

# PRESCRIBING NEWS

July 2011

## Update from Prescribing Group, July 2011

- A report was received on the community pharmacy inhaler initiative. Early results from the targeted Medicines Use Review work (based on 276 MURs so far) show that 33% of the asthmatics and 15% COPD patients had not been seen by a GP or nurse for 12 months. Community pharmacy can encourage people who normally do not attend for their reviews to do so. They have also referred people in to stop smoking services.
- Comments were submitted to MTC on new medicine applications.

## Update from Medicines and Therapeutics Committee, July 2011

- Three specialist medicines for cystic fibrosis (Promixin, Dornase and TOBI) were approved for shared care. GPs may be approached to take on prescribing after at least one month of treatment has been provided by secondary care.
- A review of eye drops for glaucoma is under way.

**MTC Needs You! It would be strengthened by more GP input. Please let the Pharmaceutical Advisers know if you are interested in attending for your consortium.**

***New web based formulary coming soon – please look out for further information!***

### Safe storage of prescriptions

There have recently been some reports of stolen prescriptions (FP10 pads). The PCT Auditors have provided advice on the safe storage of prescriptions.

### Unused Forms

- Unused forms should be kept in a **locked cabinet** and access kept to a minimum number of nominated person(s).
  - Forms should be stored in chronological order of delivery.
  - Forms taken for use by a practitioner or at the repeat prescription terminal should be recorded as detailed below.
  - It is good practice for only one working pad per GP/practitioner to be kept at any one time.

### Forms in Use

- When a new pad of prescriptions is taken for use an entry should be made on the appropriate page of the prescription pad register to include: –
  - Date taken for use
  - Serial numbers of the prescriptions taken for use
  - Person who removed them from the store
  - Practitioner who will be using them (or repeat prescription terminal).
- **Forms should not be left unattended at any time in the practice or in a car.**
- Prescriptions should be locked in a drawer when a practitioner leaves the room regardless of the reason or length of absence.

**Suspected fraudulent use of prescriptions must be reported to the Pharmaceutical Advisers.**

### Challenging non formulary prescribing

In our continuing drive to ensure appropriate use of scarce resources, it is important that prescribers in primary and secondary care follow the Joint Trusts Formulary recommendations, as these have been evaluated for efficacy, safety and cost effectiveness. The current contract with MKHFT incorporates a clause that allows the PCT to challenge non-formulary prescribing by hospital physicians, but we need your help to do this.

If a MKHFT doctor asks you to prescribe a non-formulary medicine, please would you:-

- Copy the patient letters and prescription requests for non-formulary medicines. They may be anonymised but please leave one patient ID visible eg the hospital number so that the prescriber knows which patient the letter relates to. (They will be offered an opportunity to explain why a non-formulary medicine was chosen)
- Prescribe a formulary equivalent medicine for your patient. The current formulary can be accessed from <http://www.mkhospital.nhs.uk/uploads/file/Pharmacy/Drug%20Formulary%20April%202011.doc> or seek advice from your practice pharmacist or technician or the PCT team at Sherwood Place. You may find the attached template helpful to communicate the change back to the hospital.
- Send the copy letter to the Chief Pharmacist by post or fax to the safe haven on 01908 278663

It is important that you follow the formulary in primary care too. In many cases, ScriptSwitch will prompt you to change your choice if you enter non-formulary medicines.

## Promoting Oral Health

### What is the problem?

During 2010, 157 children in Milton Keynes (aged between 18 months and 13 years) were admitted to hospital to have their milk teeth removed at a very early age because they are so badly decayed. Due to the age of these children, these teeth are extracted under general anaesthetic thereby exposing the child to an unnecessary risk of complications or even death. Hospitalisation for dental problems is a serious health issue which can be prevented.

### What can I do to help?

You can help by promoting breastfeeding and recommending that infants are introduced to drinking from a cup from the age of six months. Dietary advice should also be provided to reduce sugar intake and it should not be added to weaning foods. All parents and carers should also be encouraged to introduce toothbrushing as soon as the first tooth erupts in infancy.

