



In this issue ...

- Lothian tackles Clostridium difficile infection
- Safe use of methadone update
- VSL#3® – a probiotic for pouchitis
- LJF update – treatment of migraine
- Exenatide safety update ▼ pancreatitis and acute renal failure
- Supplement: SMC and Lothian Formulary Committee Recommendations

Lothian tackles Clostridium difficile infection

What is clostridium difficile?

Clostridium difficile is a spore forming Gram positive anaerobe. The spores are transmissible and contaminate the environment. Spores are hardy and persist for long periods of time. Symptoms can range from mild diarrhoea to those of severe colitis, and can prove fatal. Clostridium difficile can affect anyone, however, rates are higher in the elderly, the debilitated and those treated with antibiotics. The principles of managing Clostridium difficile infection (CDI) apply in primary as well as secondary care, although some of the detail described here is specific to the acute setting.

Antibiotic strategies

The use of antibiotics can lead to increased risk of developing CDI. The time lag from antibiotic exposure to CDI can be up to a couple of months.

- Use narrow spectrum agents whenever possible
- Avoid clindamycin and second and third generation cephalosporins wherever possible
- Limit use of quinolones, carbapenems and aminopenicillins
- Minimise use of antibiotics associated with 'higher risk' of causing CDI.

LUHD Antibiotic Guidelines and the Lothian Joint Formulary give guidance on empiric management of infections:

- Minimise repeat exposures to antimicrobials
- Review all antibiotics regularly; de-escalate and narrow therapy as soon as possible
- Minimise durations of courses and use stop dates
- Surgical prophylaxis should be in line with SIGN 104
- Record indication in the notes
- Avoid unnecessary intravenous use; switch to oral as soon as possible.

Clostridium difficile Toolkit for inpatient areas

The Antimicrobial Management Team (AMT) has produced a Lothian Toolkit to enable ward areas to take appropriate measures to prevent or reduce CDI. These measures are just as important as antimicrobial use. The Toolkit contains:

- A background document which includes a ward/unit checklist
- Guidance leaflet for nursing and medical staff: 'CDI: Prevention, Detection, Management'
- Example of Bristol stool chart
- Individual patient checklist to be used for every CDI case detected
- Example of CDI patient information leaflet (Lothian version, which includes detailed guidance on hand washing)
- Health Protection Scotland leaflet on washing patients' laundry at home
- Posters

This toolkit will be available on the NHS Lothian intranet under Healthcare/Antimicrobial Management Team.

Everyone is responsible

Inter-related measures of hand hygiene, antibiotic management, cleaning and isolation practices and audit/surveillance need to be addressed to ensure patient safety. The Scottish Government has introduced a new Health Efficiency and Access to Treatment (HEAT) target defined as a reduction in the rate of CDI in patients aged 65 and over by at least 30% by 31 March 2011.¹



Reference

1. CEL 11 (2009), 8 April 2009. The Scottish Government www.sehd.scot.nhs.uk/mels/CEL2009_11.pdf

Safe use of methadone update

Methadone Guidelines for Community Pharmacists are updated

The revised Guidelines for Dispensing and Supervised Self Administration of Methadone by Community Pharmacists, available on the Lothian section of the NHS Scotland Community Pharmacy website and on the NHS Lothian intranet, were launched in April.¹ These guidelines are for pharmacists and prescribers, and aim to enhance the quality of pharmaceutical care provided to patients prescribed methadone and improve safety. There have been significant updates and additions to the guidelines to reflect legislative, clinical and service developments.

Updates

- NHS Lothian guidelines for methadone treatment and supervision
- Prescribing services and contact details
- Prescription requirements and legislation
- Prescribers' responsibilities
- When to contact the prescriber.

Additions

- Dental care advice
- Management of overdose
- Child protection guidelines and referral procedures.

References

1. Guidelines for Dispensing and Supervised Self Administration of Methadone. NHS Lothian. March 2009. www.communitypharmacy.scot.nhs.uk/documents/nhs_boards/lothian/Lothian-Guidelines-Dispensing-Supervised-Self-Administration-Methadone-pdf.pdf and http://intranet.lothian.scot.nhs.uk/nhslothian/healthcare/useful_resources/dispensing_methadone.aspx
2. Lothian Joint Formulary website www.ljf.scot.nhs.uk
3. NHS Lothian Guidelines for Substitute Treatment Prescriptions for Patients making Holiday and Travel Arrangements within and outwith the United Kingdom. Version 1. April 2009. http://intranet.lothian.scot.nhs.uk/nhslothian/healthcare/useful_resources.aspx

*Thanks to Elaine Rankine, Specialist Pharmacist, Substance Misuse and
Dr Muriel Simmonte, Primary Care Facilitator, Substance Misuse.*

Safe prescribing of methadone for patients making holiday and travel arrangements

NHS Lothian Guidelines for Substitute Treatment Prescriptions for Patients making Holiday and Travel Arrangements have been developed. Methadone oral solution 1mg/mL remains the first choice.



