NHS Lincolnshire

Prescribing and Clinical Effectiveness Bulletin

Volume 4; Number 3 **March 2010**

What's new this month:

- **Liraglutide injection (Victoza) has been approved for use in type 2 diabetes mellitus. It should only be used as an alternative to exenatide where exenatide is either not tolerated or inappropriate (see page 2).**
- **Fentanyl nasal spray (Instanyl) has not been approved (see page 4).**
- **Beclometasone CFC containing metered dose inhalers are likely to be unavailable from July 2010. Any remaining patients should be switched to CFC free equivalents (see page 5)**
- **Tacrolimus formulations should be prescribed by brand (see page 7).**
- **Arrangements for prescribing and dispensing of medicines for patients in care homes should be reviewed (see page 8).**
- **Arrangements for cold storage of vaccines should be reviewed (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. Back issues of the *PACE Bulletin* and other PACEF publications are available through the NHS Lincolnshire website (www.lpct.nhs.uk). Click on 'Commissioning' and follow the links to PACEF.

SUMMARY OF PACEF DECISIONS: FEBRUARY 2010 UPDATE

Drug	Indication(s)	Traffic Light Status
Exenatide 5microgram and 10microgram injection (Byetta) * Reminder*	Licensed for use with metformin and/or sulfonylureas in type 2 diabetes in patients inadequately controlled on maximally tolerated doses of these oral therapies	GREEN. N.B. **Treatment should primarily be initiated by a diabetologist or a GP with a Special Interest in diabetes (GPSI), although the GREEN status allows for broader GP initiation.** Exenatide initiation should only be considered at Step Three within the context of the NICE initiation criteria as detailed in the text.

Fentanyl nasal spray (Instanyl)	Licensed for the management of breakthrough pain in adults already receiving maintenance opioid therapy for chronic cancer pain.	RED-RED
Liraglutide injection (Victoza)	Licensed for the treatment of adults with type 2 diabetes mellitus in combination with**:** (1) Metformin or a sulfonylurea in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or a sulfonylurea. (2) Metformin and a sulfonylurea or metformin and a thiazolinedione (glitazone) in patients with insufficient glycaemic control despite dual therapy.	GREEN. N.B. **Treatment should primarily be initiated by a diabetologist or a GP with a Special Interest in diabetes (GPSI), although the GREEN status allows for broader GP initiation.** Liraglutide initiation should only be considered at Step Three within the context of the NICE initiation criteria as detailed in the text. It should only be used as an alternative to exenatide where exenatide is either not tolerated or inappropriate.
Tacrolimus capsules (Prograf)	Licensed for the prophylaxis of transplant rejection in liver, kidney, and heart allograft recipients and the treatment of allograft rejection resistant to other immuno-suppressants	AMBER Consultant initiation and appropriate shared care arrangements are required.
Tacrolimus modified release capsules (Advagraf)	Licensed for the prophylaxis of transplant rejection in liver, kidney, and heart allograft recipients and the treatment of allograft rejection resistant to other immuno-suppressants	AMBER Consultant initiation and appropriate shared care arrangements are required.
Tacrolimus granules for oral suspension (Modigraf)	Licensed for the prophylaxis of transplant rejection in liver, kidney, and heart allograft recipients and the treatment of allograft rejection resistant to other immunosuppressants	AMBER Consultant initiation and appropriate shared care arrangements are required. Unlicensed tacrolimus liquid 'specials' should be reviewed and changed to Modigraf wherever possible.

RED-RED: This signifies that a product is **not recommended** for prescribing in **either** primary or 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 secondary care, tertiary care or a primary care hosted specialist service only and **should not be routinely prescribed in primary care**. RED drugs may be used within ULHT or LPFT subject to approval for use within each Trust. ULHT and LPFT reserve the right to determine whether or not RED drugs will be used within their Trusts. RED classification does not automatically signify that a drug will be available within secondary/tertiary 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; PACEF are working to rectify this.
GREEN: This signifies a product that is **approved for initiation in either primary or secondary care within licensed indications**. 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 ASSESSMENT: LIRAGLUTIDE INJECTION (VICTOZA)

Liraglutide (Victoza) is the second glucagon like peptide 1 (GLP-1) mimetic to receive a UK product license; the first was exenatide (Byetta). It is licensed for the treatment of adults with type 2 diabetes mellitus in combination with**:**

- Metformin or a sulfonylurea in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or a sulphonylurea.
- Metformin and a sulfonylurea or metformin and a thiazolinedione (glitazone) in patients with insufficient glycaemic control despite dual therapy.

