NHS Lincolnshire

# Prescribing and Clinical Effectiveness Bulletin

**Volume 2; Number 15** **November 2008**

## What's new this month

- **There is no compelling evidence to support the use of fesoterodine (Toviaz) as an alternative to other antimuscarinic drugs in the treatment of overactive bladder syndrome. Fesoterodine is designated RED-RED (see page 2).**
- **The Department of Health have announced a further extention to the national Human Papillomavirus (HPV) vaccination programme to include young women aged 17 to 18 years in the school year 2008/9. Further guidance on those ineligible for the vaccination on the NHS is also given. Complications arising from recent debates on the relative merits of Gardasil and Cervarix are discussed and guidance given (see page 4).**
- **NICE have recommended continuous subcutaneous insulin infusion for the treatment of type 1 Diabetes mellitus in both adults and children subject to certain criteria (see page 6).**
- **NICE have recommended drug eluting stents for use in percutaneous coronary intervention for the treatment of coronary artery disease subject to certain criteria (see page 6).**
- **NICE have issued a new clinical guideline on the diagnosis and initial management of acute stroke and transient ischaemic attack (see page 6).**
- **NICE have issued a new clinical guideline on the induction of labour (see page 8).**
- **A new Wound Management Formulary has been developed for use across NHS Lincolnshire (see page 9).**

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This bulletin has been created specifically to convey details of decisions taken at the Prescribing and Clinical Effectiveness Forum (PACEF) to all stakeholders across the Lincolnshire Healthcare Community in both primary and secondary care. Steps will be taken to ensure the widest possible distribution across NHS Lincolnshire and within United Lincolnshire Hospitals Trust and Lincolnshire Partnership Trust. Both paper and electronic copies will be circulated initially with a view to evolving into complete electronic distribution as soon as we are confident that all key stakeholders can access E-mail. There are also plans to make all bulletins, guidelines, formularies, new product assessments, care pathways and other PACEF publications available through the LPCT website.

## SUMMARY OF PACEF DECISIONS: OCTOBER UPDATE

| Drug | Indication(s) | Traffic Light Status |
|---|---|---|
| Fesoterodine prolonged release 4mg and 8mg (Toviaz) | For the treatment of the symptoms of overactive bladder syndrome (OAB) (urinary frequency and/ or urgency and/or urgency incontinence). | RED-RED |
| Sodium hyaluronate eye drops (Oxyal) | Dry eyes | RED-RED |

RED-RED: This signifies that a product is **not recommended** for prescribing in **both** primary and secondary care. All new products are classified as RED-RED pending assessment by PACEF.
RED: This signifies that a product has been approved for use within ULHT and/or LPT **only** and has **no role in primary care**.
AMBER: This signifies that a drug has been approved for use in primary care **subject to specialist initiation; a shared care guideline (SCG) may also be required**. The main purpose of the SCG will be to clearly define both specialist and GP responsibilities. Not all AMBER drugs that require SCGs are currently covered by formal documents; in the coming months PACEF will be working to rectify this.
GREEN: This signifies a product that is **approved for initiation in either primary or secondary care**. Specialist initiation and shared care guidelines are not considered necessary.

**REPORTING INCIDENTS TO THE NATIONAL PATIENT SAFETY AGENCY (NPSA)**
The NPSA are keen to encourage the anonymous reporting of patient safety errors and systems failures both from healthcare professionals and patients. The National Reporting and Learning System (NRLS) has been set up to facilitate this process. Healthcare professionals can either report patient safety incidents through their local risk management scheme or directly into the NRLS using the eForm on the NPSA website. Please access www.npsa.nhs.uk for more information. **All healthcare professionals are encouraged to report incidents, errors and systems failures; the aim is to help the NHS to learn from things that go wrong.**

