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Safe use of inhaled steroids in children

Undetected adrenal suppression in children with asthma receiving high doses of inhaled corticosteroids is a cause for concern. The aim of this article is to raise awareness of this and to promote a system for identifying children who may be at risk.

A study published last year reviewed adrenal function of children with asthma receiving fluticasone greater than the licensed dose of 400micrograms/day.¹ The review was prompted by two cases of serious adrenal insufficiency, one of which was fatal, attributed to high dose inhaled fluticasone. Of the 194 children identified, 6 showed complete adrenal suppression, and a further 82 demonstrated partial adrenal suppression. The 6 children showing complete adrenal suppression were receiving fluticasone doses in excess of 1000micrograms per day. There was no correlation between total fluticasone dose and height or weight measurements. These findings were echoed in a local review in the Royal Hospital for Sick Children, Edinburgh, where 5 of 31 children prescribed inhaled corticosteroids at doses greater than the equivalent of beclometasone 2000micrograms or fluticasone 1000micrograms had undiagnosed complete adrenal suppression.

A recent update to the BTS/SIGN asthma guideline also highlighted the occurrence of clinical adrenal insufficiency in a small number of children who became acutely unwell at the time of intercurrent illness.² The guideline notes that the dose or duration of inhaled steroid treatment that puts a child at risk of clinical adrenal insufficiency is unknown, and advises the following:

"Specific written advice about steroid replacement in the event of a severe intercurrent illness should be part of the management plan for children treated with ≥800micrograms per day of beclometasone dipropionate or equivalent. Any child on this dose should be under the care of a specialist paediatrician for the duration of the treatment."

Thanks to Dr Steve Cunningham.

In Lothian, it is recommended that children identified at their annual review as receiving high doses of inhaled corticosteroids (see table), are referred for adrenal suppression assessment, which involves a short Synacthen[®] (tetracosactide) test. Children being treated with steroids by other routes, e.g. topical, nasal, and more than 3 oral steroid courses per year, are considered more vulnerable.

Please refer patients to Dr Steve Cunningham (Adrenal Suppression), Department of Respiratory & Sleep Medicine, Royal Hospital for Sick Children, Sciennes Road, Edinburgh, EH9 1LF. If the Synacthen[®] test is normal, the child will remain under the care of the GP.

Refer children for adrenal suppression assessment if dose greater than

beclometasone dipropionate * (CFC-containing)	800micrograms/day **
budesonide	800micrograms/day †
fluticasone	400micrograms/day

Notes^{3,4}

* Doses for CFC-free beclometasone inhalers may differ from those containing CFC. The maximum licensed dose of Clenil Modulite[®] in children is 400micrograms/day. Qvar[®] is not licensed for use in children.

** The maximum licensed dose of beclometasone is 400micrograms/day.

† Doses of budesonide above 400micrograms are not recommended and should only be used under specialist supervision.

Ciclesonide and mometasone furoate are not licensed for use in children under 12 years.

References

1. Paton J et al. Adrenal responses to low dose synthetic ACTH in children receiving high dose inhaled fluticasone. Arch Dis Child 2006;91:808-13.
2. British Guideline on the Management of Asthma - 2007 Update. BTS/SIGN. www.sign.ac.uk/guidelines/fulltext/63/update2007.html
3. Current problems in pharmacovigilance. 2006;31:5. Medicine and Healthcare Products Regulatory Agency. www.mhra.gov.uk
4. MeReC Extra. Issue 27. March 2007. National Prescribing Centre. www.npc.co.uk/MeReC_Extra/2007/pdfs/MeReC_Extra_No27.pdf

Supplementary and independent pharmacist prescribing

Pharmacist prescribing is designed to encourage a team approach to the care and management of patients. It makes better use of the pharmacist's expertise, facilitates chronic disease management and can improve patients' access to medicines.

Supplementary prescribing

Supplementary prescribers work in partnership with a specific independent prescriber (doctor or dentist) to implement an agreed patient-specific clinical management plan (CMP). There are no restrictions on the clinical conditions that may be treated, although it is primarily intended for use in managing specific chronic medical conditions.

