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Survey Results ... and New COX-2 Guidelines

A survey was carried out in 2002 in order to identify and explore factors that influence Lothian GPs in their selection and use of NSAIDs. The survey also explored the co-prescription of gastro-protection with cyclo-oxygenase (COX-2) selective inhibitors and standard NSAIDs and if the use of aspirin for cardioprotection influenced their decisions.

What influences GPs when prescribing NSAIDs?

The survey identified a range of factors that influenced GPs in their decisions.

Most influence: Previous recommendations from the Lothian Drug Evaluation Panel (DEP), Lothian Joint Formulary (LJF) recommendations, own practice formulary, age of patient, a history of peptic ulcer disease and a history of gastrointestinal upset associated with NSAIDs.

Moderate influence: Advice from other physicians, concomitant use of low dose aspirin, concomitant use of gastro-protective agents, history of functional dyspepsia, history of GORD and history of alcoholic gastritis.

No influence: Information from the pharmaceutical industry, patient demand and regular smoking were generally perceived to have no influence.

Do GPs prescribe gastro-protective agents with COX-2 selective inhibitors?

Three quarters of respondents reported that they did not prescribe gastro-protection with COX-2 inhibitors. Some GPs thought that dyspepsia was as significant a risk factor as peptic ulcer disease. However, the majority was aware that a past history of dyspepsia was not an indication for prescribing a COX-2 inhibitor.

Do GPs prescribe COX-2 selective inhibitors to patients taking aspirin for cardioprotection?

Only 20% of respondents were aware of the dangers of the concomitant use of low dose aspirin with COX-2 inhibitors.

We would like to thank Moira Kinnear and Anna Gunnarsdottir from the Lothian Pharmacy Practice Unit. This project was undertaken as part of an MSc in Clinical Pharmacy, University of Strathclyde.

The Lothian Prescribing Guideline for the use of COX-2 selective inhibitors in the treatment of osteoarthritis and rheumatoid arthritis was launched in January 2003. An updated version was recently circulated to all practices.

Key messages:

- COX-2 inhibitors should only be prescribed for patients with rheumatoid arthritis or osteoarthritis who require NSAIDs and are at high risk of GI side effects.
- The High Risk Group include
 - Previous peptic ulcer
 - Previous GI bleed
 - Alcohol related diagnosis
 - Aged over 70
 - Anti-coagulants
 - Requiring very high dose NSAIDs
 - Systemic corticosteroids
- A previous history of dyspepsia does not imply "high risk".
- Patients receiving low dose aspirin for cardiovascular protection should not be prescribed COX-2 inhibitors but should receive a PPI with an NSAID such as diclofenac.
- There is no evidence to support the use of a COX-2 inhibitor with a PPI for gastro-protection.
- The Lothian Joint Formulary recommends rofecoxib and celecoxib.

Pharmacovigilance in Scotland in the 21st Century

What is an adverse drug reaction?

An adverse drug reaction (ADR) is an unwanted or harmful reaction experienced following the administration of a medicine or combination of medicines under normal conditions of use and is suspected to be related to the medicine.

Pharmacovigilance is the process of

- monitoring medicines as used in everyday practice to identify previously unrecognised, or changes in the pattern of, adverse effects
- assessing the risks and benefits of medicines
- providing information to optimise safe and effective use of medicines
- monitoring the impact of any action taken

The Committee on Safety of Medicines (CSM) Yellow Card Scheme is regarded as one of the best spontaneous reporting schemes for suspected ADRs in the world. The scheme acts as an early warning system for the identification of previously unrecognised reactions. It has helped to identify many safety issues including renal failure due to aristolochia in Chinese herbs, severe oesophageal reactions with alendronate and serious cardiovascular reactions with cisapride. About 20,000 reports are submitted each year by doctors, dentists, pharmacists, coroners and the pharmaceutical industry. Reporting patterns indicate that each year in the UK around 10,000 people are believed to have experienced a serious ADR - a figure that is likely to be a gross underestimate of the true number.

