Evidence-based healthy living

Bandolier has quietly been running the evidence rule over for healthy living. Many of us now justify the things we enjoy, drinking red wine for example, on the basis that we will live for ever if we can cope with five glasses a day. Other things we have to do to attain immortality, more or less pleasant, are to eat grapes, exercise vigorously three times a week, or even eat vegetables, and again the evidence suggests that by doing these things we are protected against heart disease, or cancer, or whatever. The evidence is that simple life shifts can indeed be worthwhile.

Bandolier uses a definition of healthy living wide enough to encompass alternative therapies which many patients use - glucosamine for arthritis and St John’s Wort for mild depression have evidence of efficacy. Bandolier has begun to aggregate stories on its Internet site into a healthy-living section using this wide umbrella definition.

This issue of Bandolier is devoted to healthy-living questions. Many concern contraception, others the benefits of new fat spreads, and even a review of the cardiovascular effects of eating eggs for those of us who still feel guilty when having the occasional bacon and egg breakfast. You will find the risk of becoming pregnant with unprotected intercourse, the chance of a condom slipping or breaking in flagrante, and how fallible home pregnancy tests can be.

Healthy-living feedback

Bandolier’s job is to find the evidence and present it to you. Not always easy in the healthy living zone. We welcome your help as to the questions which you are asked as a professional, those that you ask yourself as a consumer, and those that tickle your intellectual fancy.

Contraceptive effectiveness

Bandolier has long been mystified by something called the ‘Pearl index’ (the number of pregnancies per 100 woman years) a measure of how well a method prevents pregnancy. Is it the same as pregnancies in 100 women in one year, or are there other interpretations? Fortunately others also find this measure unhelpful, and perhaps wrong [1]. Bandolier found some new definitions for use in contraception studies helpful and clear.

Efficacy and effectiveness

Trussell and colleagues [1] define efficacy as being the inherent protection of the method in perfect-use cycles only, borrowing the term from epidemiology. Effectiveness is to do with typical use for all cycles – and therefore includes issues like compliance and has more ‘real-world’ utility, if, of course, effectiveness can be measured.

So condoms or pills may have high efficacy, but because people use them improperly, or forget to take them, the effectiveness of the method falls, and more pregnancies occur than would be expected. Oral contraceptives have high efficacy - but there are suggestions that effectiveness is much lower than the 99.9% efficacy often quoted.

Variables

There are many variables affecting conception and pregnancy rates – the capacity to conceive, frequency and timing of intercourse and the degree of compliance with a contraceptive method. Not all of the underlying nuances are captured by these broad terms, but one thing is likely to be universally true, and that is that the effectiveness of a contraceptive method will be lower than its efficacy.

Impact of effectiveness

Bandolier turned the question of effectiveness around, to know what level of effectiveness would provide what degree of protection against pregnancy. This was done for a couple where the woman had 13 cycles a year with four fertile days per cycle (52 fertile days a year), where intercourse happened twice a week, and in which only 1 in 5 conceptions led to a pregnancy.

By applying different rates of contraceptive effectiveness it is then possible to calculate (Table) how long (on average) it might be until a pregnancy occurs, or what are the odds of a pregnancy in any one year. Thus using a contraceptive
with 75% effectiveness the odds are even (1:1) that a woman will be pregnant in any one year. Odds of 10:1 against being pregnant don’t happen until effectiveness rates reach 97%, and 100:1 against until effectiveness is 99.7%.

**Neck on the block**

Yes, it is quite likely that some of the assumptions in these calculations are educated guesses. In the absence of any published figures that Bandolier could find they are still worth doing. The broad outcome of needing a very high level of effectiveness will stand.

The chance of conception will be high over a time because of the repeated number of individual opportunities, even though the chances for any particular opportunity are small. A bit like taking part in a raffle when you have bought all the tickets – most tickets won’t win, but you still get the prize.

The important thing is that women and men understand the risks. As the Table shows, unprotected intercourse carries a risk of about 1 in 24 of conception. The risk of pregnancy may be smaller because we have assumed that only 4 in 5 conceptions will not lead to pregnancy.

**Womens’ choices**

If a woman is to choose a contraceptive method, she should have information about its likely effectiveness – and therefore her risk of pregnancy. That might (perhaps should) be the prime factor. Secondary factors are the risks of common but reversible adverse effects or harms (altered cycling or weight gain) as well as those of rare but irreversible harm (heart disease, cancer). Providing that information in ways that can be understood by women of different ages and educational backgrounds seems to be a challenge which has yet to be robustly grasped.