Several processes are obligatory before supplementary prescribing may be carried out. Diagnosis of the clinical condition must first be made by the independent prescriber. There must be shared access to the patient's medical record, defined regular clinical review of the patient and communication between the independent and supplementary prescribers. An individualised CMP must be agreed. This includes details such as the illnesses or conditions which may be treated, the class or description of medicines which may be prescribed, any restrictions or limitations on prescribing, and circumstances when the advice of the doctor or dentist should be sought. The CMP should be kept simple, and may be paper-based or electronic. It may also refer to national or local guidelines. It can be written by either the supplementary or independent prescriber, but must be agreed by both. The patient's agreement must also be sought.

Independent prescribing

Pharmacist independent prescribing allows pharmacists to prescribe medicines for patients with diagnosed or previously undiagnosed medical conditions without the requirement for a CMP. The pharmacist works in partnership with the physician. Legislation governing implementation in Scotland is currently awaited.

Implementation in Lothian

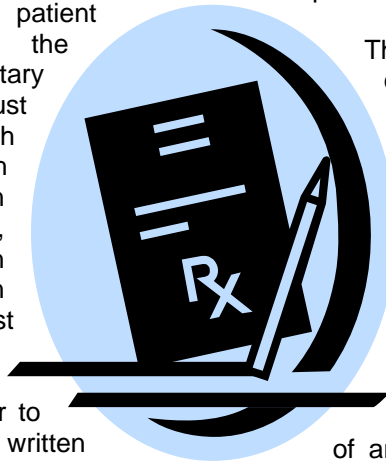
A governance framework for non-medical prescribing has been approved by NHS Lothian. All pharmacist prescribers in Lothian are advised to prescribe from the Lothian Joint Formulary. A total of 75 pharmacists have so far completed training or are in training as supplementary prescribers.

The majority are practising in primary care, with 16 currently running clinics, mostly based in GP surgeries.

The main clinical areas are diabetes, and cardiovascular and respiratory disease. Clinics have also been developed for mental health, pain management, warfarin and osteoporosis. Twenty pharmacists have attended independent prescribing courses.

Training

The training curriculum is approved by the Royal Pharmaceutical Society of Great Britain (RPSGB) and courses are run at the two Scottish schools of pharmacy. Pharmacists wishing to train as supplementary or independent prescribers must have been registered with the RPSGB for at least 2 years and be supported by their employer as well as an independent prescriber.



The supplementary prescribing training course takes a minimum of 37 days to complete and is divided into two parts. The first part of the course enables pharmacists to demonstrate that they have the underpinning knowledge to prescribe. It is assessed at university and equates to 25 days training. The second part is called the Period of Learning in Practice (PLP), and allows demonstration of the competencies required to prescribe in practice. The PLP is completed under the supervision of an independent prescriber, who acts as a mentor and is responsible for assessment. The training period may not necessarily be entirely spent with the independent prescriber, but may be gained with other members of the health care team.

For those pharmacists wishing to undertake independent prescribing, conversion courses are now available to registered supplementary prescribers. From 2008, both Scottish schools of pharmacy are scheduled to run full independent prescribing courses, allowing pharmacists to practise as supplementary and/or independent prescribers. As of June 2007, all pharmacy students graduating in Scotland will have gained the taught component of the supplementary prescribing qualification, and will be expected to complete the PLP component post-registration. Funding is generally provided through NHS Educational for Scotland (NES), and applied for through the Director of Pharmacy for the local NHS board.

Thanks to Fiona Reid, Primary Care Pharmacist, Cardiovascular Disease.

What's new in the Lothian Joint Formulary?

Respiratory Section

There have been updates to prescribing notes throughout the section to aid prescribing decision making. Advice on CFC-free beclometasone inhalers has been updated as detailed in an earlier issue of the LPB.¹

- There is currently no need to switch patients to CFC-free beclometasone inhalers
- There are currently two CFC-free beclometasone metered dose inhalers. They are not equipotent. If prescribing a CFC-free beclometasone MDI, the MHRA recommends prescribing by brand name to ensure the patient receives the correct dose and preparation.

The difference between Seretide[®] formulations has been clarified.

- Seretide Accuhaler[®] is designed to be administered as one blister per dose because each blister contains 50micrograms of salmeterol
- In contrast, Seretide Evohaler[®] should be administered as two puffs of the appropriate inhaler strength because each puff only contains 25micrograms of salmeterol per dose.

Treatment of *Chlamydia* infection in pregnancy

All pregnant women aged 25 years and younger within Lothian will be routinely screened for Chlamydia infection. The choice of antibiotic for treatment has been changed to azithromycin 1g as a single dose. Although azithromycin is not licensed for this indication it is in line with national guidelines² and clinical experience.

