LOTHIAN PRESCRIBING BULLETIN

Supporting prescribing excellence - informing colleagues in primary and secondary care

Issue No. 4
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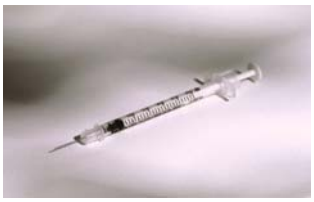


A JOINT CAMPAIGN
Pneumococcal and Flu Immunisation

During the winter of 2003/04 the Scottish Executive Health Department[1] is introducing pneumococcal polysaccharide immunisation for all adults aged 65 and over who have not already been immunised. By offering immunisation at this time patients can be protected against pneumococcal infection for winter and beyond. A single vaccination offers protection against pneumococcal infection for up to 10 years. Patients may receive pneumococcal immunisation at the same time as influenza immunisation provided it is administered in different limbs.

Patients aged 65 and over by 31 March 2004 will be sent a letter between late September and mid October from the Scottish Executive. They will be advised that they may be eligible to receive both influenza and pneumococcal vaccines in 2003/04 and that their GP practice will be contacting them shortly about arrangements. Payment levels will be announced shortly. For pneumococcal vaccine, GPs will receive payment for those aged 65 and over in 2003/04.

Key messages:

- **URGENT - establish amount of pneumococcal vaccine required for patients in target group and ensure you have ordered a sufficient quantity**
- **Please ensure all prescriptions and stock order requests are written generically**
- **If both vaccines are given at the same time, administer in different limbs**

- **Pneumococcal immunisation should be offered to:-**
  - **all aged 65 and over (no formal target)**
  - **'at risk groups', updated - see new chapter in "The Green Book"[2]**
- **Influenza immunisation should be offered to:-**
  - **all aged 65 and over (target maintained at 70%)**
  - **all aged over 6 months in specified risk groups**
  - **those living in long stay residential and nursing homes or other long stay facilities**

Continuing care areas in secondary care will be contacted by their relevant pharmacy regarding immunisation arrangements for patients.

Further information / References

1. Scottish Executive website www.scotland.gov.uk/health/flu_pneumococcal - to be live soon.
2. Immunisation Against Infectious Disease 1996 - new pneumococcal replacement chapter available at - www.doh.gov.uk/greenbook

The Multiple Sclerosis Risk Sharing Scheme

The role of the drugs *beta interferon* and *glatiramer acetate* has been evaluated over the last few years for the treatment of multiple sclerosis (MS) patients. It is generally accepted by practising neurologists in the United Kingdom that these drugs have a modest role in reducing relapse frequency in MS patients, particularly in those who have severe and frequent relapses. The effect of these drugs on the overall natural history of the disease is less clear and the National Institute for Clinical Excellence (NICE) has reported doubts about their cost effectiveness.

However, discussions with the manufacturer, the Association of British Neurologists (ABN) and the MS Society has resulted in the establishment of the 'Risk Sharing Scheme'[1]. This unique scheme enables beta interferon and glatiramer acetate to be acquired for the NHS in a manner which makes the treatment cost effective.

In this agreement the manufacturers have agreed to supply Avonex®, Betaferon® and Rebif® (beta interferon) and Copaxone® (glatiramer acetate) to the NHS at a negotiated cost. The scheme is known as risk sharing as the cost of the drugs would be adjusted if the expected outcomes are not achieved (cost could go down but not up). The cost and clinical effectiveness of the drugs will be monitored over a 10 year period as part of the scheme.

In Lothian, prior to 2002, virtually no patients had received these drugs because of reservations about both clinical benefit and cost effectiveness. Accordingly, there are a number of patients in Lothian who may be eligible to receive treatment according to the criteria in the scheme. Patients require to be assessed in a comprehensive way and then monitored should they prove to be eligible. The criteria for patients suitable for drug treatment for the scheme have been set by the ABN (see Table 1).

A Working Group has, over the last year, established the infrastructure requirements and funding to allow the scheme to operate in Lothian. Dr Belinda Weller has been appointed to a new consultant post in the department of Clinical Neuroscience at the Western General Hospital and has started a new MS clinic to review patients who may be eligible for treatment. An MS specialist nurse has been appointed and a physiotherapy post has been advertised. All drug therapy will be initiated, maintained and monitored from the hospital specialist clinic, and will subsequently be delivered to the patients by a contracted company. A newly appointed pharmacy technician is responsible for supervising supply. The costs of these drugs will have no impact on the primary care drugs budget.

