Lincolnshire NHS

Prescribing and Clinical Effectiveness Bulletin

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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 Lincolnshire PCT 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: MARCH UPDATE

Drug	Indication	Traffic Light Status
Glucosamine hydrochloride (Alateris)	**Relief of symptoms in mild to moderate osteoarthritis of the knee**	**RED-RED** **N.B. Unlicensed food supplement formulations of glucosamine hydrochloride such as Cozachew Meltdown and Cozachew Combi Meltdown are also RED-RED**
Glucosamine sulfate (all formulations including glucosamine/chondroitin combination products)	**Not licensed** **Used for relief of symptoms in mild to moderate osteoarthritis of the knee**	**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.

NICE CLINICAL GUIDELINE 59: *OSTEOARTHRITIS – THE CARE AND MANAGEMENT OF OSTEOARTHRITIS IN ADULTS* (FEBRUARY 2008)

The main recommendations are as follows:

- There are three 'core treatments' that should be considered for every person with arthritis: (1) education, advice and information (2) exercise (irrespective of age, co-morbidity, pain severity or disability) and (3) weight loss (if overweight or obese).
- Pharmaceutical treatment should commence with relatively safe pharmaceutical options: **paracetamol and/or topical non-steroidal anti-inflammatory drugs** (NSAIDs) should be considered ahead of oral NSAIDs, cyclo-oxygenase 2 (COX-2) inhibitors or opioids. Regular dosing of paracetamol may be required.
- Topical NSAIDs are particularly recommended in knee or hand OA.

PACEF Recommendations:
Regular paracetamol is endorsed as a first line treatment option in regular doses if necessary (i.e. 2 tablets every 4 to 6 hours up to a maximum of 8 tablets in 24 hours). Soluble paracetamol should be reserved for those patients with genuine swallowing difficulties.
Despite reservations over the efficacy of topical NSAIDs, PACEF endorse their use as an alternative first line option. The topical NSAID of the lowest acquisition cost should be prescribed first line. Lower cost topical NSAIDs include: generic ketoprofen 2.5% gel (100g £3.46), ibuprofen 5% gel (100g £5.31), ibuprofen 10% gel (Fenbid Forte;100g £6.50) and Ibugel Forte (100g £6.05), ketoprofen 2.5% gel (Oruvail; 100g £5.87) and ketoprofen 2.5% gel (Powergel; 100g £5.89).
The use of premium price products such as piroxicam 0.5% gel (Feldene; 112g £9.41), felbinac 3.17% foam (Traxam; 100g £7.00) and diclofenac gel (Voltarol Emulgel (100g £7.00) should be avoided where possible.

- Third line pharmaceutical treatments include: **oral NSAIDs (including COX-2 inhibitors), capsaicin, opioids and intra-articular corticosteroid injections.**
- Oral NSAIDs/Cox-2 inhibitors should be used at the lowest effective dose for the shortest period.
- When choosing an NSAID/COX-2 inhibitor, healthcare professionals should take into account individual patient risk factors. Oral NSAIDs/COX-2 inhibitors have analgesic effects of a similar magnitude but vary in their potential gastro-intestinal (GI), liver and cardio-renal toxicity.

PACEF Recommendations:
Oral NSAIDs and Cox-2 inhibitors are third line options that should only be used when absolutely necessary; the lowest effective dose for the shortest duration should be used. In terms of product selection, low dose ibuprofen (e.g. 1200mg per day) has the lowest GI risk of standard NSAIDs. Low dose ibuprofen and naproxen (1000mg per day) have a lower thrombotic risk than other NSAIDs and coxibs; epidemiological data does not suggest an increased risk of myocardial infarction (MI) with either agent. Diclofenac 150mg per day has a thrombotic risk similar to coxibs (i.e. 3 additional events per 1000 users per year). Coxibs have a reduced GI risk relative to most NSAIDs, but are associated with a small increased thrombotic risk similar to diclofenac. Coxibs are contra-indicated in cardiovascular disease. A meta analysis of case

controlled studies has also shown an increased thrombotic risk with meloxicam. In October 2006, the Committee on Human Medicines stated that: 'There is sufficient evidence to suggest that traditional NSAIDs may also have an increased risk of thrombotic events when used at high doses and for long-term treatment'.