Nocturnal enuresis (LJF for Children)

Desmomet[®] (desmopressin oral lyophilisate) is approved for use for nocturnal enuresis in children over the age of five. Following recent MHRA advice, desmopressin nasal spray should not be prescribed for nocturnal enuresis. It is still indicated for treatment of diabetes insipidus.

References

1. CFC-free beclometasone dipropionate pMDIs. Lothian Prescribing Bulletin Issue 26. www.ljf.scot.nhs.uk/lpb/LPB26.pdf
2. UK national guideline for the management of genital tract infection with *Chlamydia trachomatis*. 2006. www.guideline.gov/summary/summary.aspx?ss=15&doc_id=10176&nbr=&string

Dovonex[®] ointment discontinued

Healthcare professionals will have received a communication from LEO Pharma informing them of the discontinuation of Dovonex[®] ointment (calcipotriol), with the recommendation that prescribers use Dovobet[®] ointment (calcipotriol and betamethasone) instead. Dovobet[®] remains non-formulary within Lothian. There is a generic version of calcipotriol ointment now available on the market, which can be prescribed instead of Dovonex[®] ointment. Calcipotriol remains first choice in the LJF.

Oral fluconazole not to be used for mastalgia

Oral fluconazole (Diflucan[®]) for empirical treatment of breast pain (mastalgia) during breastfeeding is not approved for use in Lothian. The Formulary Committee and the University Hospitals Drug and Therapeutics Committee agreed that it be categorised as 'black' under the ADTC '*Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian*'. However, oral fluconazole may at times be required for use in women admitted to hospital with severe breast infections.

See LJF website www.ljf.scot.nhs.uk for further information

Vaccines for cervical cancer

Despite the success of the Scottish cervical screening programme, the lifetime risk of a woman developing cervical cancer is 1 in 124. In 2004 there were 282 new cases of cervical cancer diagnosed and 102 deaths from cervical cancer in Scotland.

Two vaccines against human papillomavirus (HPV), the virus that causes cervical cancer, have recently been produced. Gardasil® has obtained a licence and Cervarix® is expected to get a licence soon. Gardasil® costs £240 for a three-dose schedule, and is now included in the BNF.

National immunisation policy is determined by UK Health Ministers and Departments advised by the Joint Committee on Vaccination and Immunisation (JCVI). The JCVI recommend an HPV immunisation programme within the routine childhood immunisation programme. However a number of key questions still require to be addressed before JCVI recommend routine HPV vaccination. These include:

- 1 The age of routine immunisation
- 2 The extent of a catch-up campaign (if any)
- 3 The need for a booster dose
- 4 Which vaccine should be used
- 5 Acceptability of immunisation
- 6 The impact of immunisation on the cervical screening programme
- 7 Cost effectiveness of different combinations of immunisation and screening

The position in Scotland has recently been outlined by Nicola Sturgeon, Cabinet Secretary for Health and Wellbeing who said:

*"The JCVI (Joint Committee of Vaccination and Immunisation) has recommended that HPV vaccines should be introduced routinely for girls aged around 12-13 years, subject to an independent peer review of the cost benefit analysis... It is our intention for funding for this to be included in our forthcoming spending review and we will aim to implement by autumn 2008. In the meantime and for the foreseeable future, the cervical cancer screening programme remains the best protection currently available to women."*¹



A recent letter from NHS Lothian Public Health to GPs supports this national guidance. Prescribing of these vaccines is not recommended in Lothian at present.

Reference

1. Cervical cancer vaccine. Scottish Executive news release. 20 June 2007.
www.scotland.gov.uk/News/Releases/2007/06/20154748

New restrictions for piroxicam

The anti-inflammatory piroxicam should not be used for treatment of short-term painful and inflammatory conditions, but can still be prescribed for the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.¹

Key messages:



Patients who have previously received piroxicam for 'acute' (short-term) use should receive an alternative medicine if they need similar treatment in the future



Patients who are receiving piroxicam on a long-term basis for osteoarthritis, rheumatoid arthritis or ankylosing spondylitis should have their treatment reviewed at their next routine appointment, and if appropriate, alternative treatment should be considered



For all NSAIDs, the lowest effective dose should be used for the shortest period necessary

Reference

1. MHRA statement following European Medicines Agency (EMA) advice. 26 June 2007.
www.mhra.gov.uk

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