.

For many working in respiratory care the PCRS conference is a highlight of their academic year. My experience of being on the Conference Organising Committee is that it is highly rewarding and feels a great privilege to be part of the organisational journey. From reviewing the evaluations to agreeing a theme and deciding on sessions and speakers, it feels like a "shop till you drop" through current respiratory best practice culminating in the chance to try out all the new sessions and see how much our delegates enjoy them. It's a uniquely rewarding part of involvement in PCRS activities and genuinely stimulating to develop the conference with a varied and talented team.

Says Dr Katherine Hickman, Co-Chair of the Conference Organising Committee: "I would highly recommend the Conference Organising Committee to anyone who would like to get more involved - I have learned such a lot and met some fantastic people from across the respiratory spectrum. If you would like to find out more about what is involved, I would be delighted to have an informal discussion - please contact me via info@pcrs-uk.org"

If you are attending the PCRS Conference on 20th & 21st September 2019, please feel free to get in touch with me via the app or come and see me at the PCRS exhibition stand.

HAVE YOUR SAY...

PCRS will be conducting a survey later in the year on how you would like to access this publication. We are calling for all members to tell us if they want to continue to receive a paper publication (with open access online), if they would like to see only online issues (with e-notifications upon publication) or if they would be happy to have only online articles accessible at any time and promoted through our e-newsletter (In Touch) without a compiled issue. Make sure you have your say and participate in the survey when it is launched.

ERRATUM

We apologise for an error in the first version of Issue 17 edition of PCRU within the "All that Glitters is not GOLD, nor is it even NICE" article. We are grateful for our pharmacist colleagues for noting that we had placed LAMA instead of LABA in the asthma/COPD overlap column in figure 7. This was not intentional and we have now corrected this.

All_That_Glitters_COPD



Second Opinion

Your respiratory questions answered...

Question

What are PEP and IMT devices?

Answer

(Oscillating) Positive expiratory pressure devices (PEP) and Inspiratory muscle trainers (IMT) are both types of medical devices which deliver evidenced-based treatment to support airway clearance (PEP) and strengthening of the body's inspiratory respiratory muscles to facilitate easier breathing (IMT). They are most commonly used by physiotherapists who would issue devices (where funded) to appropriate patients. For example, (Oscillating) PEPs for sputum clearance would often be provided to bronchiectasis patients and IMT often to patients post-pulmonary rehabilitation (PR). Some PEPs are on the national formulary although have not been adopted on to local formularies in all areas because, compared with the evidence for other medicines, they have a lower evidence grading (probably due to medical devices never being the subject of such large studies to acquire more robust evidence).

Devices range substantially in price from £15 to over £100.

If a patient enquires about the devices, you would want to be sure of the reason they are considering purchasing:

- If it is for breathlessness and fitness, then PR should ideally have been completed first as the evidence shows IMTs help to maintain benefits of PR but are not a substitute, and adding as an adjunct to a PR programme does not give additional gains over PR alone (Charususin et al, 2018).
- If the purpose is for sputum clearance, you would expect the patient to have had a one-to-one consultation with a respiratory physiotherapist first as a number of basic treatment options should have been considered (such as the importance of good hydration, humidification, the Active Cycle of Breathing Technique (ACBT) and positioning before resorting to a device). Other treatment options should also be considered to best fit the patient's requirements and lifestyle. Additionally,

many devices do not provide the patient with a clear treatment plan and often say something like 'use as advised by your physiotherapist' or 'use after seeking advice from a qualified medical professional'. Consulting with a respiratory physiotherapist would allow treatment to be individually tailored and the patient may even be able to receive the required device without charge.

Examples of device manufacturers (others available)

- PEP: Pari-PEP, Respironics threshold PEP, Astra PEP
- Oscillating PEP: Flutter, Acapella, Aerobika, RC-Cornet
- IMT: Respironics, Powerbreathe
- IMT and Oscillating PEP: Aerosure

Contraindications to their use are shown in the table.

(Oscillating) PEP (relative)	IMT	Combined
<ul style="list-style-type: none"> • Recent upper GI or thoracic surgery/trauma • Recent dental, head, neck, ENT surgery/trauma • ICP >20 mmHg • Untreated pneumothorax • Sinusitis • Acute respiratory exacerbation • Active haemoptysis • Epistaxis • Neuromuscular weakness • Haemodynamic instability including severe right-sided heart failure with hypotension • Ear drum rupture • Nausea 	<ul style="list-style-type: none"> • Ruptured ear drum • Worsening heart failure • History of spontaneous pneumothorax or recent traumatic pneumothorax not yet healed • Marked osteoporosis with history of rib fracture • Desaturation during or after IMT • Asthma patients with low symptom perception and frequent exacerbations 	<p>As over plus:</p> <ul style="list-style-type: none"> • Epilepsy • Pulmonary embolism • Oesophageal varices • Rib fractures • Pregnancy

Continued on page 50



A logical choice

of maintenance treatment to help prevent exacerbations of COPD

Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β_2 -agonist or a combination of a long-acting β_2 -agonist and a long-acting muscarinic antagonist (for effects on symptoms control and prevention of exacerbations see section 5.1 of the SPC).¹