Children can be given liquid medication by parents/carers not realising how much sugar they are giving. Medication is also often given last thing at night in order to relieve pain or a tickly cough when the flow of saliva is reduced and therefore the sugar-containing medication remains in contact with the teeth for longer. This could lead to dental decay. There is no evidence, according to the British Dental Association, that brushing after the medicine will remove the sugar-syrupy medicines from the teeth. The British Dental Association's view is that sugar is not a necessary or active ingredient in liquid medicines. You can help by prescribing or recommending sugar-free medication where available.

There are many different kinds of toothpastes on the market, some with no fluoride added and others with different concentrations of fluoride ranging from 500 parts per million (ppm) to 1,500ppm. Understandably, this can cause confusion to parents and carers, particularly when some toothpastes are specifically marketed for young children. You can help by recommending the appropriate concentration of toothpaste and fluoride mouthrinses. It should be noted that toothpastes with low concentration of fluoride (e.g. 500ppm or less) or no fluoride toothpaste confer limited or no protection against dental decay. Please refer to the table below for the appropriate advice:

Age group	Fluoride concentration
Children up to 3 years	only a smear of toothpaste containing no less than 1,000ppm fluoride
Children 3-6 years	pea-sized amount of toothpaste containing 1,350 to 1,500ppm fluoride
Children 7 years+ and all adults	1,350ppm fluoride or above

A combination of mouthrinse and toothpaste can be used together or just mouthrinse or higher concentration fluoride toothpaste alone. Mouthrinse should be used at a different time of day to toothbrushing. It would be advisable to check that they are using an appropriate concentration of fluoride toothpaste at home (i.e. 1,350ppm and above) and it is important that they do not substitute mouthrinsing in place of toothbrushing.

Age group	Fluoride vehicle	Fluoride concentration
8years+	Daily fluoride mouthrinse – to be used at a different time to toothbrushing – it is not a substitute for toothbrushing	0.05% NaF
10years+	Toothpaste	2,800ppm
16years+	Toothpaste	5,000ppm

Thanks to Jasmine Murphy, Specialist Registrar in Dental Public Health for providing this article.

### Atorvastatin patent expiry

Please note that the patent on Lipitor has been extended to May 2012. Therefore there will be no cost savings associated with generic atorvastatin during the current financial year. This news reinforces the need to use simvastatin 40mg as the first line choice of statin.

### Tapentadol (Praxelia)

Please note that this new analgesic has not been assessed for inclusion in the Milton Keynes formulary and therefore should not be prescribed. It has not been accepted onto the Oxfordshire formulary so please return any requests from Oxford Consultants as they should not ask you to prescribe it.

### Revised recommendations in Green Book advise against use of routine paracetamol/ibuprofen for the prevention of fever following vaccination

Chapter 8 (Vaccine safety and the management of adverse reactions following Immunisation) of the Green book for "Immunisation against infectious diseases" has been updated to advise that routine use of ibuprofen or paracetamol to **prevent** a fever following vaccination is **not** recommended as there is some evidence that prophylactic administration of antipyretic drugs around the time of vaccination may lower antibody responses to some vaccines.

Local reactions are usually self limiting and do not require treatment. If they appear to cause discomfort then paracetamol or ibuprofen can still be given to treat symptoms.

### **MHRA Drug Safety Advice: Risk of VTE higher with Yasmin than with levonorgestrel-containing pills**

The June 2011 issue of Drug Safety Update features an article on the risks of venous thromboembolism (VTE) associated with use of the Yasmin® oral contraceptive (containing drospirenone). The article briefly discusses the recent epidemiological studies that have suggested the risk of VTE associated with use of drospirenone-containing pills is higher than that associated with the use of levonorgestrel-containing pills. Although epidemiological studies are associated with various limitations, the totality of the available evidence shows clearly that the risk of VTE with drospirenone-containing pills is higher than that for levonorgestrel-containing pills, and may be similar to that for the 'third generation' pills containing desogestrel or gestodene. Overall the risk remains very small and, like other oral contraceptives, is less than that associated with pregnancy.