Table 1 ABN criteria for use of disease-modifying drugs in MS (Department of Health, January 2001)[2]

Relapsing-remitting MS (interferon beta and glatiramer acetate)

- Be able to walk independently - at least 100 metres without assistance.
- At least 2 clinically significant relapses in the last 2 years.
- Age >18 years.
- No contraindications.

Secondary progressive MS (interferon beta only)

- Able to walk 10 metres with or without assistance.
- At least 2 disabling relapses in the last 2 years.
- Minimal increase in disability due to slow progression over the last 2 years.
- Age >18 years.

Key messages:

- **GPs should refer MS patients who meet the criteria.**
- **Doctors should be aware that MS patients may be receiving one of these drugs.**
- **All drugs in the scheme will be prescribed by the hospital.**

Reference:

1. Scottish Executive Health Department HDL(2002)6. "Cost Effective Provision of Disease Modifying Therapies for People with Multiple Sclerosis". 04 February 2002.
2. Guidelines for the use of Beta Interferons and Glatiramer Acetate in Multiple Sclerosis. Association of British Neurologists. January 2001. www.theabn.org/downloads/msdoc.pdf

HRT - the Million Women Study

The "Million Women Study"[1], provides important new information on the risk of breast cancer in association with using hormone replacement therapy (HRT). The Committee on Safety of Medicines (CSM) and its expert working group on HRT has considered the new facts and has recently issued guidance to prescribers[2]. Dr Alison Scott writes …*

"On 9 August 2003, a paper from the Million Women Study Collaborators (Valerie Beral et al) was published in *The Lancet*. This study investigates the incidence of breast cancer in women who are current users of hormone replacement therapy (HRT). There has subsequently been much media interest and numerous headlines leading to a significant increase in anxiety levels of women using, and GPs prescribing, HRT.

This study recruited 1.08 million women who were attending for breast screening in the United Kingdom. These women were followed up on the NHS Central Register for a minimum of 2.6 years and a maximum of 4.1 years. The main outcome measures were incidence of breast cancer and deaths due to breast cancer.

The results of this study can be summarised as follows:

1.	**Current users of HRT are at a 66% increased risk of developing breast cancer compared to never users.**
2.	**Current users are at a 22% increased risk of dying from breast cancer compared to never users.**
3.	**There is no increased risk of breast cancer in past users of HRT.**
4.	**There is a variation in risk according to the preparation being taken.** **- oestrogen-only relative risk = 1.3 (i.e. 30% increase in risk)** **- combined oestrogen/progestogen relative risk = 2** **- tibolone relative risk = 1.45**
5.	**There is a variation in risk according to the delivery modality with implants having the highest risk and patches the lowest.**
6.	**The risk of developing breast cancer increases with the duration of use of HRT. After 10 years there will be an additional 5 cases of breast cancer per 1000 women for oestrogen-only preparations and 19 additional breast cancers per 1000 women using combined preparations.**

To look at these figures in a different way, a GP would need to give combined HRT to 166 women for 5 years or 83 women for 10 years in order to see one extra case of breast cancer.

There is nothing new in these figures. Many previous studies have given the same results. This is however an impressively large study and, as such, has allowed the researchers to give new information about breast cancer incidence in women using different HRT preparations. In addition, it is a study of British women with an average age of 61, unlike the more recent studies which were carried out in America.

A commentary which appeared in the same issue of *The Lancet* suggested that doctors should revise their management of the menopause and not treat it as a disease. Many women however have their quality of life drastically reduced during this time and ask for help - are we to send them all away? There has undoubtedly been a change in attitude towards HRT. It is no longer seen as the panacea for all ails as it was 10 or so years ago - when many women commenced it. Women, most of whom will be managed in general practice, need to be counselled about the risks of breast cancer. Other issues such as increased risk of cardiovascular disease and thrombosis also need to be discussed.

Short term use of HRT to control vasomotor symptoms is undoubtedly effective. Longer term (more than 3-5 years) is however associated with increased breast cancer risks. There is no scientific evidence of these preparations being effective in improving cognitive functions or other feelings of wellbeing.

