

## NEWSLETTER

Supporting the Derbyshire Health Community

Volume 7: Issue 1

April 2008

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### JAPC Update

The Joint Area Prescribing Committee (JAPC) is a countywide group covering Derbyshire County PCT and Derby City PCT. It provides recommendations on drugs and medicines management issues.

RED drugs are those where prescribing responsibility would normally lie with a hospital consultant or a specialist. AMBER drugs are those that although usually initiated within a hospital setting, could appropriately become the responsibility of the GP, under a shared care agreement. GREEN drugs are regarded as suitable for primary care prescribing. BROWN drugs are those that JAPC does not recommend for use, except in exceptional circumstances, due to lack of data on safety, effectiveness, and/or cost-effectiveness.

The most recent updates are in the table below:

<b>Drug</b>	<b>Date considered</b>	<b>Decision</b>
Eucreas (vildagliptin + metformin)	April 2008	BROWN
Vildagliptin	April 2008	BROWN
Suboxone	April 2008	BROWN
Ionsys (fentanyl transdermal system)	April 2008	RED
Mircera	April 2008	RED
Colesevalem	February 2008	BROWN
Hyaluronic acid injection	February 2008	RED
Apraclonidine eye drops	January 2008	RED
Cabergoline (hyperprolactinaemia only)	January 2008	GREEN
Co-proxamol (unlicensed)	January 2008	BROWN
Ezetimibe (as per NICE guidance only)	January 2008	GREEN
Fostair	January 2008	GREEN

### More on statins

Further to the article in last month's newsletter, an editorial "Strategies for prescribing statins" has been published recently<sup>1</sup>. This concludes that evidence supports prescribing a standard dose without further testing or dose adjustment. The authors comment "All we can say is that everyone at high risk of cardiovascular complications should be offered a standard dose of statin. Anyone with manifest disease would be eligible, irrespective of their initial cholesterol concentration".

This is strong support for the Derbyshire statin policy. Letters have also been published supporting the editorial<sup>2</sup>. "Treat to targets benefits no one" is one headline and the other makes a robust case for the 'fire and forget' option.

1. BMJ 2008; 336:288-9  
2. BMJ 2008; 336:406

### **Salbutamol nebulers**

There are only limited indications for the use of nebulised salbutamol in managing COPD. About half the prescribing of salbutamol nebulers in Derbyshire is for the 5mg strength. These are twice as expensive as 2.5mg nebulers but do they give twice the benefit?

The NICE guidance for COPD<sup>1</sup> states:

“The dose response relationship for salbutamol in patients with largely or completely irreversible COPD is almost flat. The time to peak response is slower than in patients with asthma and the side-effect to benefits ratio is such that there is little benefit in giving more than 1mg salbutamol. Their effects on airway calibre last for up to 4 hours and can be used on a regular, or as required, basis”.

A randomised controlled trial assessing the optimal dose of nebulised salbutamol in acute exacerbations of COPD was published in 2005<sup>2</sup>. The trial took place in Leeds and 86 patients admitted with an acute exacerbation of COPD were recruited. They were randomised in a double-blind fashion to receive 2.5mg or 5mg of nebulised salbutamol every 4 hours until recovery.

There was significant improvement in maximal bronchodilation in both groups as the exacerbation resolved but there was no significant difference in outcomes including length of hospital stay or recovery of lung function between the two doses.

**We advise that patients receiving regular prescriptions for salbutamol nebulers are reviewed, especially those receiving the 5mg strength.**

1. Thorax 2004; 59 (supp): i39
2. Chest 2005; 128: 48-54

### **Adrenal suppression with inhaled fluticasone**

Two RCTs and a cohort study have shown an increased risk for developing pneumonia in those using fluticasone 500mcg twice daily for COPD (see May 07 and June 07 PACE Newsletters). Those with COPD tend to be older and at greater risk of developing adverse effects with high-dose inhaled steroids.