 **Chiesi**

Prescribing information can be found overleaf

Trimbow[®]

beclometasone/formoterol/
glycopyrronium (87/5/9 mcg)
Extrafine formulation

Inspired logic



UK-TRI-1900078 Mar 2019

Prescribing Information

Trimbow 87/5/9 Pressurised Metered Dose Inhaler (pMDI) Prescribing Information

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

Presentation: Each Trimbow 87/5/9 pMDI delivered dose contains 87micrograms (mcg) of beclomethasone dipropionate (BDP), 5mcg of formoterol fumarate dihydrate (formoterol) and 9mcg of glycopyrronium. This is equivalent to a metered dose of 100mcg BDP, 6mcg formoterol and 10mcg glycopyrronium. **Indication:** Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta₂-agonist or a combination of a long-acting beta₂-agonist and a long-acting muscarinic antagonist (for effects on symptoms control and prevention of exacerbations see section 5.1 of the SPC). **Dosage and administration:** For inhalation in adult patients (≥18 years). 2 inhalations twice daily. Can be used with the AeroChamber Plus[®] spacer device. BDP in Trimbow is characterised by an extrafine particle size distribution which results in a more potent effect than formulations of BDP with a non-extrafine particle size distribution (100mcg of BDP extrafine in Trimbow are equivalent to 250mcg of BDP in a non-extrafine formulation). **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Warnings and precautions:** Not for acute use in treatment of acute episodes of bronchospasm or to treat COPD exacerbation. Discontinue immediately if hypersensitivity or paradoxical bronchospasm. **Deterioration of disease:** Trimbow should not be stopped abruptly. **Cardiovascular effects:** Use with caution in patients with cardiac arrhythmias, aortic stenosis, hypertrophic obstructive cardiomyopathy, severe heart disease, occlusive vascular diseases, arterial hypertension and aneurysm. Caution should also be used when treating patients with known or suspected prolongation of the QTc interval (QTc > 450 milliseconds for males, or > 470 milliseconds for females) either congenital or induced by medicinal products. Trimbow should not be administered for at least 12 hours before the start of anaesthesia as there is a risk of cardiac arrhythmias. Caution in patients with thyrotoxicosis, diabetes mellitus, pheochromocytoma and untreated hypokalaemia. Increase in pneumonia and pneumonia hospitalisation in COPD patients receiving ICS observed. Clinical features of pneumonia may overlap with symptoms of COPD exacerbations. Systemic effects of ICS may occur, particularly at high doses for long periods, but are less likely than with oral steroids. These include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation, decrease in bone mineral density, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression and aggression. Use with caution in patients with pulmonary tuberculosis or fungal/viral airway infections. Potentially serious hypokalaemia may result from beta₂-agonist therapy. Formoterol may cause a rise in blood glucose levels. Glycopyrronium should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or urinary retention. Use in patients with severe hepatic or renal impairment should only be considered if benefit outweighs the risk. Consider referral of patients reporting blurred vision or visual disturbances to an ophthalmologist as causes may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy. **Interactions:** Since glycopyrronium is eliminated via renal route, potential drug interactions could occur with medicinal products affecting renal excretion mechanisms e.g. with cimetidine (an inhibitor of OCT2 and MATE1 transporters in the kidney) co-administration, glycopyrronium showed a slight decrease in renal excretion (20%) and a limited increase in total systemic exposure (16%). Possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded and therefore caution and appropriate monitoring is advised. **Related to formoterol:** Non-cardioselective beta-blockers (including eye drops) should be avoided. Concomitant administration of other beta-adrenergic drugs may have potentially additive effects. Concomitant treatment with quinidine, disopyramide, procainamide, antihistamines, monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants and phenothiazines can prolong the QTc interval and increase the risk of ventricular arrhythmias. L-dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance towards beta₂-sympathomimetics. Hypertensive reactions may occur following co-administration with MAOIs including drugs with similar properties (e.g. furazolidone, procarbazine). Risk of arrhythmias in patients receiving concomitant anaesthesia with halogenated hydrocarbons. Concomitant treatment with xanthine derivatives, steroids or diuretics may potentiate a possible hypokalaemic effect of beta₂-agonists. Hypokalaemia may increase the likelihood of arrhythmias in patients receiving digitalis glycosides. **Related to glycopyrronium:** Co-administration with other anticholinergic-containing medicinal products is not recommended. **Excipients:** Presence of ethanol may cause potential interaction in sensitive patients taking metronidazole or disulfiram. **Fertility, pregnancy and lactation:** Should only be used during pregnancy if the expected benefits outweigh the potential risks. Children born to mothers receiving substantial doses should be observed for adrenal suppression. Glucocorticoids and metabolites are excreted in human milk. It is unknown whether formoterol or glycopyrronium (including their metabolites) pass into human breast-milk but they have been detected in the milk of lactating animals. Anticholinergic agents like glycopyrronium could suppress lactation. A risk/benefit decision should be taken to discontinue therapy in the mother or discontinue breastfeeding. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from therapy. **Effects on driving and operating machinery:** None or negligible. **Side effects:** **Common:** pneumonia (in COPD patients), pharyngitis, oral candidiasis, urinary tract infection, nasopharyngitis, headache, dysphonia. **Uncommon:** influenza, oral fungal infection, oropharyngeal candidiasis, oesophageal candidiasis, sinusitis, rhinitis, gastroenteritis, vulvovaginal candidiasis, granulocytopenia, dermatitis allergic, hypokalaemia, hyperglycaemia, restlessness, tremor, dizziness, dysgeusia, hyposaesthesia, otosalginitis, atrial fibrillation, electrocardiogram QT prolonged, tachycardia, tachyarrhythmia, palpitations, hyperaemia, flushing, hypertension, cough, productive cough, throat irritation, epistaxis, diarrhoea, dry mouth, dysphagia, nausea, dyspepsia, burning sensation of the lips, dental caries, aphthous stomatitis, rash, urticaria, pruritus, hyperhidrosis, muscle spasms, myalgia, pain in extremity, musculoskeletal chest pain, fatigue, C-reactive protein increased, platelet count increased, free fatty acids increased, blood insulin increased, blood ketone body increased, cortisol decreased. **Rare:** Lower respiratory tract infection (fungal), hypersensitivity reactions, including erythema, lips, face, eye and pharyngeal oedema, decreased appetite, insomnia, hypersomnia, angina pectoris (stable and unstable), ventricular extrasystoles, nodal rhythm, sinus bradycardia, blood extravasation, paradoxical bronchospasm, oropharyngeal pain, pharyngeal erythema, pharyngeal inflammation, dry throat, angioedema, dysuria, urinary retention, nephritis, asthenia, blood pressure increased, blood pressure decreased. **Very rare:** thrombocytopenia, adrenal suppression, glaucoma, cataract, dyspnoea, growth retardation, peripheral oedema, bone density decreased. **Frequency not known:** psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes, blurred vision. (Refer to SPC for full list of side effects). **Legal category:** POM **Price and Pack:** £44.50 1x120 actuations. **Marketing authorisation (MA) no:** EU/1/17/208/002 **UK Distributor:** Chiesi Limited, 333 Styl Road, Manchester, M22 5LG. **Date of Preparation:** Jan 2019. AeroChamber Plus[®] is a registered trademark of Trudell Medical International.