The continued success of the Yellow Card Scheme is dependent on the vigilance of all UK health professionals and their willingness to report suspected ADRs. This is vital in the work of the CSM and the Medicines and Healthcare products Regulatory Agency (MHRA) to protect the public, by ensuring that drugs are used safely. The establishment of a Centre for Adverse Reactions to Drugs (Scotland) (CARDS) in October 2002 provides a welcome opportunity to improve ADR reporting and monitoring in Scotland. Based at Edinburgh Royal Infirmary, CARDS will administer the yellow card scheme in Scotland and promote pharmacovigilance in collaboration with the CSM/MHRA. The centre will facilitate reporting by health professionals across the country by providing training and education on ADR reporting. The centre will also provide regular feedback on reports submitted and undertake specific research projects in pharmacovigilance.

Also in October last year CSM/MHRA extended the Yellow Card Scheme to include reporting by all nurses, midwives and health visitors. The CSM/MHRA recognise that nurses are now more individually responsible for patient care and are involved in the prescribing of medicines as well as in their supply and administration under Patient Group Directions.

Patients will benefit from this development because more health professionals involved in their care now have the opportunity to report suspected ADRs. Nurse reporting is also being supported by the introduction of an electronic yellow card. This will enable quicker and easier submission of reports by all health professionals. It can be accessed at www.mca.gov.uk/yellowcard.

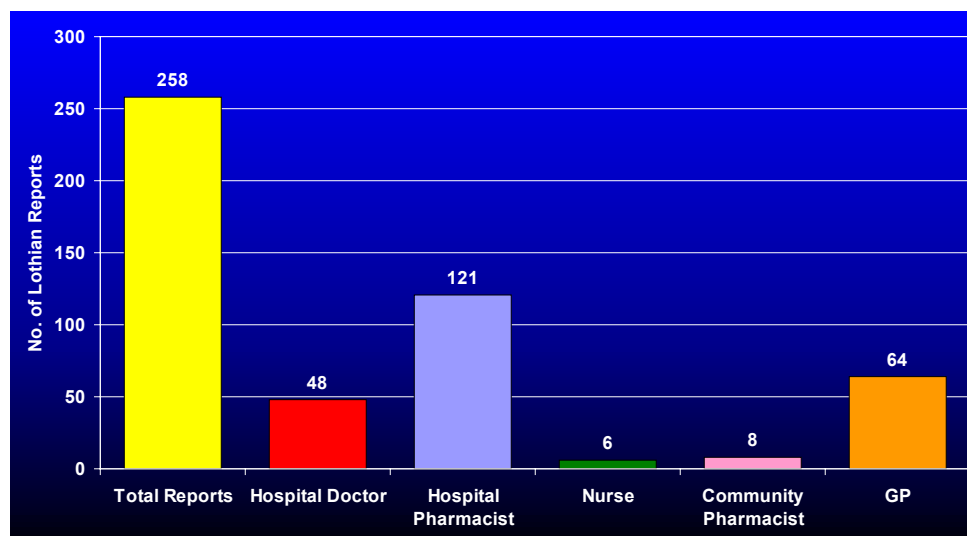
Paper copies of the yellow card can be obtained in the BNF, MIMS, Datasheet Compendium or from CSM Scotland. The contact details for CSM Scotland are as follows:

CSM Scotland, Freepost NAT3271, Edinburgh, EH16 4BR (tel: 0131 242 2919) or email: CSMScotland@luht.scot.nhs.uk.

All paper copies of yellow card reports from Scotland should now be sent to CSM Scotland. Reports submitted electronically will be fed back to CSM Scotland by the MHRA in London. The CSM/MHRA ask for reports to be submitted on all serious suspected reactions to established drugs and all suspected reactions to new medicines (indicated by the black triangle symbol ▼ in prescribing information). Further details on what to report can be found in the BNF or at the CSM Scotland website www.show.scot.nhs.uk/CSMScotland/completeryellowcard.html.