Inhaled steroid is absorbed by the lungs, which avoids first-pass metabolism, and can have systemic effects. The systemic adverse effects of higher potency inhaled corticosteroids such as fluticasone should not be taken lightly. For example, in a dose-ranging study in asthmatic patients with impaired small airway function (mean FEF<sub>25-75</sub> 65.5% predicted), it was found that the relative dose ratio for relative potency was 8.5:1mg (95% CI 5.7 to 11.2) when comparing oral prednisone with inhaled fluticasone given via a spacer, for suppression of 8 am plasma cortisol<sup>1</sup>. This is supported by a meta-analysis of 13 studies which evaluated effects on 8 am plasma cortisol, where oral prednisolone and inhaled fluticasone exhibited a 10:1mg equivalence<sup>2</sup>. NICE guidance should be followed when considering using inhaled corticosteroid in COPD.

1. Br J Clin Pharmacol 1999; 48: 579-85
2. Arch Intern Med 1999; 159: 941-55

### **The INSPIRE study**

A range of COPD treatments have been shown to reduce exacerbations. These include long-acting inhaled bronchodilators like salmeterol and tiotropium, as well as inhaled corticosteroids (ICS) alone or when combined with long-acting beta-agonists (LABA). The effectiveness of an ICS/LABA combination and of a long-acting anti-cholinergic in preventing exacerbations has not been directly compared. The aim of INSPIRE was to compare the effect of the combination of LABA/ICS, salmeterol/fluticasone propionate (SFC) with the long-acting bronchodilator tiotropium bromide on the rate of moderate and/or severe exacerbations during a 2-year treatment period INSPIRE was a multicentre, randomised, double-blind, double-dummy controlled trial.<sup>1</sup>

#### ***Method***

- Patients were recruited from 179 centres in 20 countries. Recruited patients were aged 40-80 years, with a smoking history of  $\geq 10$  pack years, a clinical history of COPD exacerbations, a post-bronchodilator FEV<sub>1</sub>  $<50\%$  predicted, reversibility to 400 $\mu$ g salbutamol  $\leq 10\%$  of predicted FEV<sub>1</sub> and a score of  $\geq 2$  on the Modified Medical Research Council Dyspnoea Scale.
- Patients entered a 2-week run-in period during which they discontinued all existing COPD maintenance medications and received oral prednisolone 30 mg/day and inhaled salmeterol 50 $\mu$ g twice daily to standardise their clinical condition prior to randomisation. Patients were then randomised to inhaled salmeterol 50 $\mu$ g plus fluticasone propionate 500 $\mu$ g combination (SFC) twice daily by Diskus/Accuhaler or

tiotropium bromide 18µg once daily by Handihaler. Subjects randomised to SFC received a once daily placebo inhalation by Handihaler and subjects randomised to tiotropium received a twice daily placebo inhalation by Diskus/Accuhaler.

- After randomisation, in addition to study medication, patients were allowed short-acting inhaled beta-agonists for relief therapy and standardised short courses of oral systemic corticosteroids and/or antibiotics where indicated for treatment of COPD exacerbations.
- The primary efficacy endpoint was the rate of healthcare utilisation exacerbations, defined as those that required treatment with oral corticosteroids and/or antibiotics or required hospitalisation. Pre-defined secondary endpoints included health status measured by the SGRQ, post-dose FEV<sub>1</sub> (measured 2 hours after inhalation of study medication) and study withdrawal rate. All cause mortality was a tertiary efficacy endpoint while all cause mortality on treatment (up to 2 weeks after treatment cessation) was an additional endpoint.