Primary Care Respiratory Update

Continued from page 48

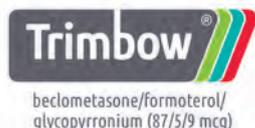
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Siohban Hollier
West Norfolk Team Lead – Pulmonary
Rehabilitation Service
(Clinical Specialist Respiratory Physiotherapist)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Chiesi Limited on 0800 092329 (UK) or PV.UK@Chiesi.com.

Reference: 1. Trimbow Summary of Product Characteristics, Chiesi Limited. Available at: www.medicines.org.uk/emc/product/761.



Delivering Excellence Locally

Featuring initiatives led by PCRS members around the UK, supported by PCRS programmes and tools

Implementing Fit to Care in Practice



Carol Stonham *PCRS Chair Elect*, explains how *Fit to Care*, the PCRS key knowledge, skills and training reference document, can be used to improve respiratory care.

A respiratory nurse practitioner and primary care representative on the Gloucestershire CCG's Respiratory Clinical Programme Board, Carol has been influential in ensuring that *Fit To Care* is accessible to all nurses providing primary and community respiratory care in her area.

Fit To Care enables nurses to check that they are trained to do the job they do. This in turn helps to reduce the variation in the standard of care provided to patients.

In Gloucestershire *Fit To Care* has been embedded in three different services to:

Upskill nurses new to general practice

Fit To Care is included in the respiratory section of an induction pack for nurses coming into general practice nursing from another discipline such as secondary or community care. The induction pack has been sent to all 72 practices in the county.

The lead nurse in a practice can use *Fit To Care* to encourage new recruits to do the training they need for their respiratory role or the new practice nurses themselves can use it argue the case for their training needs with their GP or practice manager.

A mentor provided by a programme funded by the CCG is also using *Fit To Care* when she carries out training needs assessments for new nurses. The training that is required is provided by an independent training provider which is also aware of the document.

Carol says: "We're trying to catch nurses as they are recruited into general practice to make sure that they realise their limitations and understand their training needs. *Fit To Care* can also be used by established practice nurses to check that they have the train-

ing and competencies they need to work at certain levels. Practice nurses are lone workers and unless somebody is watching their consultations they may not be aware that they might not be as skilled or up to date as they think they are. *Fit To Care* can also be used by general practice employers to understand direction they should be travelling in from an educational point of view."

Upskill nurses working in an integrated team

Fit To Care is being used by commissioners and managers currently working to integrate Gloucestershire's community and secondary care respiratory team, the county's flagship integration project.

The document is used to carry out competency assessments of current staff to gain an insight into their strengths and weaknesses and what their training needs are. There have been some vacancies in the team so *Fit To Care* has also been used as a service planning exercise to decide which type of healthcare professionals the CCG needs to advertise for.

Upskill nurses providing a new spirometry service

Fit To Care has been used to help the CCG's Respiratory Clinical Programme Group to deliver a diagnostic spirometry service in three clusters. The document has demonstrated that staff are competent to deliver the diagnostic spirometry service and has enabled managers to discover where the training gaps are. As a result some of the nurses are now doing the training they need to gain accreditation to the National Spirometry Register.

Carol says: "This shows how many different ways *Fit To Care* can be used. *Fit To Care* is definitely on our radar in Gloucester-

shire. My only concern is that practices will put the induction pack linked to *Fit To Care* into a drawer and forget about it. So there is a need to keep bringing it to their attention. If they have mislaid the *Fit To Care* document they can download it from the CCG intranet site and also from the PCRS website.

“One of my roles is respiratory training and education in primary care so I take this opportunity to remind health care professionals to refer to and use the *Fit To Care* document.”

Date of Preparation: August 2019 Version 1



Fit to Care been produced by PCRS to

- Enable healthcare professionals to assess their own competence to deliver care, and identify and seek appropriate training and ongoing professional development supported by their employers.
- Provide a reference for service managers to ensure the provision of appropriate educational support programmes for employed healthcare professionals.

Nurse develops aide memoire for structured respiratory assessment



A mnemonic to help healthcare practitioners conduct a structured respiratory assessment has been developed by **Jackie Dale** a practice educator and teacher at Sheffield University.

An advanced practice nurse, Jackie has taken a mnemonic called SOFTMASH, based around COPD and used in South Yorkshire for about 20 years, and has updated and extended it to incorporate everything that should be considered during an assessment.

She has added some extra letters and categories, turning it into SOFTMAASH PITT so that it now provides a comprehensive overview of the basics of a good respiratory assessment.

Jackie explains that it is meant to be a concise summary of everything the healthcare professional needs to consider when assessing the patient. Her aim is that it will stimulate the practitioner's thinking and curiosity so that they become more proficient.

She stresses that it is not designed to provide every single answer. However it contains all the up to date national and international respiratory guidance plus references and web links to further information.

She says feedback from nurses and trainee doctors who have used it is that they find it helpful to have all the information they need in one place.

Jackie explains: “I have designed it to be systematic in order to guide people towards adopting a structured approach to doing a respiratory assessment.

“When you get used to using it a lot, you can retain it in your head and this enables the healthcare professional to do an assessment much more quickly because it becomes ingrained.

