

## Hot Topics

- A case-control study published early in 2014 found an association between taking sodium-containing medicines in effervescent, dispersible and soluble forms and an increased risk of cardiovascular events.
- No benefit of Vitamin D supplementation in improving bone health was found, according to a systematic review.
- Probiotics may not be prescribed on States prescription. VSL<sup>R</sup> sachets, are only allowed in one single circumstance : for the maintenance of remission of ileoanal pouchitis induced by antibiotics in adult patients.
- Prescribing of fish oil supplements has fallen dramatically on the islands with the drug cost alone reducing from £16,077 per month in April 2012 to £4,392 in April 2014.

### 1. Cardiovascular risk with medicines containing sodium

The controversy associated with high levels of sodium in the diet is well documented. Current UK guidance suggests that adults should consume no more than 6g of salt (equivalent to 2.4g or 104 mmoles of sodium) per day. However many formulations of commonly-used medicines contain significant amounts of sodium. For example one tablet of soluble paracetamol may contain 388mg of sodium.

The Drugs and Therapeutics Bulletin<sup>2</sup> reported on a large case-control study from earlier this year which found an association between taking sodium-containing medicines and an increased risk of cardiovascular events. Using information from the Clinical Practice Research Datalink, the study included 1.2 million patients who were given at least two prescriptions for such formulations, or matched standard formulations between January 1987 and December 2010.

The primary endpoint was a composite outcome of incident non-fatal stroke or vascular event and 61,000 people with an incident CV event were matched with controls. For the primary endpoint, the adjusted odds ratio for exposure to sodium-containing drugs was 1.16 (95% CI 1.12 to 1.21). Further analyses of the data were undertaken and it was calculated that this was driven by increased risk of stroke (OR 1.20 with 95% CI 1.25 to 1.34). The authors concluded that the risk of stroke was probably associated with a sevenfold increased risk of hypertension (OR 7.18, 95% CI 6.74 to 7.65). The risk for all-cause mortality was also significantly higher (OR 1.29 , 95% CI 1.25 to 1.34).

The authors pointed out that the increased risk of stroke with increased sodium intake is consistent with the findings of previous studies. Mean sodium consumption from sodium-containing drugs alone in the study was 107mmol/day, so more than the now maximum recommended intake. The formulations with the highest potential daily sodium content included many commonly prescribed drugs such as paracetamol, paracetamol with codeine phosphate, metoclopramide with aspirin and ibuprofen.

This study, in an extremely large number of patients, should provide a useful reminder to local clinicians to be aware of the clinical significance of this issue. Patients with established CVD or those with risk factors, particularly hypertension, should be advised to avoid all but the very occasional dose of these products.

## 2. Vitamin D supplementation

Vitamin D supplementation does not significantly increase bone mineral density (BMD) in either the spine or the hip, according to a systematic review<sup>2</sup>. The review included 23 studies involving 4,082 people, over 90% of people were female, with a mean age of 59 years. BMD was measured at several sites (lumbar spine, femoral neck, total hip, total body or forearm). The effect of Vitamin D on BMD at all sites was small and a significant benefit was only observed at the femoral neck. There was no effect on BMD in the other areas. The findings, said the authors, "provide very little evidence of an overall benefit of Vitamin D supplementation on bone density". They also stated that, based on their findings, it may be inappropriate to continue Vitamin D supplementation as a preventative measure against osteoporosis, except for those at specific risk.

The Drugs and Therapeutics Bulletin reported the study and stated that "a policy of Vitamin D supplementation in all older people may be costly and unnecessary". Targeting supplementation only to those most likely to be deficient in Vitamin D may provide a better approach.

This adds further weight to the advice, emphasised in local guidelines, that the first line approach to improve Vitamin D levels remains exposure to half an hour of sunlight most days. Levels peak at the end of the summer and are at their lowest in spring or early summer. Lifestyle measures such as stopping smoking, reducing alcohol consumption, maintaining a healthy weight and increasing weight-bearing exercise have all been shown to improve bone as well as general health and wellbeing.

## 3. Probiotics

Please be aware that these products are not prescribable on States prescriptions. They are clearly not licensed medicines. Little if any evidence exists to support their use in achieving outcomes and they are available to buy for very reasonable prices. VSL<sup>R</sup> sachets are listed in the Borderline Substance section of the Drug Tariff, but are only prescribable for use under the supervision of a physician for the maintenance of ileoanal pouchitis in patients and where the doctor endorses the prescription "ACBS"<sup>3</sup>.

There is no clinically justifiable reason to prescribe probiotics for other patient groups and a message regarding the single indication for VSL sachets has been put on Scriptswitch.

## 4. Fish Oil Supplements

NICE Guidance on the care of people post MI states that fish oil supplements should not be prescribed to prevent further events. Eating more oily fish is also not recommended to prevent further events. Practices had already been reviewing patients on these products before the final guidelines were produced. This has resulted in a fall of 71% in the number of prescriptions for these products between April 2012 and April 2014<sup>4</sup>. The annual saving of over £140,000 will remain in the protected Health Fund and will be available to fund the future health needs of the Bailiwick's population. This is an excellent piece of work, of which all those concerned should be proud.

**Doctors are however urged to review the remaining 195 patients on prescribed fish oils and to stop and/or to consider a better value, more effective option.**

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References : 1. DTB Select January 2014, 2. DTB Select February 2014, 3. Drug Tariff July 2014 4. EPACK.net