## Results

- Of 1,499 patients screened, 1,323 were randomised. The mean age of participants was 64.5 years and 82.5% were men. 38% were current smokers and **49.5% discontinued ICS at study entry**.
- Over 2 years, 62% of the SFC group and 59% of the tiotropium group had at least one exacerbation requiring therapeutic intervention. The estimated overall rates of exacerbations were 1.28 per year for SFC and 1.32 per year for tiotropium with a ratio of rates of 0.967 (95% CI: 0.836 to 1.119) indicating no difference between rates (p=0.656).
- Exacerbations requiring antibiotics occurred more frequently in patients treated with SFC (SFC 0.97/year; tiotropium 0.82/year) (p=0.028) but those requiring systemic corticosteroids were less frequent than in the tiotropium-treated patients (SFC 0.69/year; tiotropium 0.85/year) (p=0.039). The incidence of exacerbations requiring hospitalisations was 16% for SFC and 13% for tiotropium (p=0.085).
- Mean SGRQ total score values at screening were 50.3 units for the SFC and 52.3 for the tiotropium treatment groups and improved after run-in treatment with systemic steroids and salmeterol to 48.0 and 48.2 units at baseline respectively. The total SGRQ was significantly lower in the SFC group compared to the tiotropium group at weeks 32, 56, 80 and 104, although this difference did not reach the minimum clinically important difference. At week 104, the adjusted mean treatment difference for SFC versus tiotropium was -2.1 units (95% CI: -4.0 to -0.1 units; p=0.038).
- Mortality during the study period was lower in the SFC treatment group (3%) compared with tiotropium (6%); p=0.032.
- The frequency of adverse events was 66% of patients on SFC and 62% on tiotropium (no p-value given but would be a NNH of 25).
- Serious adverse events were reported during treatment by 30% of SFC-treated and 24% of tiotropium-treated patients (no p-value given but would be a NNH of 17).
- Pneumonia was reported in 8% and 4% of patients respectively and the hazard ratio for time to reported pneumonia was 1.94 (95% CI: 1.19 to 3.17, p=0.008). The NNH is 25.

## Discussions/implications

- The strengths of the INSPIRE trial include its size, long duration and the inclusion of a large number of severe and very severe COPD patients, all of which allowed more exacerbation events to be identified.
- The primary endpoint of healthcare utilisation exacerbation rate was not significantly different between tiotropium and Seretide 50/500. As this is what the study was powered for we should really stop reading now as any significant secondary endpoints are likely to be unreliable, especially if they are of marginal significance. I've looked at them anyway!
- The SGRQ total score was lower at 2 years with SFC (p=0.038) but only by 2.1 units. As we know 4 is the minimum clinically important difference. So the authors did a post-hoc responder analysis looking at those that achieved a 4+ unit change. The results were 32% for SFC and 27% for tiotropium (NNT=20). No p-value was given and we have to be wary of this result.
- Mortality was lower in the SFC group: 3% vs 6% (p=0.032). However, even the authors say this was unexpected, admit that the trial was not powered for mortality, and say that powered studies are needed to confirm this finding. It is likely to be spurious and should be regarded as so until proven otherwise.
- This is the second RCT to show that inhaled fluticasone 1000mcg/day increases the risk of pneumonia in people with COPD.
- **The bottom line is that Seretide was not more effective than tiotropium and appears to be less safe.**

## **Fever in children**

DTB has recently published an article “When the child has a fever”<sup>1</sup>. This is the conclusion: “Fever in children is not usually harmful. Parents and carers should be reassured that fever is a natural response to infection and may help combat infections. When presented with a feverish child, the priority for healthcare professionals is to establish a diagnosis and attempt to exclude serious illness.

There is little evidence on the effects of antipyretic drug therapy on discomfort associated with fever and insufficient evidence on whether antipyretic drugs help to prevent febrile seizures. However, a child who is distressed or uncomfortable because of the fever or associated symptoms, such as myalgia or headache, is likely to benefit from treatment with paracetamol or ibuprofen. Paracetamol is the preferred option for a child with renal impairment or who is dehydrated or at risk from gastric bleeding or ulceration. There is no clear advantage from using both paracetamol and ibuprofen, either together or alternately. Tepid sponging for fever may cause the child discomfort and should be avoided.”