“It is very concise but it covers a lot of ground so if you're starting out in respiratory you can learn it bit by bit and gradually build up your knowledge. You can follow each section as a prompt while working through a reasonably good assessment in 20 minutes. People who already have a lot of respiratory knowledge can use SOFTMAASH PITT to give themselves an update.

“If you are struggling with a patient you could look back at the mnemonic to think about what else you could have done or an area you might have missed.”

Jackie says the process of updating the mnemonic has been a learning curve for her own respiratory knowledge.

She hands it out during her teaching sessions but her current challenge is working out how to get it published as a web link or a poster in order to distribute it to a wider audience.

SOFTMAASH PITT (An Aide Memoir for respiratory assessment)

Symptoms	<p>Breathlessness, (Time, Pattern, Severity, Positional?) Wheeze (audible or detailed in notes as heard by HP, inspiratory or expiratory), Sputum (ACCE) (Amount in teaspoons/tablespoons, Consistency, Colour, Expectoring ?haemoptysis)</p> <p>Cough (When? Distress level? (Consider Hull Cough Questionnaire)</p> <p>Rhinitis/sinusitis - frequent runny/blocked nose/sinuses – allergic or non-allergic symptoms? Nasal Polyps?</p> <p>Indigestion? Consider silent and acid reflux</p>
Occupation	Mechanic, farmer, firefighter, lorry driver, bakery, exposure to dusty working environment, asbestos, noxious fumes (list not exhaustive)
Family History	<p>Immediate family history of atopy, other chest diseases, family history of asthma (NB maternal asthma is the greatest risk), genetic mutation AATD, heart disease, lung cancer (emphysema higher risk)</p> <p>Early exposure of patient to smoking in womb, prematurity > 10/12 weeks? Home environment, open fires, damp conditions etc.</p>
Triggers	Allergies (see below), irritants in the air, respiratory illness, exercise, weather, feeling and expressing strong emotions, medicines, sulphites in food, hormonal changes during menstrual cycle, other medical problems such as reflux and other health conditions
Medication	<p>Beta blockers (worsen asthma), methotrexate, nitrofurantoin, amiodarone – toxic to lung - fibrosis</p> <p>NSAID and aspirin sensitivity (Consider AERD). ACE inhibitors – allergy/ cause of cough?</p> <p>Inhalers and current treatment. Check SABA – should have max 1-2 per year unless COPD. If having more why? Review diagnosis, treatment, adherence ,concordance</p> <p>Only licensed LAMA for uncontrolled asthma is Tiotropium in Respimat format</p> <p>Check ICS/LABA https://www.rightbreathe.com/</p> <p>Check if upper respiratory symptoms and allergy consider trial Montelukast? (NICE 2017) or nasal corticosteroid spray, antihistamines?</p> <p>Check adherence to prescribed medication (asthma and medication for other comorbidities)</p>
Allergy	<p>Newly diagnosed asthma patients & those with strongly suspected allergy: all HCPs who have access to pathology on ICE and who can request bloods should request specific IgE aeroallergens - pollen, mold, cat, dog, house dust mite, (horse). NOT for diagnostic purposes but to support management (NICE 2017)</p> <p>Controlling triggers can help reduce the allergy burden and symptom threshold. Perform comprehensive allergy history https://www.allergyai.com/</p> <p>Confirmed allergy</p> <p>Hay fever – seasonal / year round? } Check well controlled?</p> <p>Atopy (eczema esp. in childhood?) }</p> <p>History of anaphylaxis }</p>
Alcohol	<p>Past and present history of heavy drinking (>4 units per day) can affect the lung and make more prone to infection</p> <p>Consider B & D vitamin supplements if significant history</p> <p>Referral for help?</p>
Smoking	<p>Pack years history https://www.smokingpackyears.com/</p> <p>Age commenced smoking and quit if relevant</p> <p>Very Brief Advice and info on vaping http://www.ncsct.co.uk/ and https://www.pcrs-uk.org/resource/tobacco-dependency-pragmatic-guide</p> <p>Referral for help to quit</p>
History & Health beliefs	<p>Other relevant medical history e.g. operations affecting chest e.g. sternotomy, kyphosis, scoliosis, or potential causes of breathlessness CHD, thyroid, liver disease, CKD etc. Co-morbidities – Diabetes, CHD, VAD etc.</p> <p>Approach to illness – Adherence/concordance/ideas concerns and expectations</p>
Physical exam	<p>Note: pectus excavatum, kyphoscoliosis, pectus carinatum, surgical scars, neck circumference, posture, chest expansion, finger clubbing, skin colour, enlarged lymph nodes</p> <p>Pulse and respiration rate</p> <p>Auscultation if appropriate & trained to do so</p>
Investigations	<p>PEFR Diary if asthma suspected (not younger children) – Minimum of 2 weeks; 2 readings a day – 3 variations in each week over 24-hour period of > 20% adults; 12% children Occupational PEFR 4 weeks 4x a day & refer</p>

Continued...

SOFTMAASH PITT (An Aide Memoir for respiratory assessment) *continued...*

Quality Assured Spirometry: performed by a competent person (on ARTP register) if suspected asthma – spirometry often normal. Based on history & symptoms offer trial of treatment then repeat spirometry in 6-8 wks for FEV1 reversibility (200mls significant, 400mls confirms asthma BTS/SIGN 2016, GOLD 2019). Restrictive spirometry *always needs referral* to exclude fibrosis, lung ca etc. Do not treat reversibility associated with COPD (GOLD 2019). **Do Not Diagnose on one spirometry trace alone, perform post bronchodilator test**

Fractional Exhaled Nitrous Oxide (FeNO)

Peripheral SpO2 Saturation

Bloods: FBC, LFT, TFT, bone profile, renal, AAT, Raised blood Eosinophils >0.3 over repeated tests.