## NEW DRUG ASSESSMENTS

## FESOTERODINE FUMARATE PROLONGED RELEASE TABLETS 4MG AND 8MG (TOVIAZ)

Fesoterodine (Toviaz) is a prolonged release once daily antimuscarinic agent licensed for the treatment of the symptoms of overactive bladder syndrome (OAB); these include increased urinary frequency and/ or urgency and/or urgency incontinence. Once taken, fesoterodine is rapidly metabolised to the same active metabolite as the alternative antimuscarinic agent tolterodine (Detrusitol). PACEF reviewed two randomized controlled trials (RCTs) one of which compared fesoterodine 4mg and 8mg to placebo while the other compared both strengths to tolterodine 4mg sustained release (SR) and placebo. Unfortunately, the comparative trial against tolterodine was not sufficiently powered to detect statistical differences between fesoterodine and tolterodine SR; both drugs showed improvements over placebo against the primary endpoint of reduced number of micturations in 24 hours. The study also showed a significant placebo effect which the authors attribute to the subjective nature of the results; patients observations were recorded rather than more objective clinical measurements. Both studies demonstrated that fesoterodine 8mg was more effective than 4mg, although the incidence of adverse events, particularly dry mouth, was higher with the higher strength. A comparative table detailing the incidence of the antimuscarinic side effects (constipation and dry mouth) for each of the key agents currently available appears below:

| Antimuscarinic Agent | Constipation | Dry Mouth |
|---|---|---|
| Oxybutynin immediate release 5-20mg | 13% | 71% |
| Oxybutynin sustained release 5-20mg (Lyrinel XL) | 13% | 61% |
| Oxybutynin transdermal patch (Kentera) | 3% | 10% |

| | | |
|---|---|---|
| Fesoterodine SR 4mg (Toviaz) | 3% | 22% |
| Fesoterodine SR 8mg (Toviaz) | 5% | 35% |
| Darifenacin 7.5mg (Emselex) | 15% | 20% |
| Darifenacin 15mg (Emselex) | 21% | 35% |
| Propiverine immediate release 30mg (Detrunorm) | 4% | 23% |
| Solifenacin 5mg (Vesicare) | 5% | 11% |
| Solifenacin 10mg (Vesicare) | 13% | 28% |
| Tolteridone SR 4mg (Detrusitol XL) | 6% | 23% |
| Tolteridone immediate release 2mg (Detrusitol) | 7% | 35% |
| Trospium chloride 20mg (Regurin) | 10% | 20% |

Both studies were short-term (12 weeks); further, longer-term studies are required to provide evidence of long-term efficacy and assurance of long-term safety. Both studies also excluded patients with OAB attributed to neurological disease, making the more specialist role of this treatment uncertain. The cost of a year's treatment with fesoterodine is currently the same as tolterodine ER 4mg; tolterodine accounts for approximately 24% of all antimuscarinics currently prescribed across Lincolnshire.

**PACEF Recommendations:**
**The existing trial evidence for fesoterodine fails to make a compelling case for the agent to become part of local guidance for the treatment of OAB. NICE Clinical Guideline 40 on the management of urinary incontinence in women recommends the use of immediate release non-proprietary oxybutynin first-line if bladder training is ineffective. Alternative antimuscarinics should be considered second-line; NICE could find no clinically important differences in efficacy between agents, although some are better tolerated than others in terms of antimuscarinic side effects (see table above). The patent for tolterodine immediate release tablets is due to expire in 2012. Although this is a few years hence, PACEF were concerned that a shift from tolterodine to fesoterodine at this stage (based on no compelling evidence) could dramatically reduce future generic savings with no additional benefit to Lincolnshire patients. As a result of these concerns, fesoterodine is designated RED-RED and is not recommended for use within NHS Lincolnshire.**

## SODIUM HYALURONATE EYE DROPS (OXYAL)

Sodium hyaluronate eye drops (Oxyal) have been launched by Kestrel Ophthalmics for the treatment of dry eyes. Oxyal is not a licensed pharmaceutical and hence no Summary of Product Characteristics (SmPC) or trial data were available for PACEF to review. Some specialists recommend sodium hyaluronate (Oxyal) as a treatment for severe dry eyes along with alternatives such as paraffins, carmellose and hydroxyethylcellulose. The current edition of the *BNF* (March 2008) recommends either tear replacement products or oral pilocarpine with the choice of product dependent upon severity of the condition and patient choice. Several preparations currently available are not suitable for wearers of contact lenses. The preservative in Oxyal is OXYD, a new type of preserving system that turns into oxygen, water and saline on contact with the eye. This renders the product suitable for contact lens wearers. A cost comparison of alternative preparations for dry eye reveals the following:

| Drug | Daily dose range | Cost |
|---|---|---|
| **Sodium Hyaluronate formulations** | | |
| Sodium hyaluronate 0.15% eye drops (Oxyal) | 1-2 drops as required | £4.15 (10ml) |
| Sodium hyaluronate 0.18%(Vismed – multi) | 1-2 drops as required | £6.81 (10ml) |
| Sodium hyaluronate 0.18%(Vismed – single dose) | 1-2 drops as required | £5.10 (20 x 0.3ml) |
| **Alternative products** | | |
| Carbomer 980 0.2% gel (Geltears) | 1 drop three or four times daily | £2.80 (10g) |

| | | |
|---|---|---|
| Carbomer 0.2% liguid gel (Viscotears) | 1 drop three or four times daily | £3.12 (10g) |
| Carmellose | 1-2 drops as required | £5.75 (30 x 0.4ml) |
| Hypromellose eye drops | 1 drop as required | £1.52 (10ml) |
| Ilube | 1-2 drops 3 or 4 times daily | £4.63 (10ml) |
| Lacri-Lube | apply as required | £2.96 (5g) |
| Polyvinyl alcohol 1.4% (Liquidfilm tears) | 1 or 2 drops as required. | £1.93 (15ml) or £5.35 ( 30 x 0.4ml) |
| Polyvinyl alcohol 1.4% (Sno tears) | 1 or more drops as required. | £1.06 (10ml) |
| Tears Naturale | 1-2 drops as required | £31.68 (15ml) £13.95 ( 28 x 0.4ml) |

From this, sodium hyaluronate eye preparations emerge as expensive alternatives to more widely prescribed first and second line agents. Prescribing figures suggest that sodium hyaluronate eye preparations are not currently prescribed in Lincolnshire.

**PACEF Recommendation:**
**In view of the lack of trial evidence, the higher cost compared to alternatives and the lack of use of sodium hyaluronate eye preparations in county, sodium hyaluronate eye drops (Oxyal) are designated RED-RED.**

## IN THE NEWS

## HUMAN PAPILLOMAVIRUS VACCINATION PROGRAMME: FURTHER DEVELOPMENTS

Human Papillomavirus (HPV) vaccination is to be introduced into the national immunisation programme from the beginning of the 2008/09 school year. The *PACE Bulletin* has already covered plans to offer HPV immunisation routinely to all 12 to 13 year old girls (school year 8) to protect them against future risk of cervical cancer. Subsequently, in a letter dated 22nd July 2008, Professor David Salisbury announced **plans to extend the programme further from September 2008 to include young women aged 17 to 18 years. This is defined as all young women born between 1st September 1990 and 31st August 1991.** It is estimated that this will extend the first cohort to include an additional 300,000 young women.

A further catch-up campaign is also planned from the beginning of the 2009/10 school year for all girls aged up to 18 years (i.e. 17 years and 364 days) at 31st August 2009. All girls born between 1st September 1991 and 31st August 1993 (school years 12 and 13 in academic year 2009/10) will be offered immunisation from the beginning of the 2009/10 school year. All girls born between 1st September 1993 and 31st August 1995 (school years 11 and 12 in academic year 2010/11) will be offered the vaccine from the beginning of the 2010/11 school year. More information on the catch-up campaign will follow at a later date.

Cervarix has been announced as the brand of vaccine that will be used. A three-dose course is required over about six months. Vaccination will be offered to all young women in the cohort from September 2008 with the expectation that all courses will be completed by 31st August 2009. The vaccine will be supplied free of charge to PCTs. Any FP10 prescribing will feature as expenditure against practice and PBC Cluster prescribing budgets; the NHS price of each course of three vaccinations is £241.50.

**The Joint Committee on Vaccination and Immunisation (JCVI) have advised that a catch-up campaign for all women aged 18 years and over would not be cost-effective. However, they have advised the Dept of Health (DoH) that immunisation could benefit some individuals. This proposal remains under consideration at the DoH and further advice will be issued on this patient group in due course. Some speculation has occurred in the media around the prospect of extending the national programme to include women over the age of 18, although this remains speculation at this stage.**