Prescribers should consider low dose ibuprofen first line whenever an NSAID is indicated. Naproxen represents a suitable second line alternative, although GI risk is higher. Diclofenac is not an appropriate first line choice due to an increased thrombotic risk on a scale comparable to the risk of coxibs; particular caution should be exercised in those with cardiovascular disease. Similar concerns exist around meloxicam. Prescribing of NSAIDs of higher GI risk (e.g. piroxicam) should be kept to a minimum.

- If a person with OA needs low dose aspirin, consider other analgesics before NSAIDs or Cox-2 inhibitors.
- When offering treatment with an oral NSAID/Cox-2 inhibitor, the first choice should be either a standard NSAID or a COX-2 inhibitor (other than etoricoxib 60mg). In either case these should be **co-prescribed with a proton pump inhibitor** (PPI), choosing the one with the lowest acquisition cost (the NICE economic model uses omeprazole 20mg capsules; lansoprazole capsules would be equally low cost).

PACEF Recommendation:
Having scrutinized the NICE cost effectiveness analysis, PACEF recommend that all repeat and ongoing oral NSAID and Cox-2 inhibitor prescribing in people aged 55 and over should be supported with a concurrent PPI. Either generic lansoprazole capsules (recommended dose 15mg to 30mg daily) or generic omeprazole capsules (recommended dose 20mg daily) should be prescribed. Generic omeprazole capsules 20mg once daily currently represent the lowest cost option (£2.15 per month). These recommendations do not extend to acute or infrequent scripts.

- Topical capsaicin should be considered as an adjunct to core treatment for knee or hand OA.

PACEF Recommendation:
The licensed formulation is capsaicin 0.025% cream (Zacin) (45g, £15.04)

- Rubefacients are not recommended for the treatment of osteoarthritis.

PACEF Recommendation:
Topical rubefacient preparations such as Movelat cream/gel and Transvasin cream are no longer recommended. Low cost topical NSAID formulations are preferred. Topical rubefacients should no longer be initiated in new patients, but may be continued in those patients already deriving benefit.

- Intra-articular corticosteroid injections should be considered as an adjunct to core treatment for the relief of moderate to severe pain in people with OA. Intra-articular hyaluronan injections are not recommended.
- Referral for arthroscopic lavage and debridement is not recommended for osteoarthritis (OA), unless the person has knee OA with a history of mechanical locking.

- Other 'outer circle' treatment options include: self-management techniques (local heat and cold, assistive devices such as walking sticks and tap turners), surgery (joint arthroplasty) and other non-pharmaceutical treatments (transcutaneous electrical nerve stimulation (TENS), supports and braces, shock absorbing shoes or insoles, manual therapy [manipulation and stretching is particularly useful for OA of the hip]).
- Electro-acupuncture should not be used to treat people with OA.
- Referral for joint replacement surgery should be considered for people with OA who experience joint symptoms (pain, stiffness and reduced function) that have a substantial impact on their quality of life and are refractory to non-surgical treatment.
- The use of glucosamine or chondroitin products is not recommended for the treatment of OA. The evidence for glucosamine hydrochloride is poor. For glucosamine sulfate the evidence is not strong enough to justify prescribing on the NHS. Those who wish to purchase OTC glucosamine should be advised that it reduces pain in some people to a modest degree. If glucosamine is recommended it should be sulfate at a dose of 1500mg daily for a three month trial.

PACEF Recommendation:
Previously issued PACEF advice on glucosamine still stands with minor amendments:
The evidence base in support of glucosamine is relatively weak and often conflicted. Nonetheless, there is some evidence of benefit linked to the use of glucosamine sulfate 1500mg daily in the symptomatic relief of OA of the knee. Current evidence also suggests that glucosamine sulfate has a better safety profile than alternatives (e.g. NSAIDs), although long-term safety data is lacking. PACEF remain unconvinced that the potential benefits of glucosamine sulfate 1500mg daily can be extrapolated to glucosamine hydrochloride formulations such as Alateris; the premium price of the Alateris formulation in comparison to generic glucosamine sulfate and low cost branded formulations has also caused concern. As a result of this, glucosamine hydrochloride 625mg tablets (Alateris) are designated RED-RED. Prescribers wishing to utilize glucosamine sulphate should advise patients to purchase supplies either from their local health food store or community pharmacy. NICE have recommended that glucosamine should not be prescribed on the NHS. As a result of this all glucosamine formulations are designated RED-RED.