BNP if new onset oedema/PND/orthopnoea/raised JVP/bibasal creps

Specific IgE, RAST test (Post diagnosis – do not use to diagnose asthma)

CXR: 30% are normal in pts with lung Ca and CXR can't diagnose COPD. But must be performed at diagnosis to exclude other pathology

ECG

Sputum: Bronchiectasis – random sample when well each year, C&S if infection suspected and always before commencing antibiotics. If frequent infectious exacerbations, history of chronic asthma consider referral for HRCT, & specialist Antibiotic treatment <https://www.brit-thoracic.org.uk/document-library/clinical-information/bronchiectasis/bts-guideline-for-bronchiectasis-in-adults/>

Other tests include: **Methacholine & Histamine challenge** -referral to hospital as required

Tools

COPD Assessment Test (CAT) (COPD)

Asthma Control Test (Asthma) or RCP 3 questions Modified Medical Research Council (mMRC) Breathlessness or MRC Breathlessness score

PEFR diary

Gad 7 or 9

Nijmegen (suspected breathing pattern disorder)

Hull Cough Questionnaire (Reflux)

Epworth sleepiness score

} May be useful in helping to differentiate diagnosis

Treatment

If prescribing Inhalers – **Check and optimise inhaler technique** <https://www.rightbreathe.com/> www.asthmauk.org.uk If first prescription, ask a trained Pharmacist to check technique by detailing on prescription

<https://www.pcrs-uk.org/asthma-right-care>

Check current Guidance

Asthma: BTS/SIGN 2019, NICE 2017, GINA 2019, PCRS (<https://www.pcrs-uk.org/resource/asthma-guidelines-practice>)

COPD: NICE 2019, GOLD 2019

<https://www.pcrs-uk.org/resource/pcrs-consensus-guide-managing-copd>

Always prescribe by brand. Trial of treatment and review PAAP – (personalised asthma action plan) www.asthmauk.org.uk and in COPD self management plans (<https://shop.blf.org.uk/collections/self-management-hcp>)

COPD – www.blf.org, For COPD patients consider mucolytic trial for 6 weeks and use only when needed. Consider soluble form vaccinations: Green Book (PHE)

PCV13 (over 65 Immunosuppressed) Chapter 25 p4 & 6

PPV23 (COPD & asthma if hospital exacerbations or on ICS/prednisolone)

Annual flu vaccine

Shingles vaccine if age appropriate

Referral for pulmonary rehabilitation (Lung Life program)

Referral to specialist physiotherapist for chest clearance advice and devices to aid mucus excretion e.g. Acapella, RC Conect, Aerobika (FP10), exercise

Review appointment – GP, nurse

Referra – other e.g. consultant respiratory physician, social prescribing

How optimising COPD prescribing improved care and saved £256,000



A CCG medicines optimisation team improved the care of COPD patients by encouraging local GP practices to adopt new guidelines and change their prescribing behaviour. The project, involving 31 practices, also achieved savings of £256,000 for an investment of £40,000 by South Devon and Torbay CCG between Easter 2016 and February 2018.

Sarah-Jane Rowlands, medicines optimisation and practice pharmacist, reports here.

Why there was a need for change

Local prescribing for COPD had not kept pace with advances in evidence and the strategy set out by the 2016 GOLD guidance update (at that time NICE guidance had not been updated since 2010).

The CCG medicines optimisation team was concerned about high inhaled corticosteroid (ICS) prescribing, frequently at high doses, and low dual-bronchodilator (LAMA/LABA) uptake.

There was high spending in primary care on COPD drugs and opportunities were being lost to reduce non-elective activity in primary and secondary care and improve patient outcomes such as reducing symptom burden, exacerbation rates and harm from ICS adverse effects.

Barriers to optimal prescribing were confusion amongst clinicians about the plethora of new treatment options and inhalers.

What the team did

Two respiratory consultants developed clear local one-page prescribing guidance explaining how the GOLD 2016 update could be implemented in primary care.

Implementation of the new guidance was piloted in two GP practices and the improvement measured.

Seven consultant-led education events were then held for 177 local GPs, nurses and pharmacists. These explained how to implement the new prescribing guidelines and provided guidance on best practice in diagnosis and holistic care for COPD and how to safely withdraw unindicated ICS.

A further 10 lunchtime meetings were held for people who wanted additional help.

PRIMIS GRASP COPD software was used in each GP practice to conduct a baseline audit from which improvements were measured.

Resources were provided to practices including: an ICS step-down protocol, a patient information booklet, resource packs, access to consultant support and two primary care respiratory nurses who shadowed clinics and answered queries.

Results

Primary care undertook face-to-face reviews of 4,420 patients (72% of the COPD population). Outcomes achieved were:

- £256,000 net savings were made for a £40,000 investment
- LAMA/LABA uptake increased from 9.4 to 130 items/month/1000 patients,
- There was a reduction in high-dose ICS from the 53rd to the 9th percentile nationally (26.3% to 16.0%). 1377 patients (31.5%) had their ICS reduced or stopped
- 217 (5%) under-treated patients were offered treatment (at a cost of £79,000/year).
- Prescribing compliance with the new local guidelines increased from 26.4% to 60.3%.
- An incorrect diagnosis of COPD was identified in 125 patients (2.8%)

Evaluation of longer term outcomes, including A&E admissions, exacerbations and non-fatal pneumonia continues.

Lessons learned

Sarah-Jane Rowlands, medicines optimisation and practice pharmacist, says this project has demonstrated that embedding new guidelines and best practice into routine COPD care can happen at pace and scale and ICS over-prescribing in COPD can be addressed.

Key to the success of the project was the development of close working relationships between respiratory consultants,

the CCG medicines optimisation pharmacists and GP practices. The educational events were well attended and this increased buy-in and momentum.

Sarah-Jane adds: “We invited GPs, nurses and specialist nurses from the hospital to the educational events to make sure we were all singing from the same hymn sheet. A few community pharmacists also attended. In these meetings a consultant explained what had changed and why we were doing this. We had members of practices sat at the same tables so they could think how they could implement the new guidance in their practices. We also had case studies so clinicians not only had the knowledge but understood how to put that knowledge into practice.

