Lothian guidance on vitamin D

Guidance developed by a multiprofessional group was approved at the NHS Lothian Difficult Decisions Forum (DDF) in May 2012. The DDF is co-chaired by the Medical Director and the Director of Pharmacy, and was set up in 2011 to lead difficult discussions and provide recommendations on competing priorities in NHS Lothian.

Some of the UK population may be at risk of vitamin D deficiency. Up to a quarter of people in the UK have low levels of vitamin D in their blood, which means they are at risk of the clinical consequences of vitamin D deficiency. Low vitamin D levels have been linked to adverse outcomes including rickets and, potentially, multiple sclerosis. Advocates of high dose vitamin D supplementation use this association to support their claims both for more widespread treatment and the use of higher doses. However, although the association with rickets is clear, a causal link has not been established between vitamin D levels in the general population and these conditions.

Prevention

Pregnant and breastfeeding women / Infants and young children aged 6 months to 5 years

- The Healthy Start vitamins (folic acid, vitamins C and D for pregnant women, vitamin A, C and D for children) are the appropriate and recommended preparations for preventive purposes for pregnant women and young children

- Families who are not in receipt of Healthy Start vouchers can purchase other suitable vitamin preparations (such as Abidec® drops for infants and children up to 12 years old) over-the-counter from their local community pharmacy.

People aged 65 years and over and people who are not exposed to much sun

- Patients aged 65 years and over can take existing calcium and vitamin D supplements – please refer to the Lothian Joint Formulary section 9.6 www.ljf.scot.nhs.uk

- Calcichew-D³® Forte is a combination product containing 500mg calcium and 400 units (10 micrograms) colecalciferol, which provides vitamin D at the recommended dose; it can be prescribed on a preventive basis, following assessment of risk factors, such as dietary deficiency, limited sunlight exposure and risk of osteoporosis

- Calcichew-D³® Forte is in wide use already with a well established safety profile and efficacy; this and equivalent products are widely prescribed and can also be purchased in pharmacies (approximately £4 per month).

Treatment

Widespread high dose treatment is not discussed in the joint CMO letter, and is not supported in NHS Lothian. This is because an application for widespread use has not been submitted to, or assessed by, the Lothian Formulary Committee. Recommendations on the use of pure vitamin D preparations (for treatment) are influenced by decisions at a national level (outcome of SMC review of new pure vitamin D product) and local level FAF3 applications for high dose supplements are underway for paediatrics and adults.

Pure vitamin D in an unlicensed form is available for some indications (e.g. treatment of rickets in young children), rheumatology patients and HIV patients.

A vitamin D preparation (colecalciferol, Fultium-D³®) for the treatment of vitamin D insufficiency and deficiency in adults and elderly patients has been submitted to the Scottish Medicines Consortium (SMC) for consideration, with a recommendation expected in September 2012.
Background to the Lothian guidance

UK Health Departments recommendations
The UK Chief Medical Officers wrote to health professionals in February 2012 to raise awareness of the risk of vitamin D deficiency in some of the UK population, in particular the concern for at-risk groups such as pregnant women and infants and young children. All UK Health Departments recommend that all pregnant and breastfeeding women should take a daily supplement containing 10 micrograms (400 units) of vitamin D, and that all infants and young children aged 6 months to 5 years should take a daily supplement containing vitamin D in the form of vitamin drops, to help them meet the requirement set for this age group of 7-8.5 micrograms of vitamin D per day. Infants who are fed infant formula will not need vitamin drops until they are receiving less than 500mL of infant formula a day, as these products are fortified with vitamin D. Breastfed infants may need to receive drops containing vitamin D from one month of age if their mother has not taken vitamin D supplements throughout pregnancy.

All UK Health Departments recommend that people aged 65 years and over and people who are not exposed to much sun should also take a daily supplement containing 10 micrograms (400 units) of vitamin D.

Healthy Start is a benefits-related public health initiative which entitles pregnant women and families with children aged up to four years who are receiving Healthy Start vouchers to free Healthy Start vitamins. NHS Boards should not be expected to cover these costs for families that are not in receipt of benefits.

There are obstacles to the distribution of Healthy Start vitamins. Current arrangements in Lothian provide patchy coverage as they rely on contact with maternity and child health professionals.

The Lothian Difficult Decisions Forum has agreed in May 2012 that a definitive decision about distribution of Healthy Start vitamins in Lothian should be deferred until the Scottish Government has completed its current round of negotiations for a national approach to distribution of Healthy Start vitamins through community pharmacies. If these negotiations fail to reach a solution then alternative arrangements in NHS Lothian will be sought.

Key evidence
An expert committee of the US Institute of Medicine advised against basing decisions on the supplementation dose on the current thresholds used to identify vitamin D deficiency, noting that randomised control trials have yet to demonstrate a dose response, e.g. for colorectal cancer and other outcomes studied. This observation places the local discussions about high dose vitamin D supplementation into context. Much of that debate has been informed by studies reporting on vitamin D levels in Scotland that are below these putative thresholds.

There are a few high quality intervention studies that have looked at the impact of vitamin D supplementation on health outcomes (e.g. growth in infancy, mortality in older people) rather than relying simply on biochemical determination of vitamin D levels.

The NICE guideline on routine care of pregnant women extrapolates findings of an intervention study with South Asian women and their children to other vulnerable pregnant women, predicting an impact on reducing the prevalence of rickets.

A recent Cochrane systematic review and meta-analysis explored the impact of vitamin D supplementation for prevention of mortality in adults, identifying a six percent reduction in mortality, predominantly in elderly women mainly in institutions and dependent care (Relative Risk 0.94, 95% CI 0.91 to 0.98, I² = 0%; 74,789 participants, 32 trials). The dose varied substantially in the studies included in the meta-analysis, but the analysis only showed a mortality reduction with doses less than 20 micrograms (optimal dose depends on age but based on these findings is likely to range between 15 and 20 micrograms for older people). Mixed preparations were shown to have some complications and a less clear impact on mortality. Ideally, therefore, supplementation for this age group should be through a pure vitamin D preparation at a slightly higher dose than that available in many multivitamin preparations.

References