Reference:


<table>
<thead>
<tr>
<th>Assumption 1: 13 cycles/year</th>
<th>Assumption 2: 4 fertile days/cycle</th>
<th>Assumption 3: 4x13 = 52 fertile days/year = odds of 1 in 7</th>
<th>Assumption 4: sex on average twice a week = odds of 1 in 3.5</th>
<th>Assumption 5: 1 in 5 conceptions lead to pregnancy</th>
<th>Chance of conception for any one day without contraception = 1/7 x 1/3.5 = 1 in 24</th>
<th>Chance of conception in any one year without contraception = 365/24 = 15 chances total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days a year able to conceive</td>
<td>Contraceptive effectiveness (%)</td>
<td>How long does it take to become pregnant?</td>
<td>Odds of pregnancy in any one year</td>
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<td></td>
</tr>
<tr>
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<td>487</td>
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<td>90</td>
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<td>39</td>
<td>3.3</td>
<td>3:1</td>
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</tr>
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<td>95</td>
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<td>7:1</td>
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<tr>
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<td>121667</td>
<td>3925</td>
<td>327.1</td>
<td>335:1</td>
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</tr>
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</table>

Table: Bandolier’s calculations of the impact of contraceptive effectiveness on the chance of a woman becoming pregnant in any one year
CONTRACEPTION AND ABORTION IN SWEDEN

Information about women’s use of different contraceptive methods is not always easy to come by, but a longitudinal survey of a cohort of women in Gothenburg[1] provides a useful insight about how choices change with age.

Study

The study began in 1981 with a random sample of a quarter of women aged 19 years living in Gothenburg. The women were invited by letter to return a questionnaire on contraceptive history, reproductive history and related factors. Most (91%) did so. These women were then followed up at various times, most recently in 1991, when 484 (74% of original sample of 656 women) completed the questionnaire, and there was full information from 430 women who completed questionnaires in 1981, 1986 and 1991.

Additional information came from computerised hospital records: all births and abortions are carried out in hospital in Sweden. A population register showed no differences between the women who completed the questionnaire and those who did not, and the rest of the population of the same age.

Results

The oral contraceptive pill was the method of choice of the women when they were 19 and 24 years, but far fewer at age 29 (Figure 1). Use of condoms increased somewhat, but IUD use rose from a negligible percentage to 1 in 5 by age 29 years (sterilisation is rare in Sweden). At 24 and 29 years the majority of women not using contraception were either pregnant, had recently been pregnant, or wished to become pregnant.

Reasons for stopping use of the oral contraceptive and IUD are given in the paper, with fear of oral contraceptives a common cause, alongside bleeding disorders, weight gain and mental side effects.

The outcomes of pregnancy at the three ages is shown in Figure 2. At age 19 59% of pregnancies were terminated, a figure which fell to 10% at age 29 with a concomitant increase in the proportion of live births. There were 188 legal abortions performed for these 430 women. Ectopic pregnancy occurred at about 1% in all three ages.

Comment

This is a detailed examination of women’s attitudes to contraceptive choices. It may reflect cultural Swedish differences (high abortion rates, low sterilisation rates), but the overall picture is informative. Half of the abortions occurred when women were aged 20 to 24 years, perhaps reflecting a peak of sexual activity at a time when contraceptive knowledge is still weak.

Reference:


Figure 1: Contraceptive choices made by a cohort of Swedish women at ages 19, 24 and 29 years.

Figure 2: Pregnancy outcomes in women aged ≥19, 20-24, and 25-29 years.
CONDOM FAILURE

Male latex condoms are used both to protect against pregnancy and against sexually transmitted infections. How effective they are depends upon proper use. Breakage during intercourse, or slippage, will render the condom ineffective. How often does this happen? A number of studies have been conducted (we found no systematic reviews); three examples illustrate the size of the problem.

Studies and results

Ninety-two monogamous heterosexual couples (aged 18 to 40 for women, 18-50 for men) were enrolled in a prospective study of Durex Ramses condoms [1]. At each sexual encounter a diary was completed which included information on condom use, and breaks and slips.