Further speculation has also arisen in the media around the relative merits of the two HPV vaccines currently available in the UK and the mechanics of the DoH process through which the national contract was awarded to GlaxoSmithKline (manufacturers of Cervarix). One focus of concern was the disparity between the licensed indications of the two available vaccines; these are tabulated below:

| Vaccine | Licensed Indication | Evidence Base |
|---|---|---|
| Cervarix | Prevention of **premalignant cervical lesions** and **cervical cancer** causally related to **HPV types 16 and 18** | Demonstrated efficacy in women aged 15 to 25 years following vaccination; immunogenicity has been demonstrated in girls and women aged 10 to 25. |
| Gardasil | Prevention of **premalignant genital lesions (cervical, vulvar and vaginal), cervical cancer** and **external genital warts** causally related to **HPV types 6,11,16 and 18.** | Demonstrated efficacy in women aged 16 to 26 years following vaccination; immunogenicity has been demonstrated in girls and aged 9 to 15. Protective efficacy has not been evaluated in males. |

The table illustrates that Gardasil is licensed against a wider range of indications than Cervarix. However the criteria through which the national tendering exercise was evaluated considered far more factors than simply licensed indications and weighted certain criteria much more highly than others. Key points related to each of the products are as follows:

- Although both vaccines consist of virus like particles (VLPs), there are important differences in formulation. Specifically, Gardasil is adjuvanted with aluminium hydroxyphosphate sulphate and Cervarix with aluminium hydroxide with monophosphoryl lipid A (ASO4). The ASO4 adjuvant has been shown to generate a stronger and longer-lasting immune response. In trials this has translated into a higher and longer antibody response to HPV-18 for Cervarix compared to Gardasil. The clinical significance of this remains uncertain.
- In its phase II and phase III trials, Cervarix showed considerable evidence of cross-protection against incident infections with HPV-45 (related to HPV-18) and HPV-31 (related to HPV-16); Gardasil appears to have a much weaker effect on HPV-18 and the related HPV-45.
- Data on the efficacy of vaccination of men is not yet available.

The national programme is designed to specifically target HPV 16 and 18 as two high-risk HPV types that cause 70% of cervical cancers. The pre-agreed national evaluation criteria weighted quality and duration of protection against cervical cancers caused by HPV strains 16 and 18 much more highly than any other parameter considered. On this basis, the factors detailed above illustrate the reasons why Cervarix emerged most positively from such an evaluation: as a result of the adjuvant used, Cervarix generates a stronger and longer-lasting immune response against HPV strains 16 and 18 than its competitor.

**PACEF Recommendations:**

**All girls who are likely to qualify for HPV vaccination either as part of the first cohort or the two-year catch-up campaign should be advised to wait to receive the vaccination through the national programme. Under no circumstances should young women who are entitled to free HPV vaccination as part of the national programme be prescribed HPV vaccine on the NHS. The JCVI have advised the DoH that a catch-up campaign for all women aged 18 and over would not be cost-effective, but have recommended that the DoH should consider sanctioning vaccination for further higher-risk individuals. This is currently under consideration at the DoH. Women who wish to receive the vaccination who are not covered by the national programme should be encouraged to wait to see if the national programme is extended further in accordance with JCVI recommendations; alternatively they could choose to access the vaccine through a private clinic although the cost of this is likely to be prohibitive for many. Data on the efficacy of HPV vaccination in men and boys is not yet available. Any approaches from male patients for vaccination against HPV should be refused.**

**The nationally approved vaccine is Cervarix and patient pressure to prescribe Gardasil outside of the context of the national programme should be resisted. Both vaccines are only licensed for**

**use within the context of official recommendations; these are defined as the recommendations of the DoH and the JCVI. Both of the HPV vaccines currently available (Cervarix and Gardasil) are designated as RED-RED and should not be prescribed on the NHS under any circumstances in Lincolnshire primary care on the NHS.**

**All of these recommendations are made by the Lincolnshire Prescribing and Clinical Effectiveness Forum on behalf of NHS Lincolnshire. Where patients are refused vaccination outside of the national programme, any complaints and concerns should be directed to the Complaints Dept at NHS Lincolnshire.**

**NICE TECHNOLOGY APPRAISAL 151: *CONTINUOUS SUBCUTANEOUS INSULIN INFUSION FOR THE TREATMENT OF DIABETES MELLITUS* (JULY 2008)**

The NICE recommendations are as follows:

- **Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a treatment option for adults and children of 12 and over with type 1 diabetes mellitus (DM)** provided that: (1) attempts to achieve target HbA1c levels with multiple daily injections (MDI) result in disabling hypoglycaemia; or (2) HbA1c levels have remained high (8.5% or above) on MDI (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.
- **CSII is recommended as a treatment option for children younger than 12 with type 1 DM** provided that: (1) MDI therapy is considered impractical or inappropriate and (2) children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18.
- CSII therapy should be initiated only by a trained specialist team (i.e. a physician with a special interest in insulin pump therapy, a diabetes specialist nurse and a dietitian).
- Following initiation in adults and children of 12 and over, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control (i.e. a fall in HbA1c) or a sustained decrease in the rate of hypoglycaemic episodes.
- CSII therapy is not recommended for the treatment of type 2 DM.

**NICE TECHNOLOGY APPRAISAL 152: *DRUG-ELUTING STENTS FOR THE TREATMENT OF CORONARY HEART DISEASE* (JULY 2008)**

The NICE recommendation is as follows:

- **Drug eluting stents are recommended for use in percutaneous coronary intervention for the treatment of coronary artery disease**, within their instructions for use only if: (1) the target artery to be treated has less than a 3mm calibre or the lesion is longer than 15mm; and (2) the price difference between drug-eluting stents and bare-metal stents is no more than £300.

**NICE CLINICAL GUIDELINE 68: *STROKE – DIAGNOSIS AND INITIAL MANAGEMENT OF ACUTE STROKE AND TRANSIENT ISCHAEMIC ATTACK (TIA)* (JULY 2008)**

It is emphasized to readers that this CG applies to the **initial** management of acute stroke and TIA. The NICE recommendations are as follows:

Rapid recognition of symptoms and diagnosis

- In people with sudden onset of neurological symptoms a validated tool such as the Face Arm Speech Test (FAST) should be used outside hospital to screen for a diagnosis of stroke or TIA. Exclude hypoglycaemia as the cause of sudden-onset of neurological symptoms.
- In A&E the Recognition of Stroke in the Emergency Room (ROSIER) tool is recommended as a means to achieve rapid diagnosis.

- People who have had a suspected TIA who are at high risk of a stroke ($ABCD^2$ of 4 or above) should have: (1) **aspirin 300mg daily** started immediately; (2) specialist assessment and investigation within 24 hours of onset of symptoms (specialist assessment includes exclusion of stroke mimics, identification of vascular treatment, identification of likely causes, appropriate investigation and treatment); and (3) measures for secondary prevention introduced as soon as the diagnosis is confirmed, including discussion of individual risk factors.
- People with crescendo TIA (two or more TIAs in a week) should be treated as being at high risk of stroke, even though they may have an $ABCD^2$ score of 3 or below.

Specialist care for people with acute stroke

- All people with suspected stroke should be admitted directly to a specialist acute stroke unit following initial assessment, either from the community or the A&E department.
- Brain imaging should be performed immediately (i.e. the next slot or within 1 hour whichever is sooner) for people with acute stroke if any of the following apply: (1) indications for thrombolysis or early anticoagulation treatment; (2) on anticoagulant treatment; (3) a known bleeding tendency; (4) a depressed level of consciousness (Glasgow Coma Score below 13); (5) unexplained progressive or fluctuating symptoms; (6) papilloedema, neck stiffness or fever; and (7) severe headache at onset of stroke symptoms.
- Otherwise perform brain imaging as soon as possible (within a maximum of 24 hours after onset of symptoms).

Thrombolysis with alteplase

- Consider giving alteplase for treatment of acute ischaemic stroke if indicated by exclusion of intracranial haemorrhage.
- Where indicated, alteplase must be used within 3 hours of symptom onset; treatment must be performed by a physician specialised in neurological care. It should be administered only within a well-organised stroke service or by trained and supported staff in A&E.
- Consider BP reduction to 185/110mmHg or lower in people who are candidates for thrombolysis.

Nutrition and hydration

- On admission, people with acute stroke should have their swallowing screened by an appropriately trained healthcare professional before being given oral food, fluid or medication.
- Malnutrition should also be screened for using the Malnutrition Universal Screening Tool (MUST). Screening should be done on admission and then weekly.
- Initiate nutritional support for people with stroke at risk of malnutrition; this may include oral nutritional supplements, specialist dietary advice and/or tube feeding.
- For people unable to take adequate nutrition and fluids orally, nasogastric feeding should be initiated within 24 hours of admission. Nasal bridle tube or gastrostomy feeding are alternatives in people unable to tolerate an NG tube.