Liraglutide is administered as a once daily subcutaneous injection into the abdomen, thigh or upper arm. It is formulated as a pre-filled pen. The starting dose is 0.6mg daily increased to 1.2mg daily after at least one week on the lower dose; the dose can be increased further to 1.8mg daily.

The main evidence supporting the use of liraglutide comes from a series of randomised clinical trials and open label studies known collectively as the Liraglutide Effect and Action in Diabetes Trials (LEAD). The primary outcome from all these trials and studies was the change in HbA1c levels from baseline; the percentage of patients achieving the American Diabetic Association target of an HbA1c of less than 7.0% was also recorded. The LEAD trials compare glycaemic control with liraglutide (prescribed either as monotherapy or in combination with other oral anti diabetic drugs) against oral anti-diabetic drugs, insulin glargine or exenatide. Results from these trials showed that, on average, 35 to 58% of patients achieved HbA1c levels of less than 7% with an average reduction in HbA1c level of between 1 and 1.5. The primary outcome of all the LEAD studies is a disease oriented outcome; there are no studies evaluating the effect of liraglutide on patient orientated outcomes such as reduction in cardiovascular events, improvement in quality of life or reduction in mortality. As noted in previous *PACE Bulletins*, there is a similar lack of outcomes data with exenatide and all of the new DPP-4 inhibitors (or gliptins).

Liraglutide appears to be slightly better tolerated than exenatide with a lower incidence of nausea and a lower risk of hypoglycaemia. As reported previously in the *PACE Bulletin*, exenatide has been associated with an increased incidence of pancreatitis; initial data for liraglutide suggests that this is much less of a problem with the newer agent. However, it is important to note that the incidence of pancreatitis is three times higher in type 2 diabetics than in the general population and a direct link between exenatide and pancreatitis remains to be established.

Liraglutide has been associated with thyroid adverse events including increased calcitonin levels (1%), goitre (0.8%) and thyroid neoplasms (0.8%). The manufacturer currently advises caution if liraglutide is used in patients with pre-existing thyroid disease. There has been some speculation of a link between liraglutide and thyroid cancer following reports from animal studies which showed an increased incidence of thyroid C cell tumours. Advice from the European Medicines Agency (EMEA) has concluded that there is not sufficient data to confirm a link between liraglutide and malignant neoplasm. Clinical data reported at a European diabetic conference in September 2009 showed that from 4,600 case studies of people receiving treatment with liraglutide there was no significant evidence of a link with thyroid cancer. In January 2010 the American Food and Drug Administration approved the use of liraglutide for the treatment of type 2 diabetes in adults. This approval was conditional on the manufacturer (Novo Nordisk) conducting further post marketing studies evaluating the cardiovascular safety of liraglutide in a high risk population and a five year epidemiological study evaluating thyroid and other cancer risks as well as risks from hypoglycaemia, pancreatitis and allergic reactions.

Liraglutide is more expensive than exenatide as illustrated in the cost comparison below:

Drug	Daily dose range	Cost per pack	Daily cost	Annual cost
Liraglutide 6mg/ml	1.2mg – 1.8mg daily	2x3ml £78.48 3x3ml £117.72	1.2mg - £2.61 £1.8mg - £3.92	1.2mg £950 1.8mg £1,427
Exenatide 5mcg	5mcg twice daily	60 dose pen £68.24	5mcg - £2.27	£826
Exenatide 10mcg	10mcg twice daily	60 dose pen £68.24	10mcg £2.27	£826

PACEF Recommendation

PACEF are convinced by the clinical effectiveness data emerging from the LEAD studies, but remain concerned about the long term safety of liraglutide and the high cost in comparison to exenatide (the 1.8mg dose is nearly double the price of exenatide). After careful consideration of the clinical data, further data provided by Novo Nordisk and the work undertaken by the FDA we have designated liraglutide as GREEN subject to the following criteria:

Liraglutide should primarily be initiated by a diabetologist or a GP with a Special Interest in diabetes (GPSI), although the GREEN status allows for broader GP initiation. NICE Clinical Guideline 87: *Type 2 diabetes – the management of type 2 diabetes* (May 2009) defines a third line role for GLP-1 mimetics as follows:

Consider adding a GLP-1 mimetic as third line therapy to first line metformin and a second line sulfonylurea when control of blood glucose remains or becomes inadequate (HbA1c > 7.5% or other higher level agreed with the individual) and the person has: (1) a BMI >35kg/m^2 in those of European descent (with appropriate adjustment for other ethnic groups) and specific psychological, biochemical or physical problems arising from high body weight or: (2) a BMI < 35kg/m^2 and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related co-morbidities. Only continue GLP-1 mimetic therapy if the person has had a beneficial metabolic response (a reduction of at least 1.0 percentage point in HbA_{1c} and a weight loss of at least 3% of initial body weight at 6 months).