1. DTB 2008; 46(3): 17-20

## **Smoking cessation**

NICE has issued Public Health Guidance No. 10, ‘Smoking cessation services’. These are the key priorities under the prescribing section:

- Offer NRT, varenicline or bupropion, as appropriate, to people who are planning to stop smoking.
- NRT, varenicline or bupropion should normally be prescribed as part of an abstinence-contingent treatment, in which the smoker makes a commitment to stop smoking on or before a particular date (target stop date). The prescription of NRT, varenicline or bupropion should be sufficient to last only until 2 weeks after the target stop date. Normally, this will be after 2 weeks of NRT therapy, and 3-4 weeks for varenicline and bupropion, to allow for the different methods of administration and mode of action. Subsequent prescriptions should be given only to people who have demonstrated, on re-assessment, that their quit attempt is continuing.
- Varenicline or bupropion may be offered to people with unstable cardiovascular disorders, subject to clinical judgement.
- Consider offering a combination of nicotine patches and another form of NRT (such as gum, inhalator, lozenge or nasal spray) to people who show a high level of dependence on nicotine or who have found single forms of NRT inadequate in the past.
- Do not favour one medication over another. The clinician and patient should choose the one that seems most likely to succeed.
- When deciding which therapies to use and in which order, discuss the options with the client and take into account.
  - whether a first offer of referral to the NHS Stop Smoking Service has been made
  - contraindications and the potential for adverse effects
  - the client’s personal preferences
  - the availability of appropriate counselling or support
  - the likelihood that the client will follow the course of treatment
  - their previous experience of smoking cessation aids

You can access the full document at [www.nice.org.uk/nicemedia/pdf/PH010quickrefguide.pdf](http://www.nice.org.uk/nicemedia/pdf/PH010quickrefguide.pdf)

## **Otitis media with effusion**

NICE has issued Clinical Guideline No. 60, ‘Surgical management of otitis media with effusion in children’. These are the key priorities for implementation:

### **Diagnosis of OME**

- Formal assessment of a child with suspected OME should include:
  - clinical history taking, focusing on:
    - poor listening skills; indistinct speech or delayed language development; inattention and behaviour problems; hearing fluctuation; recurrent ear infections or upper respiratory tract infections; balance problems and clumsiness; poor educational progress
  - clinical examination, focusing on:
    - otoscopy; general upper respiratory health; general development status
  - hearing testing, which should be carried out by trained staff using tests suitable for the developmental stage of the child, and calibrated equipment
  - tympanometry.

### **Children who will benefit from surgical intervention**

- Children with persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25-30 dBHL or worse averaged at 0.5, 1, 2 and 4kHz (or equivalent dBA where dBHL not available) should be considered for surgical intervention.

### **Surgical interventions**

- Once a decision has been taken to offer surgical intervention for OME in children, insertion of ventilation tubes is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

### **Non-surgical interventions**

- The following treatments are **not** recommended for the management of OME: antibiotics; topical or systemic antihistamines; topical or systemic decongestants; topical or systemic steroids; homeopathy; cranial osteopathy; acupuncture; dietary modification, including probiotics; immunostimulants; massage.
- Hearing aids should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable.

### **Management of OME in children with Down's syndrome**

- Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss.

### **Management of OME in children with cleft palate**

- Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment.
- Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss.

You can access the full document at [www.nice.org.uk/nicemedia/pdf/CG60quickrefguide.pdf](http://www.nice.org.uk/nicemedia/pdf/CG60quickrefguide.pdf)

### **Irritable bowel syndrome**

NICE has issued Clinical Guideline No. 61, 'Irritable bowel syndrome in adults'. These are the key priorities for implementation:

- Healthcare professionals should consider assessment for IBS if the person reports having had any of the following symptoms for at least 6 months:
  - **Abdominal pain or discomfort**
  - **Bloating**
  - **Change in bowel habit**
- All people presenting with possible IBS symptoms should be asked if they have any of the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present:
  - unintentional and unexplained weight loss
  - a change in bowel habit to looser and/or more frequent stools persisting for more than 6 weeks in a person aged over 60 years.
  - rectal bleeding
  - a family history of bowel or ovarian cancer
- All people presenting with possible IBS symptoms should be assessed and clinically examined for the following 'red flag' indicators and should be referred to secondary care for further investigation if any are present:
  - anaemia
  - inflammatory markers for inflammatory bowel disease
  - abdominal masses
  - rectal masses

If there is significant concern that symptoms may suggest ovarian cancer, a pelvic examination should also be considered.