The product information for Yasmin has been updated to reflect this evidence and healthcare professionals are given the following advice:

- The risk of VTE in association with drospirenone-containing pills, including Yasmin, is higher than that for levonorgestrel-containing 'second generation' pills and may be similar to the risk for 'third-generation' pills that contain desogestrel or gestodene
- Levonorgestrel-containing pills have the lowest thrombotic risk and are the safest pill for a woman who wants to start or switch contraception.
- Any prescribing decision should take into account each woman's personal risk factors and any contraindications, including her experience with other contraceptive formulations
- All combined oral contraceptives (COCs), including Yasmin, should be prescribed with caution to obese women (BMI >30), or those with a higher baseline risk of VTE for other reasons
- Estimates are not precise, but for women who do not use a contraceptive pill about one case of VTE per 10 000 is expected each year. By comparison, about six cases of VTE are expected to occur in every 10 000 pregnancies. In healthy women who take Yasmin, between three and four cases of VTE are expected to occur in every 10 000 women each year. The previous estimate was between two and four cases in every 10 000 women each year. All these estimates relate to women who are otherwise in good health
- There is no reason for women to stop taking drospirenone-containing COCs or any other COC on the basis of these findings.

### **MHRA Drug Safety Advice: Bisphosphonates and atypical femoral fracture**

Atypical femoral fractures have been reported rarely with bisphosphonate therapy, mainly in patients receiving long-term treatment for osteoporosis.

During bisphosphonate treatment, patients should be advised to report any thigh, hip, or groin pain. Any patient who presents with such symptoms should be evaluated for an incomplete femur fracture.

Discontinuation of bisphosphonate therapy in patients suspected to have an atypical femur fracture should be considered while they are evaluated, and should be based on an assessment of the benefits and risks of treatment.

The need to continue bisphosphonate treatment for osteoporosis should be re-evaluated periodically based on the benefits and potential risks of bisphosphonate therapy for individual patients, particularly after 5 or more years of use.

### **Insulin Pen changes from Dec 2011**

Did you know some insulin pen devices from Sanofi Aventis will no longer be available from the end of the year Dec 2011?

#### **Pens being discontinued:**

OptiSet (disposable)  
OptiClik (cartridge)  
OptiPen Pro 1(cartridge)

#### **The alternative pens from Sanofi Aventis are:**

SoloSTAR (disposable) Insulins: Lantus / Apidra and Comb 25

ClikSTAR (cartridge) Insulins: Lantus / Apidra / Comb 15 / Comb 25 / Comb 50 / Basal / Rapid

**Autopen 24 (for Glargine / Lantus only)** will still be available but no longer supplied by Sanofi Aventis. They are available on prescription. If you have any queries: Owen Mumford 01993 812021

Please contact us at: [julie.petzing@mkpct.nhs.uk](mailto:julie.petzing@mkpct.nhs.uk) or leave a message on the team mobile: 07824828897 or office phone 01908 619765, if you need any advice on patient specific needs.

### **Graduated compression hosiery**

A short guide is available as a supplement to this edition of Prescribing News.

### **Travel vaccines**

There is still some confusion about charging for travel vaccines. For clarification, you can charge patients (cost of vaccine + VAT + "an additional amount for providing the service") for the following as long as you do not claim reimbursement from the prescription pricing authority.

- Hepatitis B (not in a combined injection)
- Meningitis
- Rabies
- Japanese encephalitis
- Tick Borne encephalitis
- Influenza for travel
- Yellow fever
- Hepatitis A booster dose

All other vaccines are available on the NHS and no charge can be made for them. Please do not use Hepatitis A + B combinations as a way of avoiding patient charges as these cost the NHS more than using Hepatitis A and charging the patient for Hepatitis B if its use is indicated.

## **Tiotropium RespiMat and increased risk of mortality?**

A systematic review and meta-analysis found that in randomised controlled trials (RCT), use of the RespiMat mist inhaler was associated with increased mortality compared to placebo in patients with chronic obstructive pulmonary disease (COPD).