Within this context, exenatide should remain the GLP-1 mimetic of choice. It is estimated that 10 to 12% of patients will be unable to tolerate exenatide; such patients may be appropriate for liraglutide as an alternative. To improve the gastro-intestinal tolerability of liraglutide, treatment should commence on 0.6mg daily. After at least one week, the dose should be increased to 1.2mg. Some patients may benefit from a further increase in dose to 1.8mg after at least one further week. Prescribers should be mindful of the exceptionally high cost of the 1.8mg dose of liraglutide in comparison to lower doses of liraglutide and the cost of exenatide.

RAPID DRUG ASSESSMENT: FENTANYL NASAL SPRAY (INSTANYL)

Fentanyl nasal spray (Instanyl) is licensed for the management of breakthrough pain (BTP) in adults already receiving maintenance opioid therapy for chronic cancer pain. It is available in three strengths, 50mcg, 100mcg and 200mcg per dose. Intranasal fentanyl, as with the other short-acting fentanyl preparations, may be used for up to four BTP episodes per day; a period of four hours should elapse before treating a subsequent episode.

The clinical evidence supporting the use of fentanyl nasal spray is sparse and amounts to two randomised controlled trials (RCTs) only one of which is comparative This open-label study compares fentanyl nasal spray with fentanyl lozenge and reports that significantly more patients experienced faster pain relief with intranasal fentanyl compared to the fentanyl lozenge. The overall median time to onset of pain relief was 10.6 minutes for intranasal fentanyl compared to 15.7minutes for fentanyl lozenge. There is no trial data comparing buccal or sublingual tablets of fentanyl or other opiates with intranasal fentanyl.

The EMEA have noted that the safety profile for intranasal fentanyl does not seem to differ from the safety profile of other fentanyl containing products indicated in the treatment of BTP. A cost comparison of the treatments currently available reveals the following:

Drug	Strength	Cost (£) per dose
Fentanyl nasal (Instanyl)	All strengths	£5.95 per dose
Fentanyl buccal (Effentora)	All strengths	£5.14 per dose
Fentanyl sublingual (Abstral)	All strengths	£4.99 per dose
Fentanyl lozenge (Atiq)	All strengths	£6.19 per dose
Morphine tablets (Sevredol)	10mg	£0.10 per dose
Morphine tablet (Sevredol)	20mg	£0.20 per dose

Morphine solution	10mg/5ml	£0.09 per 5ml (10mg) dose
Morphine solution	20mg/ml	£0.17 per 20mg dose.
Oxycodone (OxyNorm) capsules	5mg	£0.21 per dose
Oxycodone (OxyNorm) capsules	10mg	£0.41 per dose
Oxycodone (OxyNorm) capsules	20mg	£0.83 per dose

PACEF Recommendation
The trial evidence supporting the use of fentanyl nasal spray (Instanyl) is weak and inadequate; in particular the paucity of comparative data is a concern. PACEF propose to undertake a wider review of fentanyl formulations later in the year as a number of new products are scheduled for UK launch in 2010. In the meantime, fentanyl nasal spray (Instanyl) is designated RED-RED.

FINAL WITHDRAWAL OF CFC CONTAINING BECLOMETASONE METERED DOSE INHALERS

Following Teva's discontinuation of the Beclazone metered dose inhaler (MDI), Neolab became the sole supplier of CFC containing beclometasone (BDP) MDIs to the UK marketplace. Neolab have now announced their decision to discontinue supply of BDP CFC-containing inhalers. Based on current usage, stocks will be exhausted by July 2010.

PACEF Recommendation
All remaining patients prescribed BDP CFC-containing MDIs should be identified and switched to a CFC-free equivalent. Clenil Modulite BDP CFC-free MDIs are recommended as the first choice alternative. Patients should be transferred over on the same strength and at the same dose; they should be encouraged to use their Clenil Modulite inhaler with a spacing-device (ideally a Volumatic) to maximise lung deposition and to minimise the potential for unwanted oropharyngeal effects. Clenil Modulite inhalers should be prescribed by brand to avoid confusion with Qvar inhalers. Qvar should also be prescribed by brand, but at half the dose relative to conventional beclometasone CFC-containing inhalers. A cost comparison is printed below for information. Prescribers are reminded that other inhaled steroids (budesonide, fluticasone, mometasone, ciclesonide) are not recommended for routine prescribing.