- A diagnosis of IBS should be considered only if the person has abdominal pain or discomfort that is either relieved by defaecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following four symptoms:
  - altered stool passage (straining, urgency, incomplete evacuation)
  - symptoms made worse by eating
  - abdominal bloating (more common in women than men), distension, tension or hardness
  - passage of mucus

Other features such as lethargy, nausea, backache and bladder symptoms are common in people with IBS, and may be used to support the diagnosis.

- In people who meet the IBS diagnostic criteria, the following tests should be undertaken to exclude other diagnoses:
  - full blood count (FBC)
  - erythrocyte sedimentation rate (ESR) or plasma viscosity
  - c-reactive protein (CRP)
  - antibody testing for coeliac disease (endomysial antibodies [EMA] or tissue transglutaminase [TTG]).
- The following tests are not necessary to confirm diagnosis in people who meet the IBS diagnostic criteria:
  - ultrasound
  - rigid/flexible sigmoidoscopy
  - colonoscopy; barium enema
  - thyroid function test
  - faecal ova and parasite test
  - faecal occult blood
  - hydrogen breath test (for lactose intolerance and bacterial overgrowth)
- People with IBS should be given information that explains the importance of self-help in effectively managing their IBS. This should include information on general lifestyle, physical activity, diet and symptom-targeted medication.
- Healthcare professionals should review the fibre intake of people with IBS, adjusting (usually reducing) it while monitoring the effect on symptoms. People with IBS should be discouraged from eating insoluble fibre (for example, bran). If an increase in dietary fibre is advised, it should be soluble fibre such as ispaghula powder or foods high in soluble fibre (for example, oats).
- People with IBS should be advised how to adjust their doses of laxative or antimotility agent according to the clinical response. The dose should be titrated according to stool consistency, with the aim of achieving a soft, well-formed stool (corresponding to Bristol Stool Form Scale type 4).
- Healthcare professionals should consider tricyclic antidepressants (TCAs) as second-line treatment for people with IBS if laxatives, loperamide or antispasmodics have not helped. TCAs are primarily used for treatment of depression but are only recommended here for their analgesic effect. Treatment should be started at a low dose (5-10 mg equivalent of amitriptyline), which should be taken once at night and reviewed regularly. The dose may be increased, but does not usually need to exceed 30 mg.

You can access the full document at [www.nice.org.uk/nicemedia/pdf/CG61IBSQRG.pdf](http://www.nice.org.uk/nicemedia/pdf/CG61IBSQRG.pdf)

### **Drug safety update**

This can be found at [www.mhra.gov.uk/drugsafetyupdate](http://www.mhra.gov.uk/drugsafetyupdate)

These are some key items from the March issue.

#### **Ketoconazole: *restricted indications***

Because of the risk of serious hepatotoxicity, oral ketoconazole should be used only for dermatophytosis, *Malassezia* folliculitis, and chronic candidosis that cannot be treated topically.

#### **Advice for healthcare professionals:**

- Ketoconazole tablets are not suitable as a first-line treatment or for superficial infections
- Ketoconazole tablets should be initiated by a physician who is experienced in the management of fungal infections
- Use only when potential benefits are considered to outweigh potential risks, taking into consideration the availability of other effective antifungal therapy
- Risk of serious hepatotoxicity increases with duration of treatment
- Liver function must be monitored before starting treatment, at week 2 and week 4 of treatment, and then monthly

#### **Modafinil: *serious skin reactions, hypersensitivity, and psychiatric symptoms***

Modafinil should be withdrawn in patients who experience a rash or psychiatric symptoms.