In exceptional circumstances, e.g. for a longer trip abroad methadone tablets (unlicensed)² may be a better option than transporting large volumes of methadone oral solution. The prescriber must ensure that this is clinically appropriate for the individual patient and that appropriate risk management systems are in place. Methadone tablets will not continue on returning home.

NHS prescriptions for methadone tablets in Lothian will be monitored closely.

A copy of the guidance is available to download from the NHS Lothian intranet under Healthcare / useful resources.³

VSL#3[®] – a probiotic for pouchitis

VSL#3[®] sachet is a once daily probiotic preparation. In Lothian, it has recently been approved for use and categorised **AMBER** (general use with restrictions; 'Additional List'), under the ADTC 'Policy for the use of unlicensed (and off-label use) medicines in NHS Lothian'. It is prescribable under ACBS (Advisory Committee on Borderline Substances) conditions 'under the supervision of a physician for the maintenance of remission of ileoanal pouchitis only in adults as induced by antibiotics'.

Pouchitis is a non-specific acute inflammation within an ileal reservoir. It leads to increased frequency of loose stool and abdominal cramping. The cumulative incidence of pouchitis varies from 20 to 50%.² Treatment is usually with antibiotics, but around 10% of patients experience refractory or frequently recurrent pouchitis.³

A Bandolier review looked at the evidence for the use of probiotics in this area.³ Four trials were found, with three of these concerning VSL#3[®]. Two of the trials were for prophylaxis against pouchitis. Results were good, with low rates of pouchitis with VSL#3[®] compared to placebo. The number needed to treat (NNT) to prevent pouchitis over about a year was 1.2, which is good evidence for this preparation in this patient group.

References

1. ADTC 'Policy for the use of unlicensed (and off-label use) Medicines in NHS Lothian. June 2008. www.ljf.scot.nhs.uk
2. Mimura T, Rizzello F et al. Once daily high dose probiotic therapy (VSL#3) for maintaining remission in recurrent or refractory pouchitis. Gut 2004;53:108-14.
3. Probiotics for pouchitis. Bandolier No 138, August 2005. www.medicine.ox.ac.uk/bandolier

LJF update – treatment of migraine

The LJF migraine section was reviewed and amended taking into account recommendations made in SIGN 107¹ published in November 2008. Further to the information detailed below, the advice on migraine prophylaxis has changed. Full information can be found at www.ljf.scot.nhs.uk.

The LJF, in line with SIGN, now advocates a stepwise approach to management of migraine, starting with an analgesic +/- antiemetic and escalating to 5HT₁ receptor antagonist (triptan).

LJF Treatment of acute attack 4.7.4.1

Step 1

**First choices: aspirin
ibuprofen
paracetamol**

SIGN 107 recommends soluble analgesics as they are absorbed quickly and may have a faster onset of action¹. However, they are more expensive and contain relatively large quantities of sodium. **LJF advice is, therefore, to reserve soluble analgesics for patients with gastric stasis or swallowing difficulties.**

Opioid analgesics should not be routinely used for acute migraine, due to the potential for development of medication overuse headache. This includes combination analgesics, particularly those with codeine.

Step 2

First choice: sumatriptan tablets

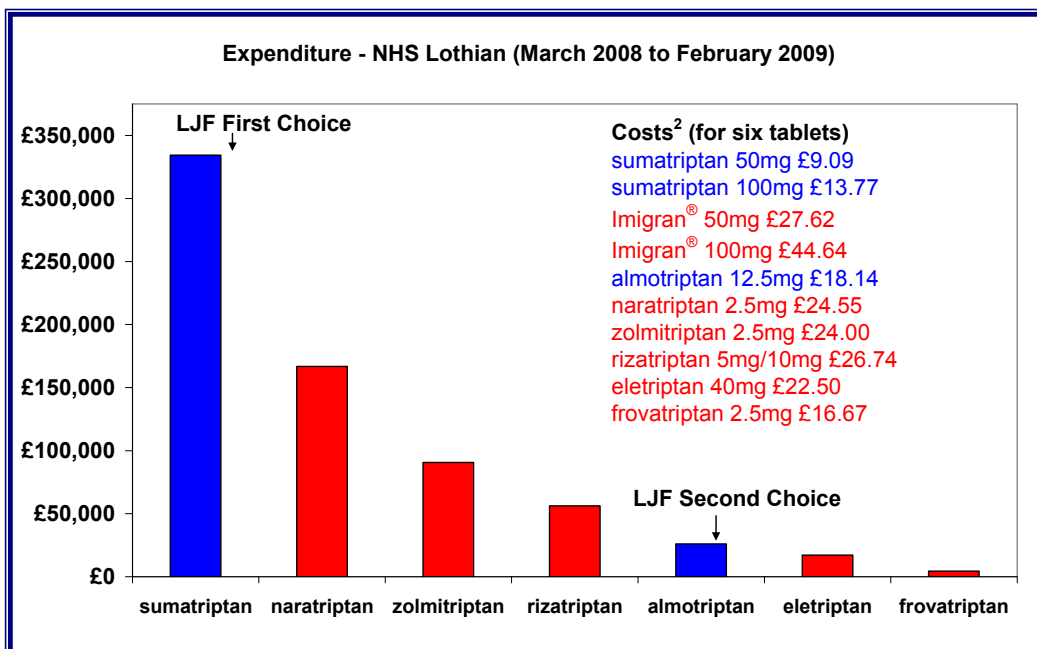
Second choice: almotriptan tablets

Sumatriptan 50mg and 100mg are equally efficacious. The 50mg dose produces fewer side effects, therefore it is considered the optimum dose. Sumatriptan is the only generic triptan available, and is available at a reduced cost.