There were 4,637 attempts to use condoms. On six occasions the condoms broke before intercourse, leaving 4,631 condoms used for intercourse. Thirteen breaks occurred during intercourse (0.28%), and the total breakage rate was 0.41%. Complete slips were recorded on 29 occasions (0.63%) and 21 of these were recorded by the same couple. The overall failure rate of 0.91%, or an effectiveness rate of 99.1%. The total failure rate was 1.04%.

In France a random telephone survey [2] of 20,000 individuals drew on 4,500 sexually active people, of whom 731 had used a condom in the previous year and 707 provided information on difficulties of use.

The rate of breakage at last use in heterosexual intercourse was 3.4% and the rate of slippage 1.1%, for a total failure rate of 4.5%, or an effectiveness rate of 95.5%.

In Australia 3658 condoms were used by 184 men in a study [3] which looked, inter alia, at penis size as a factor for breakage or slippage.

The rate of breakage was 1.34% and of slippage 2.05%, with a total failure rate of 3.39%. Penis size was not related to slippage, but penis circumference was strongly associated with breakage.

Comment

It seems that the reported rate of condom failure through slippage and breakage is significant. While 95% effectiveness of a contraceptive method sounds good, actually it leaves a woman with a chance of pregnancy which may be considered unacceptable. At 95% it is 7:1 against in any one year, rising to 33:1 against at 99%. As any follower of the turf could tell us, outsiders at 33:1 win races every day.


THIRD-GENERATION PILLS

In October 1995 a warning letter was sent to doctors about an increased risk of thrombosis from “third-generation” oral contraceptive pills. The estimate was that the risk of these events with new pills was about twice that with a previous “generation” of pills. The result was much consternation – the media had the news before most GPs – and hype, with many women stopping using the pills or any contraception at all. Bandolier 21 did its own calculations showing risks to be very small.

It is educational, with that background, to read a paper from one of the authors of the key study which quietly and thoughtfully examines the possibilities of bias and causality, and comments rationally on how we may evaluate such information in future [1].

For new readers

The original information suggested that venous thromboembolism, which occurs in about 1 in 10,000 women on second-generation pills, happened twice as often with third-generation pills – an excess risk of 1 in 10,000. Most (99%) young women in whom this occurs are treated successfully, so the risk of any additional serious outcomes would be at most 1 in a million if there was an additional risk.

Spitzer looks at the additional risk (an odds ratio, or relative risk of about 2) and asks whether it could be produced by bias, and even if true whether it has credibility.

Bias

A number of different sources of bias could have occurred:

♦ Confounding: where the effect of exposure risk is distorted because of association of exposure with other factors influencing the outcome.
♦ Effect modification: a factor modifies the effect of a suspected causal factor.
♦ Prescribing bias: preferential prescription of drugs depending on characteristics of patient or drug.
♦ Referral bias: differential hospital referral of patients for diagnosis with similar symptoms but different clinical backgrounds.
♦ Healthy user effect: occurs when doctors change patients from a well-established product because they are concerned that the patient may be at unnecessary risk or is not doing well.

Spitzer argues that healthy user bias had an effect and that referral bias and prescription bias operated to drive the estimate of risk upwards. While the observed odds ratio was about 1.5, it was about 1.0 for new users of oral contraceptives.

Causality

Austin Bradford-Hill set out guidelines that have been used to elucidate causality from association [2]. The third-gen-
eration pill story was one of association, so asking questions about causality is useful in determining the underlying credibility of the association.

As the Table shows, applying the Bradford-Hill criteria gives an underwhelming conclusion as to causality.

Comment

Spitzer’s conclusions are that the clinical importance and public health significance of any differences among oral contraceptive products with respect to cardiovascular outcomes are trivial and undetectable because they occur so infrequently. His opinion is that all oral contraceptives on the market are safe and getting safer.

The importance of this paper is not just that it combines common sense and epidemiology so intelligently, but also because it makes issues of bias and causality so easily understandable. This is a classic teaching text which ought to be a must for any critical appraisal course.

For those who want a review of the association between oral contraceptive use and cardiovascular disease (myocardial infarction, stroke, thromboembolism), a useful paper is the 1998 review from Boston [3]. This examined epidemiological studies up to June 1997. No meta-analysis was done, and the numbers of women using oral contraceptives was small, but the conclusions indicate little or no increased risk for serious cardiovascular disease with oral contraceptives.