Cost comparison: Selected beclometasone inhalers

	Beclometasone CFC-containing inhalers (200 dose)	**Clenil Modulite (CFC-free) inhalers (200 dose)**	**Qvar (CFC-free) inhalers (200 dose)**	**Easyhaler beclometasone (Breath-operated dry powder inhaler) (200 dose)**
50mcg	£4.06	£3.70	£7.87*	
100mcg	£6.85	£7.42	£17.21**	
200mcg	£16.58	£16.17		£14.93
250mcg	£14.45	£16.29		

* Equivalent to 100mcg conventional BDP CFC-containing
** Equivalent to 200mcg conventional BDP CFC-containing

NEW TRIALS IN BRIEF

IMPROVING STATINS ADHERENCE: A SIMULATION

Using data from an Australian cohort study of 41,000 people, the estimated population benefits of three cardiovascular (CV) primary prevention scenarios were simulated:

1. Statin treatment at the current NICE primary prevention treatment threshold (≥20% 10 yr CVD risk) and assuming 50% adherence to the statin prescribed.
2. As above but with adherence increased to 75%.
3. Reduce the primary prevention treatment threshold calculated to treat as many people as scenario 2 (about >15.5% 10 yr CVD risk).

In scenario 1, 9,279 patients were treated with174 CV onsets and 70 CV deaths averted. Both alternative scenarios improved CV outcomes. In scenario 3, 6991 patients were 'adherent' resulting in an additional 70 CV onsets and 18 CV deaths being averted. In the improved adherence scenario (2), an additional 91 CV onsets and 37 CV deaths were averted, compared to scenario 1.

PACEF Comment
Whilst it might logically be expected that scenario 2 would prevent more CV events and deaths than scenario 3 because higher risk people are treated , this study demonstrates the possible impact of the benefits of improving adherence to statins, particularly in relation to preventing deaths.

Reference:
Shroufi A, Powles JW. Adherence and chemoprevention in major cardiovascular disease: a simulation study of the benefits of additional use of statins. *J Epidemiol Community Health* 2010; 64: 109 - 113

SURVIVAL AS A FUNCTION OF HBA1C IN PEOPLE WITH TYPE 2 DIABETES MELLITUS

Two cohorts of patients with type 2 diabetes mellitus aged 50 and older were identified from the UK General Practice Research database (November 1986 to November 2008). Cohort one consisted of almost 28,000 patients whose treatment had been intensified from oral monotherapy to combination therapy with oral blood-glucose lowering agents. Cohort two consisted of 20,000 patients whose treatment had been intensified to include insulin. The primary outcome was all-cause mortality. In both cohorts a mean HbA1c of about 7.5% was associated with the lowest mortality. Risk of death rose significantly on both sides of this, reaching a hazard ratio of 1.52 (1.32 – 1.76) for people in the lowest 10th of HbA1c values (median HbA1c 6.4%) and 1.79 (1.56 – 2.06) for patients in the top 10th (median HbA1c 10.5%). The U shaped association was particularly strong for patients using insulin.

PACEF Comment:
This study appears to show a U shaped mortality curve for HbA1c in patients over 50 with diabetes mellitus. As this is observational data, it would be inappropriate to draw hasty conclusions. However, this study contributes to a growing debate around the potential risks of intensive blood glucose management, particularly in well established type 2 diabetics.

Reference:
Currie CJ et al. Survival as a function of HbA1c in people with type 2 diabetes: a retrospective cohort study. *The Lancet*, early online publication, doi:10.1016/S0140-6736(09)61969-3.

MOTOR VEHICLE CRASHES IN DIABETIC PATIENTS WITH TIGHT BLOOD GLUCOSE CONTROL

This case-control study suggests that diabetics who have tight glycaemic control may be at higher risk of car accidents. Using data on drivers with diabetes obtained from Canadian licensing authorities over a 2 year period the authors found 795 diabetics with a documented HbA1c level; 81% were on insulin. Of the 795 diabetics identified, 57 had been involved in a car accident; mean HbA1c levels were significantly lower in those who had been involved in a crash compared to those who hadn't (HbA1c 7.4% vs. 7.9%)

PACEF Comment:
Under Canadian law, doctors are only required to submit data to the Canadian licensing authority relating to those with uncontrolled diabetes; well controlled diabetic drivers are unlikely to report to the licensing authorities unless they have a car accident. As a result of this, PACEF took the view that the data on which this study was based was seriously flawed and the conclusions were insufficiently robust to influence practice.