SIGN 107 recommends almotriptan, eliotriptan and rizatriptan as first choice.¹ **However, LJF continues to recommend sumatriptan as first choice, based on current prescribing patterns, efficacy, cost and availability both OTC and on prescription.**

Current prescribing patterns in primary care

The graph shows that there are significant volumes of non-formulary triptans being prescribed.



There also continues to be significant amounts of non-generic prescribing of sumatriptan. This has a significant cost implication. Prescribing by brand name (Imigran[®]) accounted for £82,000 (25%) of all sumatriptan prescribed, if prescribed generically this could have saved NHS Lothian approximately £55k.

References

1. SIGN 107 Diagnosis and Management of headache in adults, November 2008. Scottish Intercollegiate Guidelines Network. www.sign.ac.uk
2. BNF 57, March 2009. www.bnf.org.uk

Exenatide safety update ▼ pancreatitis and acute renal failure

Exenatide is an incretin mimetic that stimulates insulin release from pancreatic beta cells in a glucose-dependent manner. Administered by injection, it is indicated for the treatment of type 2 diabetes mellitus in combination with metformin, with or without sulphonylureas, in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.¹ In Lothian exenatide is approved for use by prescribers with a specialist interest in diabetes.²

Since the marketing of exenatide in November 2006, the Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency has monitored its safety. Acute pancreatitis is a known adverse effect of exenatide but continued reporting of serious and fatal cases has led to re-evaluation of this issue. Up to February 2009, the MHRA has received six case reports of pancreatitis (including one suspected case report from Scotland) and a further three reports of acute pancreatitis in the UK in association with exenatide treatment.^{3,4}

There were a total of 396 cases reported worldwide up to September 2008, with an estimated 800,000 patient-years of exposure since licensing. In addition, nine reports of necrotising or haemorrhagic pancreatitis have been received worldwide (two fatal).³ The product information for exenatide is being updated to contain further information about this risk.

In addition, up to 30 January 2009, the MHRA had received seven case reports of acute renal failure (including two suspected case reports from Scotland) in association with exenatide therapy in the UK.

If you require any further information regarding these (or any other) possible adverse drug reactions with exenatide, please contact Yellow Card Centre Scotland on 0131 242 2919.

Key messages:

- 🔑 If pancreatitis is suspected, treatment with exenatide should be suspended immediately; if pancreatitis is diagnosed, exenatide should be permanently discontinued
- 🔑 Exenatide is not recommended for use in patients with end-stage renal disease or severe renal impairment (creatinine clearance <30 mL/min)¹
- 🔑 Exenatide is a Black Triangle ▼ medicine and as such all suspected adverse reactions to exenatide should be reported via the Yellow Card Scheme.

References

1. Byetta solution for injection, prefilled pen. Lilly Summary of Product Characteristics. www.emc.medicines.org.uk [Accessed 18 May 2009].
2. Lothian Joint Formulary. www.ljf.scot.nhs.uk
3. Exenatide (Byetta): risk of severe pancreatitis and renal failure. Drug Safety Update 2009; 2(8):6-7. www.mhra.gov.uk
4. Exenatide reports in MHRA data for YCC Scotland 2008 Yellow Card reporting.

Reminder for GPs - prescribing of exenatide

Please prescribe the quantity for exenatide as the *number of pens*, in order to avoid overcharging. This will avoid the quantity prescribed as only '60' being charged as 60 pens even although the intention was 60 doses (1 pen).

Correspondence address:
Medicines Management Team (MMT)
Pentland House
47 Robb's Loan
Edinburgh
EH14 1TY Tel: 0131-537-8510

Email: prescribing@nhslothian.scot.nhs.uk

Editorial Team:

Dr Adrian Cullen, General Practitioner
Ms Melinda Cuthbert, Principal Pharmacist, Medicines Information
Ms Anne Gilchrist, Lead Pharmacist, MMT (Chair)
Dr Sara Hornibrook, General Practitioner
Mr William John, Primary Care Pharmacist
Ms Joanne Kemp, MMT Administrator

Ms Alpna Mair, Primary Care Pharmacist
Ms Jane Pearson, Formulary Pharmacist
Ms Carol Philip, Primary Care Pharmacist
Dr Philip Rutledge, Consultant in Medicines Management
Dr Richard Williams, Prescribing Convener, GP Sub-Committee

View the Lothian Joint Formulary at www.ljf.scot.nhs.uk