#### **Advice for healthcare professionals:**

- Modafinil should be discontinued at the first sign of rash and not restarted
- Modafinil should be discontinued in patients who experience any psychiatric symptoms and not restarted
- Modafinil should be used with caution in patients with a history of psychosis, depression, or mania
- Modafinil should be used with caution in patients with a history of alcohol, drug, or illicit substance abuse

## **Bleeding risks with SSRIs**

Evidence for the association of SSRI use with increased risk of upper GI haemorrhage (UGIH) has been discussed previously in this newsletter. A new meta-analysis confirms this association and also estimates the interaction with concurrent NSAID therapy<sup>1</sup>.

Random effects meta-analysis of four observational studies involving 153,000 patients showed an odds ratio of 2.36 (95% CI: 1.44 to 3.85;  $P = 0.0006$ ) for SSRI associated UGIH. The odds ratio increased to 6.33 (95% CI: 3.40 to 11.8;  $P < 0.00001$ ) with concomitant NSAIDs. In patients aged above 50 years with no UGIH risk factors, the Number-Needed-to-Harm (NNH) per year was 411 for SSRIs alone, and 106 with concomitant NSAIDs.

The authors conclude “Selective serotonin reuptake inhibitor use, alone and in combination with NSAIDs, substantially increases the risk of UGIH. Clinicians should consider this when managing patients at risk of, or presenting with UGIH.”

A recent case-control study in a cohort of new users of coumarins in the Netherlands, investigated whether there was increased bleeding risk with concurrent use of SSRIs<sup>2</sup>. Users of SSRIs were at significantly increased risk of hospitalisation because of non-gastrointestinal tract bleeding (adjusted OR, 1.7; 95% CI, 1.1 to 2.5) but not because of gastrointestinal tract bleeding (adjusted OR, 0.8; 95% CI, 0.4-1.5). Users of nonsteroidal anti-inflammatory drugs had a similar increased risk of non-gastrointestinal bleeding (adjusted OR, 1.7; 95% CI, 1.3 to 2.2), whereas the risk of gastrointestinal bleeding was higher (adjusted OR, 4.6; 95% CI, 3.3 to 6.5). Data was not provided to be able to calculate the NNH.

The authors concluded “In users of coumarins, SSRI usage was associated with increased risk of hospitalisation because of non-gastrointestinal bleeding but not because of gastrointestinal bleeding.” They go on to say “The results of our study indicate that the advantages of SSRIs in users of coumarins must be carefully weighed against the adverse effect of an increased bleeding risk. Given the limitations of our study, we cannot advise against concurrent use of SSRIs and coumarin anticoagulants; however, intensified monitoring of users of SSRIs seems justified. It is also possible to consider an alternative to an SSRI when initiation of antidepressant therapy is necessary in a patient using a coumarin”.

1. Aliment Pharmacol Ther 2008; 27:31-40
2. Arch Intern Med 2008; 168:180-5

## **Overprescribing PPIs**

Overprescribing PPIs is expensive and not evidence based according to a recent BMJ editorial<sup>1</sup>. The authors claim that studies consistently show that proton pump inhibitors are being overprescribed worldwide in both primary and secondary care. Between 25% and 70% of patients taking these drugs have no appropriate indication. This means that, at the very least, £100m from the NHS budget and almost £2bn worldwide is being spent unnecessarily on proton pump inhibitors each year.

In a UK centre, the suggested length of treatment with a proton pump inhibitor was specified in fewer than one hospital discharge letter in five. Only a third of letters indicated a date for the prescription to be reviewed and only half specified why the drug was started.

The authors point out that widespread use of PPIs is not without problems – “side effects should not be overlooked. An increase in the prevalence of pneumonia and *Campylobacter* enteritis is reported, as well as a doubling of the risk of infection with *Clostridium difficile*. Acute interstitial nephritis and osteoporosis are unusual but recognised consequence of treatment with proton pump inhibitors. Such effects are fortunately rare. The adverse effect of overprescription on drug budgets around the world is the real problem.”