Early mobilisation

- The person should be encouraged to sit up as soon as possible (where clinical condition permits).
- The person should be mobilised as soon as possible (where clinical condition permits).

People with TIA – assessment, early management and imaging

- Start **daily aspirin 300mg** immediately.
- Introduce measures for secondary prevention as soon as diagnosis confirmed (e.g. individual risk factors).
- Assess risk of subsequent stroke using a validated scoring system such as $ABCD^2$ and refer for specialist assessment.

Pharmacological treatment for people with acute stroke

- For **acute ischaemic stroke without primary intracerebral haemorrhage**, give aspirin 300mg as soon as possible (certainly within 24 hours). If the oral route is impractical due to dysphagia, give rectally or by enteral tube. Continue for 2 weeks after symptom onset (or until discharge if sooner) and then initiate long-term antithrombotic treatment. The *BNF* recommends aspirin 75mg daily as an appropriate dose for long-term treatment. If previous dyspepsia with aspirin is reported, give a concurrent proton pump inhibitor (PPI). If the person has a proven hypersensitivity to aspirin-containing medicines or a history of severe dyspepsia induced by low dose aspirin give an alternative antiplatelet drug. Do not give anticoagulants routinely for acute stroke.
- For **acute venous stroke** (cerebral venous sinus thrombosis, including secondary cerebral haemorrhage), give full-dose anticoagulation (initially full dose heparin and then warfarin [INR 2-3]) unless there are co-morbidities that preclude its use.
- For **stroke secondary to acute arterial dissection**, treat with either anticoagulants or antiplatelet agents.
- For **acute ischaemic stroke** associated with antiphospholipid syndrome, treat in the same way as acute ischaemic stroke.
- For **haemorrhagic stroke,** reverse anticoagulation for patients receiving anticoagulants before their stroke. A combination of prothrombin complex concentrate and intravenous vitamin K is recommended.
- **Statin therapy should not be started immediately after an acute stroke; start statins after 48 hours.** While, statin therapy is of benefit in terms of secondary prevention of ischaemic stroke, it may increase the risk of early haemorrhagic expansion or transformation in the acute phase. There may be an association between low cholesterol and haemorrhagic stroke. If the patient is already taking statins, continue treatment throughout.

**PACEF Recommendation:**
**This Clinical Guideline helps to clarify the role of a range of therapies post TIA and stroke including aspirin, alternative antiplatelet agents, PPIs and statins. Prescribers are reminded that these guidelines are for the initial management of stroke and are not necessarily reflective of longer-term treatment. For example, the *BNF* recommends aspirin 75mg daily as an appropriate dose for long-term antiplatelet therapy.**

**NICE CLINICAL GUIDELINE 70: *INDUCTION OF LABOUR* (JULY 2008)**

- Women should be informed that most women go into labour spontaneously by 42 weeks.
- At the 38 week antenatal visit, all women should be informed of the risks of pregnancies that exceed 42 weeks and their options. Information should cover: membrane sweeping, induction of labour between 41 and 42 weeks and expectant management.
- Where induction of labour is offered, healthcare professionals should explain: the reasons for induction and when, where and how it will be carried out; the arrangements for support and pain relief; alternative options; the risks and benefits of induction; and the options should induction be unsuccessful.
- Women with uncomplicated pregnancies should usually be offered induction of labour between $41^{+0}$ and $42^{+0}$ weeks to avoid the risks of prolonged pregnancy.
- **Vaginal $PGE_2$ is the preferred method of induction of labour unless there are specific clinical reasons for not using it. Vaginal gel (Prostin E2), tablet (Prostin E2) or controlled release pessary formulations (Propess) are advocated.**
- If induction fails, subsequent management options include: a further attempt to induce labour or caesarean section.
- **Induction methods that are not recommended include: oral $PGE_2$, extra-amniotic $PGE_2$ (Prostin E2), intravenous (IV) $PGE_2$ (Prostin E2), intracervical $PGE_2$ (Prostin E2), vaginal nitric oxide donors, IV oxytocin alone, oestrogen, hyaluronidase, corticosteroids and mechanical procedures (if used routinely).**

- **There is no available evidence to support the following alternative approaches to induction of labour: acupuncture, homeopathy, herbal supplements, castor oil, hot baths, enemas, sexual intercourse.**
- In the event of intrauterine fetal death, offer choice of immediate induction or expectant management. In the event of ruptured membranes, infection or bleeding, immediate induction is preferred. If induction is chosen, offer oral mifepristone (Mifegyne), followed by vaginal $PGE_2$ (Prostin E2) or misoprostol. Misoprostol is not currently licensed for this indication; informed consent should be obtained and documented. Mifepristone and misoprostol should only be offered if there is intrauterine fetal death.