“We were aware it was quite a big ask for the practices to review hundreds of patients fairly swiftly, but this needed to be done in a timely fashion because there was a lot of benefit to be gained for patients and the system as a whole.

“To increase motivation we kept practices up-to-date with interim results to show them what they were achieving. We benchmarked the outcomes against peer practices providing some friendly competition.”

Looking to the future

This work is ongoing. Since the project, South Devon and Torbay CCG has merged with the rest of Devon to become one large county-wide CCG. Colleagues in East and West Devon are now looking to implement the new local guidance which will be updated to include the latest (2018) NICE COPD guidance. Housebound patients and non-attenders will be followed up with a further £79,000 of savings expected to be achieved.

Sarah-Jane says: “What we did was nothing out of the ordinary. If you have the right people in the room and someone to drive it forward, this project could be replicated anywhere at both GP practice and CCG level. All we did was implement a new guideline and the basics of care.

“We were successful because we had visible consultant support, good clinical leadership and provided plenty of resources to support practices.”

Date of Preparation: August 2019 Version 1

PCRS Respiratory Leadership Programme

Case Study: Leadership skills give physiotherapist confidence to pitch for service improvement



Siobhan Hollier won a commissioner's approval for an idea to improve her pulmonary rehabilitation service after perfecting the 'lift pitch' technique in a Respiratory Leadership Programme workshop.

Siobhan, a Clinical Specialist Physiotherapist with BOC Healthcare and team lead for the pulmonary rehabilitation service in West Norfolk, had identified that her service would benefit from integrating ambulatory oxygen assessment and delivery.

The service was not joined up because oxygen was delivered by a different service. Organising oxygen for patients had to be done by respiratory physiotherapists as an extra task in addition to their existing workload.

Now, thanks to skills learned at the Respiratory Leadership Programme, Siobhan was able to deliver an effective 'lift pitch' to a commissioner during a meeting she was attending and was able to convince him that her idea would both improve patients' quality of life and also benefit staff and the service. The 'lift pitch' teaches attendees to outline their idea for a project in the short time that it takes a lift to reach the top floor.

Siobhan says having the oxygen provided within the pulmonary rehabilitation service now enables staff to sort out the oxygen patients need straight away and prevents them from being bounced between different services.

"Previously I had to refer the patient to a different service and they then had to go and have an appointment to sort out the equipment and it could take a month. Now the integrated service saves my team's clinical time and reduces paperwork. The patient is able to obtain the ambulatory oxygen they need within a week," explains Siobhan.

Siobhan says being confident about delivering a lift pitch enabled her to bend the commissioner's ear during an opportunistic snatch of time. "I don't think I would have been successful had I not practised my lift pitch so many times. In the workshop we worked on our lift pitches from lots of different angles, making us think about our projects from the patient, policy and commissioner perspective, thinking each time about the mind-set of the recipient. Having thought about how to draw out the important message for a target audience helped me enormously when I found myself face-to-face with the commissioner. It enabled me

to get my key points across clearly and succinctly and he was really receptive."

She says the Respiratory Leadership Programme has improved her confidence as a leader: "It has taught me a lot about presentation skills and how to get a message across. The group has also been great for networking. Having relocated to my current job 18 months earlier, they have been able to signpost me to other PCRS members in my region who I can contact for support and advice."

Siobhan says she plans to use her new leadership skills to work on getting all the BOC Healthcare pulmonary rehabilitation services accredited to ensure they are all of the same high standard.

Having learned about how to harness effective patient feedback at one of the workshops, she also now plans to redesign her service's patient questionnaire to make it more effective. "We started an audit recently to look at the quality of the feedback we get and are now asking whether we are asking the right questions," she says.

Siobhan says she has also learned a lot about the dynamic of the team and has a greater understanding of people's barriers to change and why projects fail. "I have realised the importance of having a team goal which is now something I am thinking about in my own service. It is important to make sure the team is all working towards the same end," she says.

Siobhan is also gaining leadership experience within PCRS. She facilitated the June Respiratory Leadership workshop meeting and has gained the confidence to take on a new role as a member of the PCRS Education Committee.

The next PCRS Respiratory Leadership Programme workshop is on the theme of 'Bringing out the Best in Yourself and Others' to be held on 8-9 November, Ramada Birmingham, Solihull.





Affiliated Groups

Working together to make a real difference
in respiratory care

PCRS Affiliated Groups connect colleagues who are passionate about developing respiratory care together in your local area. If there isn't a group near you, why not create your own?



PCRS is here to help you with

- **Support and resources** to help you get started and develop a new group.
- **An affiliation scheme** offering enhanced credibility and support for your group from a national network.
- **A regular newsletter**, packed with ideas to help support your group.
- **An annual meeting** for Group Leaders to support personal and collective respiratory development in your area.
- **Free PCRS membership** for leaders of an affiliated local group.

Be part of a thriving respiratory care network

We're here to help you with improving respiratory care for patients. We know it can be daunting and frustrating – especially when facing budget cuts, juggling workloads and trying to keep up with the latest developments.

PCRS has around 50 affiliated local groups in the UK, including nursing groups, primary care groups sharing knowledge about clinical developments and multi-disciplinary communities of practice driving service improvement in a local area.

Affiliated Group Leaders Networking Event

19th September 2019, The International Centre, Telford

Find out about our affiliated groups by visiting
<https://pcrs-uk.org/affiliated-groups>



Affiliated Groups

PCRS Affiliated Group Leaders Networking Event, 19 September 2019, The International Centre, Telford

- Interested in setting up a local group?
- Want some inspiration on how to get your group funded, get more attendees at your meetings, succession planning?
- Want to hear from successful group leaders on what they have achieved and tips to take home?
- Want to find out about how technology can help support your groups?