Does your use of PPIs need a review?

1. BMJ 2008; 336:2-3

## Managing neuropathic pain

A new guideline 'Managing neuropathic pain in primary care' has been ratified for use by JAPC. It presents a treatment plan to be followed before considering referral and a formulary of recommended drug choices. It also includes the Neuropathic Pain Scale to aid diagnosis and to detect change in pain after treatment. If you would like a copy, contact a member of your Medicines Management team or myself.

### **Treating neuropathic pain – a 3-month plan**

Review patient/diagnosis/treatment monthly. Refer at month 4 if not improved.

Review pain after one month; if no improvement, review treatment regimen as below.

Review pain after one month; if no improvement, review treatment regimen as below.

Review pain after one month; if no improvement refer patient to a specialist. Remember that the patient will still require treatment while awaiting referral.

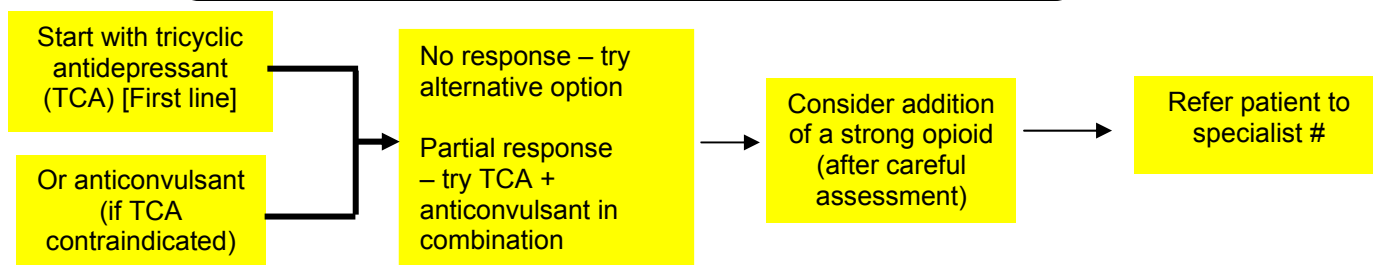
**Month 1**

**Month 2**

**Month 3**

**Month 4**

NB Other physical treatments, eg TENS, may be of benefit and can be used concurrently



#### # Considerations for referral:

- No significant improvement after a maximum of 3 months of treatment
- The patient is responding but suffering unacceptable side-effects
- The patient does not want drug therapy
- Need further advice or diagnosis on the particular clinical symptom set

## OTC medicines for coughs and colds

Further to the article in last month's PACE Newsletter, the MHRA has announced that certain cough and cold medicines are no longer suitable for children under the age of two years ([www.mhra.gov.uk/NewsCentre/Pressreleases/CON014446](http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON014446)).

The cough and cold medicines which will no longer be licensed for children under the age of 2, contain the ingredients:

- brompheniramine, chlorphenamine and diphenhydramine (antihistamines);
- dextromethorphan and pholcodine (antitussives);
- guaifenesin and ipecacuanha (expectorants);
- phenylephrine, pseudoephedrine, ephedrine, oxymetazoline and xylometazoline (decongestants).

A leaflet from the Proprietary Association of Great Britain (available to download via [www.pagb.co.uk](http://www.pagb.co.uk)) provides the following advice for parents or carers:

'Here are three simple steps to help your baby, toddler or child who has a cough or cold:

- 1) Use either paracetamol or ibuprofen to relieve pain and lower your child's temperature if they are uncomfortably hot.
- 2) For a cough, simple cough mixtures containing glycerol, honey and lemon are best. For children over the age of two a range of over-the-counter cough medicines are available.
- 3) Vapour rubs and inhalant decongestants, which can be applied to a child's clothing, can be used to provide relief from a stuffy or blocked nose. In addition, for children under two, particularly those who are having difficulty feeding, plain saline nose drops from the pharmacy can be used to help thin and clear secretions.'