**NEW WOUND MANAGEMENT FORMULARY**

A new Wound Management Formulary has recently been distributed to all key stakeholders across Lincolnshire primary care. The Formulary has been developed from an amalgamation of the three wound management formularies that existed from the previous three Lincolnshire PCTs; decisions have been taken in full consultation with LPCT Tissue Viability Nurse Specialists and practitioners from with United Lincolnshire Hospitals Trust in an attempt to agree a common range of preferred products recommended for use across both primary and secondary care. In addition to listing preferred products, the Formulary also provides guidance on the context within which particular products and types of product should be used. This is the first edition of an evolving document which will be updated on an annual rolling programme.

Key practical points from the Formulary that prescribers may find useful are as follows:

Antimicrobial dressings

- Antimicrobial products should only be used where there is an increased risk of infection or clinical signs of infection are apparent.
- Once an infection has resolved, treatment with an antimicrobial dressing should be discontinued.
- First line options are Inadine, Actisorb Silver 220, Actilite, Activon Tulle and Activon Honey. Practitioners are advised to treat initially with first line options before commencing treatment with more expensive second line options.
- Antimicrobial products should be used for 10 – 14 days. If at this point there has been no clinically significant change to the wound then use should be discontinued.
- Antimicrobials and in particular Silver products should not be used prophylactically.

Foam Dressings

- Allevyn, Allevyn adhesive and Tegaderm foam adhesive are the first line formulary options.
- Mepilex , Mepilex Bordered and Mepital are products which have been removed from the formulary due to increasing costs and the potential for inappropriate use. The only exception to this is Mepilex 10 x 10 cm which is recommended second line specifically in those with friable skin.
- The ‘Plus’ products outlined as second line are advised to be more absorbent and are appropriate for use on the more heavily exudating wounds.

Hydrogels

- Citrugel and Aquaform are the recommended first line products. They are not suitable for heavily exudating wounds.

Adhesive Perforated Dressings

- These products are indicated mainly for use in acute wounds (e.g. surgical incisions, cuts and abrasions).
- Cosmopor E is the only adhesive perforated product recommended on formulary.

Film Membranes

- C –View and Mepore Film are the only recommended formulary film membranes. These products should be used preferentially over Tegaderm and Opsite.

Wound Cleansers

- Routine cleaning is not recommended as it does not remove bacteria. The requirement for cleaning should be evaluated in response to individual need and as a result of a holistic assessment.
- Tap water is indicated for the cleansing of chronic wounds and surrounding skin.

Copies of the Formulary can be accessed via the PCT website at http://www.lpct.nhs.uk/1/1/0/Home.htm and following the link to Policy and Guidance and then Public Health Policies and Guidance. Alternatively, a copy can be requested from Rebecca Phillips at Rebecca.Phillips@lpct.nhs.uk. Clinical advice and further information can be accessed through the locality Tissue Viability Nurse Specialists. These are:

- North West – Alison Tyrer Telephone No: 01522 512999 ext 205 / 513643
- North East - Pam Pirrie – Telephone No: 01507 543300 (until November 2008)
- South East – Hilary Field – Telephone No: 01775 719871
- South West – Angela Wilson – Telephone No: 01476 590416

**SAFETY ALERT: OPIATE AND SNORING OR SLEEP APNOEA**

The Coroner has asked the PCT to inform all prescribers of the recent death of a man who was taking pethidine and morphine for longstanding back pain. During the inquest, it emerged that the man had a history of snoring; expert testimony suggested that the patient may have been suffering from sleep apnoea. Prescribers are asked to remain vigilant to the risks of prescribing opioid analgesics in patients with impaired respiratory function; the *BNF* states that opioid analgesics should be used with caution in this context.

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7th November 2008