Further Reading

1. *PACE Bulletin*, Volume 1, Number 8 (December 2007)
2. National Prescribing Centre, 'Cardiovascular and gastrointestinal safety of NSAIDs', *MeReC Extra*, 30 (November 2007)

REDUCING PHARMACEUTICAL WASTE CAMPAIGN 2008

The increasing volume of items prescribed and dispensed across NHS primary care is continuing to drive the generation of ever increasing quantities of pharmaceutical waste. Periodically across Lincolnshire, we have run public information campaigns to raise awareness of the issue and to drive responsible repeat prescription ordering and safe disposal of unwanted medicines. For 2008, every Primary Care Trust in the East Midlands Strategic Health Authority area has agreed to participate in a single coordinated public information campaign extending across the whole geographical area**. From the week beginning Monday April 28th 2008, all community**

pharmacies, dispensing GP surgeries and non-dispensing practices have been asked to display posters and to distribute leaflets associated with the campaign. At the same time, coordinated media coverage will seek to raise the profile through TV and radio slots, newspaper coverage and strategically placed posters in Lincolnshire buses.

As a precursor to the campaign, a pharmaceutical waste audit was conducted in both a Lincolnshire dispensing practice and a community pharmacy over a two-week period. All medicines returned for disposal over this period were identified and recorded. The following key issues emerged as learning points from the two audits:

- The scale of pharmaceutical waste identified equated to approximately 4.4% of all items dispensed. Extrapolated up to the county as a whole this equates to approximately £6M of prescribed medication wasted per year and compares closely to previous estimates. For any practice wishing to raise the profile of this issue in the surgery by quoting facts and figures on a poster, it would be reasonable to claim that 4.4% of your annual expenditure on prescribed medicines is wasted every year.
- Most of the medicines returned were from four key *BNF* chapters: Gastro-intestinal System (GI), Cardiovascular System (CVS), Central Nervous System (CNS) and Endocrine System.
- Almost half of the GI drugs returned were antisecretory agents, predominantly proton pump inhibitors (PPIs). These drugs are commonly prescribed in regular once daily doses, but are often taken by patients as necessary. As a result of this, it can be relatively easy for a patient to build up a stock-pile. Failure to comply with once daily therapy, particularly within the context of concurrent NSAID or Cox-2 inhibitor therapy might give cause for concern.
- The bulk of the cardiovascular drugs returned were preventative treatments for asymptomatic conditions, such as antihypertensives, lipid regulating drugs and antiplatelet agents. Poor understanding of the importance of preventative therapy can result in poor compliance and increased cardiovascular risk for the individual.
- Most of the returned CNS medicines were analgesics. It is relatively common for a patient to be unable to tolerate or be insufficiently responsive to an initial analgesic and to require an alternative. Where this occurs, the initial supply will need to be disposed of. Another significant component of CNS waste was antidepressant drugs. For both analgesics and antidepressants, prescribers should be aware of the risk of intolerance or inadequate response and try to avoid giving large quantities on the first prescription.
- Drugs used in the treatment of diabetes were the major contributor to endocrine system returns. Poor compliance with anti-diabetic drugs is well documented and could be a significant contributor to poor diabetic control.
- Other items in significant volume identified in the bins included antibiotics (patients often fail to complete the course and return the balance), blood glucose monitoring strips (often over-used and over-ordered by patients), eye preparations (patients can have difficulty opening and using eye drop bottles) and calcium and vitamin D supplements (another preventative treatment where compliance may be an issue, particularly in those who find their formulation unpalatable).
- Only 12.6% of the items returned were out-of-date suggesting that the bulk of medication is disposed of for other reasons. These include: poor tolerability or efficacy, poorly coordinated or excessive repeat prescription ordering, deliberate over-ordering and stock-piling, continued repeat ordering despite

poor compliance, dosage change or change in medication and death of the patient.

Some or all of this information may be useful in practices or community pharmacies wishing to raise the profile of the campaign above and beyond the basic messages included in the standard leaflets. We intend to repeat both audits after the completion of the campaign and will feedback on any additional findings through the *PACE Bulletin.* We are also intending to repeat the campaign in 2009 to maintain the current profile.

Many thanks to Tabitha Crouch, Prescribing Technician, who undertook these audits and contributed to the compilation of this feature.

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