Tiotropium is effective in providing symptomatic benefit in patients with COPD. It is available in two formulations, the HandiHaler, which is a dry powder inhaler (DPI), and the RespiMat device. The RespiMat delivers the drug in solution as a fine mist, and is recommended for patients with difficulty in using the DPI. Bioavailability and peak blood levels from the RespiMat are significantly higher than from the DPI. There is evidence of an increased risk of cardiovascular adverse effects from inhaled anticholinergic drugs, and the authors of this study became aware of concerns over mortality differences in clinical trials of the RespiMat device. This systematic review and meta-analysis was intended to examine the evidence behind these concerns. The authors carried out a comprehensive literature search for randomised placebo-controlled trials of Tiotropium mist inhaler that lasted at least 30 days and where mortality data were reported. Fixed effect meta-analysis was used to estimate relative risks (RR) of all cause mortality, and heterogeneity was assessed.

The initial search yielded 57 potentially relevant articles, of which 14 were reviewed in full (reason for exclusion, not RCT in COPD) and 5 (n=6,522; tiotropium 3,686, placebo 2,836) were eligible for the meta-analysis. A sixth study reported preliminary results and was used in a sensitivity analysis. Across the five trials, 137 patients died and tiotropium mist inhaler was associated with a significantly increased risk of mortality compared with placebo (90 vs. 47; RR 1.52; 95% CI, 1.06 to 2.16; P=0.02). Both doses of tiotropium were associated with increased risk: 10 microgram (RR 2.15; 95% CI 1.03 to 4.51; P=0.04) and 5 microgram (RR 1.46; 95% CI 1.01 to 2.10; P=0.04). The results were not substantially affected by sensitivity analyses.

Based on the average control event rate from the long term trials, the authors estimated a number needed to treat for a year with the 5 microgram dose to see one additional death: this was 124, however because of the small numbers the confidence interval was wide (95% CI 52 to 5682). They conclude that in this analysis, there was an increased risk of death associated with use of the tiotropium mist inhaler compared to placebo. There was suggestion of a dose-response effect, however the numbers involved were too small for this to be robust. They note the limitations of their analysis, but comment that the trials were done in a standardised manner and there is biological plausibility. An ongoing trial that is comparing the two formulations will clarify some of the uncertainties, and other work will provide more information on the use of inhaled anticholinergic drugs in high-risk populations.

An accompanying Editorial comments on the study and while noting that the use of relative risks in studies of this type is valid, he emphasises that the absolute risks were low: mortality in trials that lasted a year was 1.8% vs. 2.6% to give a difference of 0.8% or 8 patients in 1,000. The NNT for harm from this estimate was 121, again with a wide confidence interval (95% CI 51 to 5,556). The point estimate was, however, considerably larger than that for salmeterol in asthma. He concludes that until the comparative trial data are available the DPI would be the safer option, and patients who prefer the mist inhaler should be counseled on the possible increased risk.

**This fits with the local formulary placement where the RespiMat formulation should be reserved for patients with poor manual dexterity who are unable to use the HandiHaler.**

## **FSRH issues revised guidance on missed contraceptive pills**

The Faculty of Sexual and Reproductive Healthcare has issued new guidance on what to do when contraceptive pills have been missed. The guidance defines a missed pill as one that is more than 24 hours late. If more than one pill is missed, the rule applies to consecutive pills. The rule applies to active pills, not to placebo pills in ED preparations.

The following are key elements of the revised advice (taken directly from source):

- If it is reasonably certain that the woman is not pregnant, COCs can be initiated on any day of the menstrual cycle, not just the first day. Additional contraceptive precautions are required for the first 7 days if the pills are started after Day 5 of the cycle.
- If one active pill is missed, advise the patient to take it as soon as they remember (even if it means taking two at the same time), and there is no need to take additional precautions.
- If two active pills are missed, advise the patient to take the last pill as soon as they remember (even if it means taking two at the same time), and additional precautions should be taken for the next 7 days.
- Advice on use of Qlaira®, Evra® and NuvaRing® can be found in the Summaries of Product Characteristics and patient information leaflets available at <http://www.medicines.org.uk/emc>

## **The Pharmaceutical Advisers can be contacted on 01908 278713 / 278708 / 278744.**

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