Come along for a drink and a natter to our networking event on 19 September from 16:45 to 18:15. We'll discuss how technology can help you in managing your group and keep members engaged and we'll share some successes of other group leaders and learn from their achievements.

This is an ideal opportunity to quiz other passionate and inspiring group leaders and learn more about how to get a new group established, get the most out of an existing group and learn what PCRS can do to support you.

Find out more at <https://www.pcrs-uk.org/affiliated-group-leaders-events>



PCRS is grateful to Atlantic Pharma and Circassia Pharmaceuticals plc for the provision of sponsorship through funding to support the activities of the Affiliated Group Leaders programme. The programme has been solely organised by PCRS.

Thinking of setting up a local group? Benefits of PCRS-UK Affiliated Groups

Working in primary care can, at times, feel quite lonely and isolating. With the ever-present pressures of today's NHS, there just aren't enough hours in the day to keep up to date or just take time to enjoy our jobs.

That's where PCRS affiliated local groups come in. They offer a lifeline for nurses and other healthcare professionals enabling them to stay in touch, network with colleagues, learn about clinical issues, share best practice and, moreover, offer a welcome chance for some fun and camaraderie.

See <https://pcrs-uk.org/affiliated-groups> to see if there is an affiliated group near you.

PCRS can offer support to get you started. We can introduce you to members who are already running successful groups so that they can help mentor you through the initial stages and we also provide a resource pack (see <https://www.pcrs-uk.org/resource-pack-help-you-get-started>). See <https://pcrs-uk.org/local-groups-getting-inspired> for more information on how to get started.

Affiliating your group to PCRS confers FREE PCRS membership for the group leader and the opportunity to attend group leader workshops.

We can:

- Promote your events/meetings by sending emails to members in your area and adding your meetings to our events listing on our website
- List your group on our website and promote it to our members
- Point you in the direction of tools and resources that you can use as a basis for discussion and local update
- Send you a regular newsletter especially for group leaders offering tips and advice for managing your group and sharing information

To affiliate your group visit

<https://www.pcrs-uk.org/affiliation-pcrs-uk>



90% of
tickets
already
gone!

6 CPD
hours



Clinical Roadshow 2019

A free, interactive event to support GPs

With only five events left in 2019, don't miss your chance to gain best-practice respiratory care advice from our panel of expert speakers. Offering hands-on sessions and the chance to share experiences with your peers, this is an event not to be missed.

Can't make it to the remainder of our events this year? Then visit our website to view the latest digital resources that will help you delivery best possible respiratory care.

Find your nearest event

- » Birmingham – 17th October 2019
- » Leeds – 29th October 2019
- » Milton Keynes – 31st October 2019
- Sold out** » Peterborough – 12th November 2019
- » Manchester – 21st November 2019

What will you learn?

- How to interpret diagnostic test results
- How to write an effective PAAP
- COPD management
- Antimicrobial prescribing
- How to detect lung cancer early

“I have appreciated the atmosphere of the meeting: openness, critical review of guidelines, humour, practical tips and real-life cases.”

www.respiratoryacademy.co.uk/event-registration

The Primary Care Respiratory Academy has been developed and is produced by Cogora, the publisher of *Pulse*, *Nursing in Practice*, *Healthcare Leader*, *Management in Practice* and *The Pharmacist*, working in partnership with PCRS. All educational content for the website and events has been initiated and produced by PCRS/Cogora.

The Primary Care Respiratory Academy is sponsored by *Boehringer Ingelheim*, *Chiesi*, *GlaxoSmithKline* and *Orion Pharma*.



Are you working in respiratory care?



Our multi-disciplinary study days offer the opportunity to update knowledge, learn new skills, network and share best practice.

Attend our study days this autumn.

Sign up today: blf.org.uk/hcp



DO YOU HAVE SEVERE ASTHMA PATIENTS WHO ARE STILL SYMPTOMATIC ON ICS/LABA?

BTS/SIGN Guidelines recommend LAMA add-on therapy for uncontrolled adult asthma patients on ICS/LABA¹

SPIRIVA® RespiMat® (tiotropium) is the only LAMA licensed for asthma



SPIRIVA® RespiMat® (tiotropium) is indicated as add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year²

BTS: British Thoracic Society, SIGN: Scottish Intercollegiate Guidelines Network, ICS: inhaled corticosteroids, LABA: long-acting β_2 -agonist, LAMA: long-acting muscarinic antagonist



The RespiMat® inhaler was used successfully by children as young as 6 years old^{3,4}

SPIRIVA®
RESPIMAT®
(tiotropium)



References: 1. BTS/SIGN British guideline on the management of asthma. Revised September 2016. Available at <https://www.brit-thoracic.org.uk/document-library/guidelines/asthma/btssign-asthma-guideline-2016> (accessed May 2019). 2. SPIRIVA® RespiMat® 2.5 µg Summary of Product Characteristics. 3. Kamin W *et al. Pulm Ther* 2015;1:53–63. 4. Kamin W *et al. Pulm Ther* 2015;1:53–63. Supplementary appendix.

Prescribing Information (UK) SPIRIVA® RESPIMAT® (tiotropium)