Reference:
Redelmeier DA et al. Motor vehicle crashes in diabetic patients with tight glycemic control; a population-based case control analysis. PLoS Med 2009; 6(12):e1000192

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY: *DRUG SAFETY UPDATE* (FEBRUARY 2010)

TACROLIMUS GRANULES FOR ORAL SUSPENSION (MODIGRAF): FORMULATIONS ARE NOT INTERCHANGEABLE WITHOUT CAREFUL THERAPEUTIC MONITORING

Tacrolimus is now available as Prograf capsules, Advagraf prolonged release capsules and a new granule formulation (Modigraf) that can be used to prepare an oral liquid for twice daily dosage. Previous advice from the MHRA issued in December 2008 has emphasized that Prograf and Advagraf are not interchangeable preparations and that switching between the two is not recommended. Modigraf is potentially useful for those who are unable to swallow capsules (e.g. paediatric patients); the liquid formulation also allows flexible dosing based on bodyweight; Modigraf granules have approximately 18% increased bioavailability compared to Prograf capsules. Where switching between preparations is unavoidable, follow the manufacturer's advice on converting patients from Prograf to Modigraf given in the product information. Monitor patients carefully when switching between formulations of tacrolimus (including unlicensed tacrolimus formulations) and Modigraf. The transfer of patients from any unlicensed treatment to Modigraf should be closely supervised by a transplant specialist.

When prescribing or dispensing tacrolimus preparations care should be taken to ensure that the patient receives the correct preparation; tacrolimus preparations should be prescribed by brand to avoid any potential confusion. Now that Modigraf is available, existing patients on unlicensed tacrolimus 'specials' need to be reviewed as the use of unlicensed or licensed off-label medicines is only justified where a licensed alternative would not meet the patients needs.

PACEF Recommendation:
Prescribers should ensure that all prescribing of tacrolimus preparations is by brand name to avoid confusion. Pharmacists should be clear on the brand to be supplied against all prescriptions for tacrolimus. All existing patients on unlicensed tacrolimus 'specials' should be reviewed and, where possible, transferred to tacrolimus granules (Modigraf). The transfer of patients from any unlicensed treatment to Modigraf should be closely supervised by a transplant specialist. Tacrolimus capsules (Prograf), modified release capsules (Advagraf) and granules (Modigraf) are all designated AMBER requiring specialist initiation and appropriate shared care arrangements.

ORLISTAT (ALLI) SAFETY UPDATE

Pharmacists currently selling over-the-counter orlistat (alli) should be aware of the following safety information:

- Patients with kidney disease should consult a doctor before starting alli; use of orlistat can rarely lead to hyperoxaluria and oxalate nephropathy.
- Patients taking levothyroxine should consult a doctor before starting alli; reduced control of hypothyroidism may occur when alli and levothyroxine are taken at the same time.
- Patients taking an antiepileptic drug should consult a doctor before starting alli; loss of seizure control has been reported during concomitant treatment with orlistat and antiepileptic drugs such as sodium valproate and lamotrigine.

- alli has recently been linked to reports of pancreatitis in a number of patients.
- Hepatitis, cholelithiasis and increased transaminases and alkaline phosphatise are all possible side effects of alli. Patients that experience yellowing of the skin and eyes, itching, stomach pain and liver tenderness should stop taking the capsules and seek medical advice.

DEPARTMENT OF HEALTH ALERT: *THE USE OF MEDICINES IN CARE HOMES FOR OLDER PEOPLE* (JANUARY 2010)

Older people living in care homes are at greater risk of medication error than most other groups. Complicating factors include: complex multi-component drug regimes, high susceptibility to adverse events, cognitive impairment in some and complex medicines management systems in care homes often involving multiple prescribers and pharmaceutical service providers.

The Care Homes Use of Medicines (CHUM) Study

The CHUM Study examined medication, prescribing, dispensing, administration and monitoring across 55 care homes in three areas of England (West Yorkshire, Cambridgeshire and central London). It was designed to determine the prevalence of all forms of medication errors in care homes, to assess the potential for these errors to cause harm and to establish underlying causes. Data collected included interviews with home staff, GPs and pharmacists, clinical medication reviews undertaken on randomly selected residents, comparison of prescriptions and medicines administration records (MARs) with dispensed medicines, type of monitored dosage system (MDS) used (where relevant). For each of the randomly selected residents, two drug rounds were observed. For each error identified, the potential harm was assessed using a validated 10 point scale with 0 signifying not harmful and 10 signifying death.