At the end of the day, many women may now be thinking of discontinuing HRT. Our experience has been that this is likely to be more successful if done as a process of gradual 'withdrawal'. At Dean Terrace, we recommend that women reduce to one tablet on alternate days for 3-4 weeks, then one tablet every third day for another 3-4 weeks, etc. This is easier to achieve with a continuous combined or oestrogen-only preparation. Women on a sequential preparation are (theoretically) at risk of inadequate progestogenic effect if they do not take all of the progestogen phase of their tablets.

Most importantly of all, women need to be counselled adequately and allowed to make their own decisions about continuation, discontinuation or recommencement of HRT."

References:

1. Million Women Study Collaborators. Breast cancer and hormone replacement therapy in the Million Women Study. Lancet 2003;362:419 www.thelancet.com
2. Hormone replacement therapy (HRT) and breast cancer - results of the UK Million Women Study. Committee on Safety of Medicines. www.mca.gov.uk/aboutagency/regframework/csm/csmhome.htm

**** Our thanks to Alison Scott, Locum Consultant Gynaecologist, Family Planning Clinic, Dean Terrace (Tel. 0131-332-7941) for this article.***

New Drug Treatments for Erectile Dysfunction

The Formulary Committee has agreed that tadalafil (Cialis®) should be added as a second choice to the Lothian Joint Formulary (LJF), following its recent approval by the Scottish Medicines Consortium (SMC). The Formulary first choice remains sildenafil (Viagra®). However, tadalafil may be a suitable alternative for patients who develop visual disturbances with sildenafil or for whom a longer duration of action is required.

Tadalafil is subject to the same NHS prescribing restrictions as other drug treatments for erectile dysfunction. Although vardenafil (Levitra®) was also approved by the SMC, the Formulary Committee has agreed that this does not appear to offer any significant advantages over sildenafil and it has therefore been classified as 'not preferred' in Lothian.

LJF section 7.4.5
Drugs for erectile failure (impotence)

First choice: **sildenafil** *tablets* (Viagra®)

Second choices: **tadalafil** *tablets* (Cialis®)
or **alprostadil** *injection* (Caverject® Dual Chamber)

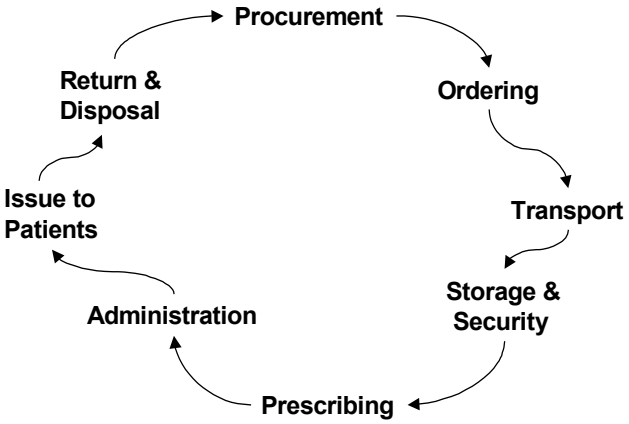
Launch of LUHT 'Policies and Procedures for Medicines'

The Lothian University Hospitals NHS Trust (LUHT) Drug and Therapeutics Committee published this policy in January 2003.

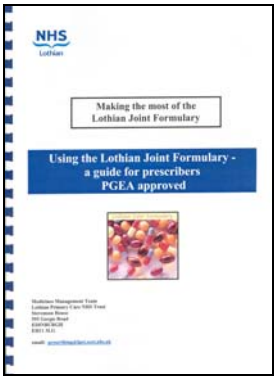
It has been distributed via ward managers throughout the Acute Trust and is available in all clinical areas. The document contains information on the flow of medicines within the Acute Trust.

This document will be of interest to all staff involved with medicines at any part of the cycle.

More information can be obtained from your ward manager or the LUHT Drug and Therapeutics Committee.



Learn More About the Lothian Joint Formulary



Two self-learning modules are now available. Both of these modules are designed to help prescribers explore the contents of the Lothian Joint Formulary, and also show how to access the wide range of prescribing information available in Lothian. One of the modules has been developed to inform GPs how to make the most of eLJF-GPASS. These might also be of interest to nurses and pharmacists. If you would like a copy of either module please contact the MMT at prescribing@lpct.scot.nhs.uk.

Both modules are approved for 3 hours PGEA

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