Inhalation solution containing 2.5 microgram tiotropium (as bromide monohydrate) per puff. **Indication:** COPD: Tiotropium is indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD). **Asthma:** Spiriva RespiMat is indicated as add-on maintenance bronchodilator treatment in patients aged 6 years and older with severe asthma who experienced one or more severe asthma exacerbations in the preceding year. **Dose and Administration:** COPD Adults only age 18 years or over: 5 microgram tiotropium given as two puffs from the RespiMat inhaler once daily, at the same time of the day. **Asthma** Adults and patients 6 to 17 years of age: 5 microgram tiotropium given as two puffs from the RespiMat inhaler once daily, at the same time of the day. In adult patients with severe asthma, tiotropium should be used in addition to inhaled corticosteroids (≥ 800 µg budesonide/day or equivalent) and at least one controller. In adolescents (12 - 17 years) with severe asthma, tiotropium should be used in addition to inhaled corticosteroids (> 800 - 1600 µg budesonide/day or equivalent) and one controller or in addition to inhaled corticosteroids (400 - 800 µg budesonide/day or equivalent) with two controllers. For children (6 - 11 years) with severe asthma, tiotropium should be used in addition to inhaled corticosteroids (> 400 µg budesonide/day or equivalent) and one controller or in addition to inhaled corticosteroids (200 - 400 µg budesonide/day or equivalent) with two controllers. **Contraindications:** Hypersensitivity to tiotropium bromide, atropine or its derivatives, e.g. ipratropium or oxitropium or to any of the excipients; benzalkonium chloride, disodium edetate, purified water, hydrochloric acid 3.6 % (for pH adjustment). **Warnings and Precautions:** Not for the initial treatment of acute episodes of bronchospasm or for the relief of acute symptoms. Spiriva RespiMat should not be used as monotherapy for asthma. Asthma patients must be advised to continue taking anti-inflammatory therapy, i.e. inhaled corticosteroids, unchanged after the introduction of Spiriva RespiMat, even when their symptoms improve. Immediate hypersensitivity reactions may occur after administration of tiotropium bromide inhalation solution. Caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Inhaled medicines may cause inhalation-induced bronchospasm. Tiotropium should be used with caution in patients with recent myocardial infarction < 6 months; any unstable or life threatening cardiac arrhythmia or cardiac arrhythmia requiring intervention or a change in drug therapy in the

past year; hospitalisation of heart failure (NYHA Class III or IV) within the past year. These patients were excluded from the clinical trials and these conditions may be affected by the anticholinergic mechanism of action. In patients with moderate to severe renal impairment (creatinine clearance ≤ 50 ml/min) tiotropium bromide should be used only if the expected benefit outweighs the potential risk. Patients should be cautioned to avoid getting the spray into their eyes. They should be advised that this may result in precipitation or worsening of narrow-angle glaucoma, eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes from conjunctival congestion and corneal oedema. Should any combination of these eye symptoms develop, patients should stop using tiotropium bromide and consult a specialist immediately. Tiotropium bromide should not be used more frequently than once a day. **Interactions:** Although no formal drug interaction studies have been performed, tiotropium bromide has been used concomitantly with other drugs commonly used in the treatment of COPD and asthma, including sympathomimetic bronchodilators, methylxanthines, oral and inhaled steroids, antihistamines, mucolytics, leukotriene modifiers, cromones, anti-IgE treatment without clinical evidence of drug interactions. Use of LABA or ICS was not found to alter the exposure to tiotropium. The co-administration of tiotropium bromide with other anticholinergic-containing drugs has not been studied and is therefore not recommended. **Fertility, Pregnancy and Lactation:** Very limited amount of data in pregnant women. Avoid the use of Spiriva RespiMat during pregnancy. It is unknown whether tiotropium bromide is excreted in human breast milk. Use of Spiriva RespiMat during breast feeding is not recommended. A decision on whether to continue/discontinue breast feeding or therapy with Spiriva RespiMat should be made taking into account the benefit of breast feeding to the child and the benefit of Spiriva RespiMat therapy to the woman. Clinical data on fertility are not available for tiotropium. **Effects on ability to drive and use machines:** No studies have been performed. The occurrence of dizziness or blurred vision may influence the ability to drive and use machinery. **Undesirable effects:** COPD: Common ≥ 1/100 to < 1/10 Dry mouth, uncommon (≥ 1/1,000 to < 1/100) Dizziness, headache, cough, pharyngitis, dysphonia, constipation, oropharyngeal candidiasis, rash, pruritus, urinary retention, dysuria. Rare (≥ 1/10,000 to < 1/1,000): Insomnia, glaucoma, intraocular pressure increased, vision blurred, atrial fibrillation, palpitations, supraventricular tachycardia, tachycardia, epistaxis,

bronchospasm, laryngitis, dysphagia, gastroesophageal reflux disease, dental caries, gingivitis, glossitis, angioneurotic oedema, urticaria, skin infection/skin ulcer, dry skin, urinary tract infection. Not known (cannot be estimated from the available data): Dehydration, sinusitis, stomatitis, intestinal obstruction including ileus paralytic, nausea, hypersensitivity (including immediate reactions), anaphylactic reaction, joint swelling. **Asthma:** Uncommon (≥ 1/1,000 to < 1/100) Dizziness, headache, insomnia, palpitations, cough, pharyngitis, dysphonia, bronchospasm, dry mouth, oropharyngeal candidiasis, rash. Rare (≥ 1/10,000 to < 1/1,000): Epistaxis, constipation, gingivitis, stomatitis, pruritus, angioneurotic oedema, urticaria, hypersensitivity (including immediate reactions), urinary tract infection. Not known (cannot be estimated from the available data): Dehydration, glaucoma, intraocular pressure increased, vision blurred, atrial fibrillation, supraventricular tachycardia, tachycardia, laryngitis, sinusitis, dysphagia, gastroesophageal reflux disease, dental caries, glossitis, intestinal obstruction including ileus paralytic, nausea, skin infection/skin ulcer, dry skin, anaphylactic reaction, joint swelling, urinary retention, dysuria. Serious undesirable effects consistent with anticholinergic effects: glaucoma, constipation, intestinal obstruction including ileus paralytic and urinary retention. An increase in anticholinergic effects may occur with increasing age. Prescribers should consult the Summary of Product Characteristics for further information on undesirable effects. **Pack sizes and NHS price:** Single pack: 1 RespiMat inhaler and 1 cartridge providing 60 puffs (30 medicinal doses) £23.00. **Legal category:** POM. **MA number:** PL 14598/0084. **Marketing Authorisation Holder:** Boehringer Ingelheim International GmbH, D-55216 Ingelheim am Rhein, Germany. Prescribers should consult the Summary of Product Characteristics for full prescribing information. Prepared in April 2018.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).