256 residents were recruited from 55 care homes. The majority of the residents were women (69%) and very old (mean age 85). The majority of the residents (86%) were receiving at least some of their medicines in a MDS. Overall, 178 of the 256 residents had at least one medication error (either prescribing, monitoring, administration or dispensing). Examples of some of the errors detected were as follows:

- Donepezil continued despite a letter from a hospital specialist asking for it to be stopped. Mean harm score 1.8.
- Lisinopril prescribed for a patient with high potassium level. Mean harm score 5.8.
- Amiodarone ineffectively monitored. Mean harm score 5.8.
- Continued administration of bendroflumethiazide despite discontinuation by the doctor due to low serum sodium. Mean harm score 4.6.
- Aspirin EC dispensed instead of zopiclone in a MDS. Mean harm score 5.0.

For each prescribing, dispensing or administration event, there was an 8-10% chance of an error occurring, and for monitoring a 15% chance. This is as high, or worse, than for people living in their own homes or hospital.

The main findings of the study were:

- Two thirds of care home residents (69.5%) in this study were exposed to one or more medication errors.
- The prevalence of prescribing errors was similar to that found in primary care (8.3%); the prevalence of administration errors was a little higher than in hospital (8.4%); the prevalence of dispensing errors (9.8%) was three times higher than the rate found in primary care. The higher rate of dispensing errors is likely to be linked to the difficulties associated with dispensing MDSs.
- Residents (mean age 85 years) were taking an average of 7.2 medicines each (range 1 to 22).
- On any one day, 70% of patients experienced at least one medication error.

- The mean score for potential harm was relatively low, although the potential for serious harm was significant.

PACEF Comment:
All primary medical care contractors and providers of pharmaceutical services should already have received a copy of this alert. Prescribers and community pharmacists should review current service provision to ensure that: (1) arrangements are in place to effectively monitor those drugs requiring ongoing monitoring (e.g. levothyroxine, amiodarone); (2) medicines administration record (MAR) charts in care homes accurately reflect the patient's current repeat medication. Community pharmacists visiting homes can provide an invaluable service by attempting a reconciliation exercise between the patient's prescribed medicines and the MAR chart; (3) dispensing arrangements around the provision of Monitored Dosage Systems are reviewed to ensure that lessons learned from errors are implemented and that the risks around MDS provision are minimised; (4) actions identified during a visit to a care home are effectively implemented on return to the practice or pharmacy.

References
Barber N. D. et al., 'Care Homes Use of Medicines Study: prevalence, causes and potential harm of medication errors in care homes for older people', *Qual Saf Health Care* 2009; 18: 341-346 doi: 10.1136/qshc.2009.034231
Barber N. D. et al., *Care Home Use of Medicines Study (CHUMS): Medication errors in nursing and residential care homes – prevalence, consequences, causes and solutions*, Report to the Patient Safety Research Portfolio, Dept of Health
The use of medicines in care homes for older people, DH Alert (2010)001 (6th January 2010)

NATIONAL PATIENT SAFETY AGENCY RAPID RESPONSE REPORT: *VACCINE COLD STORAGE* (FEBRUARY 2010)

Between January 2005 and April 2009, the NPSA received 260 reports of incidents related to vaccination cold storage from a range of NHS organisations. Among the incidents related were: delays in storage of vaccines after delivery, storage at the wrong temperature, fridge failure or a fridge being inadvertently switched off, failure to monitor fridge temperature, inadequate equipment and inappropriate use of domestic fridges. Vaccines must be stored between 2 and 8^0C; failure to store vaccines correctly can reduce vaccine effectiveness and cause vaccination failures.

PACEF Comment:
All departments and providers (including independent contractors) holding vaccine stocks must ensure that the cold chain in maintained, that stock is stored between 2 and 8^0C according to manufacturers instructions and that regular monitoring and recording of fridge temperature takes place. A designated person and deputy responsible for receipt and storage of vaccines should be identified for each site. Where a vaccine is inadvertently stored outside of the recommended temperature range urgent advice should be sought to establish the viability of the vaccine.

Reference
National Patient Safety Agency Rapid Response Report 2010/RRR008, *Vaccine cold storage* (January 2010)

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