In 2002 the CSM/MHRA received a total of 258 reports from Lothian NHS Board. This accounted for 18.8% of the 1,369 reports received from Scotland for this period. Table 1 shows the breakdown of reports by reporter origin for Lothian NHS Board. General practitioners, hospitals doctors and hospital pharmacists were the 3 top reporting groups. Only 2.3% of the reports from within Lothian in 2002 came from the nursing profession. CSM Scotland looks forward to increased reporting from the nursing profession in the future.

Table 1 - Comparison of yellow card reports in 2002 from Lothian by reporter group



Key messages:

- All paper copies of yellow card reports from Scotland should now be sent to CSM Scotland.
- Nurses, health visitors, and midwives are now able to submit yellow cards when appropriate.
- Reports can now be submitted electronically.

Scotland and Lothian reporting statistics were obtained from CSM Scotland Annual Report 2002

We would like to thank Melinda Cuthbert, Senior Pharmacist, Pharmacovigilance, CSM Scotland.

BAN to rINN - Change of Drug Names

From December 2003, in the UK, all drugs should be prescribed using the Recommended International Non-proprietary Name (rINN) instead of the British Approved Name (BAN). Most drugs are already prescribed by their rINN, however some changes will be necessary and there are too many to list here. For example, thyroxine will become levothyroxine.

Up until now BANs have been used in the UK with dual use of rINNs, and in most cases these are identical. This will bring the UK in line with the rest of Europe and should reduce the potential for medication errors. It is envisaged that electronic prescribing systems will change over gradually.

Key messages:

- Check your BNF 46 (see page x Name changes).
- The LJM will also continue to include the former names as synonyms.
- Reassure and explain changes to patients.
- All handwritten prescriptions should now indicate rINNs.

Exceptions to the above are adrenaline and noradrenaline which will not change to their rINNs.

Additional information

Medicines and Healthcare products Regulatory Agency www.mhra.gov.uk.

British National Formulary www.bnf.org.uk.

Pharmaceutical Journal, 6 September 2003 - pull-out poster.

Resuscitation Boxes - Standardised Across Lothian

Lothian Area Drug and Therapeutics Committee (ADTC) has ensured that resuscitation boxes within Lothian contain the same drugs, same formulations and same delivery systems.

This consistency across sites will reduce the risk of errors when practitioners (particularly junior doctors and nurses) move between different sites in Lothian.

In primary care, for procedures where resuscitation guidelines apply, general practitioners or visiting specialists should use the standardised box.

Paediatric emergency boxes will be standardised in the future.

The Lothian Resuscitation Box contains:

- 1 x atropine injection 3mg/30mL Minijet®
- 5 x adrenaline injection 1 in 10,000 10mL Minijet®
- 1 x calcium chloride injection 10% 10mL Minijet®
- 1 x amiodarone injection 300mg/10mL pre-filled syringe

GPs requiring further information should contact Steven Short or Colin Halliday, Resuscitation Officers, LPCT (tel: 0131 537 6748), email: Steven.Short@lpct.scot.nhs.uk or Colin.Halliday@lpct.scot.nhs.uk.

Venlafaxine (Efexor®) in Patients Under 18 Years

The Committee on Safety of Medicines (CSM) has advised that venlafaxine (Efexor®) should not be used in children and adolescents under the age of 18 years to treat depressive illness. A letter with more information has recently been distributed to all GPs. Please review all patients under 18 years being prescribed venlafaxine.

Pneumococcal Vaccine Revisited - Re-immunisation Not Recommended

A note of clarification following on from the leading article in the last issue of this bulletin (Issue No. 4, August/September 2003) 'Pneumococcal and Flu Immunisation', which included the statement 'A single vaccination offers protection against pneumococcal infection for up to 10 years.'

- Re-immunisation is not currently recommended for patients who have received 23-valent polysaccharide vaccines, e.g. Pneumovax II®.
- However, re-immunisation should be offered to individuals in whom antibody levels are likely to have declined more rapidly such as those with no spleen, with splenic dysfunction or with nephrotic syndrome.
- For full details see Pneumococcal chapter, August 2003, The Green Book www.doh.gov.uk/greenbook.

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