



- **Safety review of tiotropium**

In 2008 concerns were raised by the US Food and Drug Administration (FDA) about a potential increase in the risk of stroke, heart attack, or death from a cardiovascular cause related to the use of tiotropium. The FDA has now completed its review and believes the available data do not support an association between the use of tiotropium and an increased risk for these serious adverse events.

The March 2008 Early Communication from the FDA described data submitted by the manufacturer that suggested there may be a small excess risk of stroke in patients using tiotropium compared to placebo (2 cases of stroke per 1000 treated patients). The Updated Early Communication from October 2008 reported two additional publications that suggested an increased risk of death, heart attack or stroke in patients using tiotropium or drugs that work similarly to tiotropium.

Since these initial communications, FDA has completed its analysis of the *Understanding the Potential Long-Term Impacts on Function with Tiotropium* (UPLIFT) trial. UPLIFT was a large, 4-year clinical trial that compared tiotropium to placebo in 5,992 patients with COPD.

In the UPLIFT trial, there was no significant increase in the risk of stroke [0.95 (95% CI 0.70, 1.29)], heart attack [0.73 (95% CI 0.53, 1.00)], or cardiovascular death [0.73 (95% CI 0.56, 0.96)] between tiotropium and placebo.

In November 2009, the FDA Pulmonary - Allergy Drugs Advisory Committee also reviewed data from the UPLIFT trial and voted that the UPLIFT findings adequately resolve the potential safety concerns for stroke, heart attack and cardiovascular death.

- **Improving statin adherence saves more deaths than lowering treatment threshold**

A simulation study using trial data (J Epidemiol Community Health 2010; 64: 109-13) suggests that improving adherence to statins among those currently considered eligible for treatment would prevent more cardiovascular deaths than lowering the present treatment threshold.

Effectiveness of statins in practice is lower than that in trials because at least half those people started on the drugs will have stopped taking them within five years. While discussions on improving outcomes have mostly been related to lowering treatment thresholds, thus increasing the number of people receiving the drugs, it is possible that similar benefits could be gained by improving adherence in those already eligible for them. The aim of this simulation study was to investigate the potential effects of the two strategies.

Details of how the study was undertaken can be found at <http://tinyurl.com/yavee2p>

The authors conclude that according to their model, twice as many CVD deaths would be prevented by improving adherence in patients currently eligible for statin treatment as would be prevented by lowering the treatment threshold to produce a similar number of people taking the drugs. Improving adherence in those at higher risk gives greater benefits than extending prevention to those at lower risk, and more work is therefore needed on ways to improve long-term adherence.

- **Who should authorise practice nurses to practice under a PGD in a GP practice?**

The NeLM PGD website has been up-dated to answer this frequently asked question. The GP practice as the commissioned provider and the practice nurse employer must ensure that only suitably qualified and fully competent healthcare professionals, employed by the practice, work under the PCT approved PGDs. The responsibility to authorise practice nurses to practice under a PGD can be delegated in line with management and governance responsibilities. For further details on this issue and other "frequently asked questions"

see <http://www.portal.nelm.nhs.uk/PGD/viewRecord.aspx?recordID=961&referer=http://www.portal.nelm.nhs.uk/PGD/pgdfaq.aspx>

- **Dosulepin – NICE guidance**

NICE CG 90 Depression in Adults (October 2009) advises that dosulepin should no longer be prescribed due to its potential for cardiac side-effects.

In the last 12 months prescribers in NHS Northamptonshire issued 20,525 prescriptions for dosulepin. Whilst it is appreciated that it may be difficult to stop dosulepin for many patients, we would advise that reviews of treatment are undertaken wherever possible.

- **NHS prescribing of anti-malarial tablets**

Can we remind prescribers that anti-malarials should not be prescribed at NHS expense. In the last 12 months 47 of our practices have prescribed a total of 89 prescriptions for anti-malarials at a cost of just over £3,000. These prescriptions should be issued privately.

This edition is also available on HNN (Health Network Northants)

<http://www.northants.nhs.uk/Display/Dynamic.jsp?topicid=14070&lhsid=514&oid=2854&currentid=2854>

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