Table: Causality and thromboembolism with third-generation oral contraceptives

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experiment</td>
<td>No experiment was done, and no experiment could reasonably be done to test the association</td>
</tr>
<tr>
<td>Strength</td>
<td>The odds ratios are weak (less than 2)</td>
</tr>
<tr>
<td>Consistency</td>
<td>Relative risks are consistently weak, and some studies include no additional risk</td>
</tr>
<tr>
<td>Gradient</td>
<td>Emerging evidence suggests that lower doses of ethinyl oestradiol have higher odds ratios for thromboembolism. The gradient is paradoxical</td>
</tr>
<tr>
<td>Biological plausibility</td>
<td>There is none</td>
</tr>
<tr>
<td>Specificity</td>
<td>The outcome is not specific for the intervention. Other factors (obesity, immobility, pregnancy) cause thromboembolism</td>
</tr>
<tr>
<td>Coherence</td>
<td>There is none. Thromboembolism rates in second generation pills are lower now than 10 years ago</td>
</tr>
<tr>
<td>Temporality</td>
<td>Not an issue</td>
</tr>
<tr>
<td>Analogy</td>
<td>There are none</td>
</tr>
</tbody>
</table>

Implanonn

Implantable contraceptives have been regarded as effective, but have been plagued by reports of adverse effects and difficulties in removing some types of implant. Some are not now available in the UK because of these problems. In what might be something of a first, a systematic review of clinical studies of a new type of implant – Implanon – has been published before the device is available [1]. Implanon is a single 4 cm by 2 mm flexible rod containing etonorgestrel.

Review

Non-comparative studies of Implanon, and comparative randomised, open studies of Implanon and Norplant in women requiring long-term contraception. The duration was 24 months. Outcomes included pregnancy, ease of insertion and removal of the implant, changes in menstrual bleeding patterns, weight changes and adverse effects.

Results

Two years of data was available from 1333 women using Implanon and 601 using Norplant. No woman became pregnant.

Insertion of Implanon was completed in under three minutes in 90% of women (median one minute), and removed in under five minutes in 83% of women (median two minutes). Norplant, by comparison was inserted in under three minutes in 37% of women (median four minutes) and removed in under five minutes in 36% (median eight minutes).

Bleeding pattern changes were frequent with both implants, and a feature of the data presentation is that percentages of women with particular bleeding abnormalities are given. This provides information that can be used for women to
make informed choices about whether the contraceptive method is acceptable to them.

After 24 months of use, 64% of women using Implanon gained at least 1 kg, and 37% gained at least 3 kg. Body mass index increases of more than 10% were found in 20% of women with Implanon and 17% with Norplant. Discontinuations with Implanon tended to be predominantly in the first year, and 82% of women continued with the device for 24 months (Figure). Reasons for discontinuations were mixed, but were mainly due to bleeding irregularities and a mixture of adverse experiences.

Comment

This form of implanted contraceptive had no method failures in over 70,000 cycles of use, and 82% of women used it for at least two years. Women who withdrew did so mainly because of menstrual irregularity and weight gain. The importance of this paper is that it provides solid information about the consequences of using this method of contraception. There will be no pregnancies, but there are some consequences that some women might prefer to avoid: they should use other methods.

For women who wish absolutely to avoid pregnancy, and who know the risks of bleeding irregularity and weight gain, this might be one of their choices if the device becomes available in the UK.

Reference:

HOME PREGNANCY TESTS REVIEWED

A characteristic of modern life is the availability of pregnancy testing kits bought from pharmacies and elsewhere to allow women to confirm or exclude that they are pregnant. How reliable are they? A review of studies [1] suggests that all is not as simple as it seems, and that they need to be looked at with a cold and fishy eye.

Review

A thorough search strategy identified 55 studies, of which 45 were immediately excluded because they were reviews or because the kit examined was not compared with a reliable laboratory standard. Of the remaining 10, five more were excluded because studies had no control groups of non-pregnant patients, sensitivity and specificity could not be calculated from data given, the kit demonstrated poor performance or was not available, or because the study was small. In this latter category was the report which tested kits on three (yes, 3) subjects.

Results

That left five reasonable studies.

♦ When the subjects using the tests were volunteers who tested previously collected samples the overall sensitivity was 91% (range 52% to 100%). Specificity ranged from 61% to 100%.

♦ When the subjects using the test were women who collected and tested their own samples, the overall sensitivity was 75% (range 53% to 82%). Specificity was also low, in the range 52% to 75%.

Comment

Home pregnancy testing kits usually claim accuracy of over 95% (whatever that may mean). The reality is that the literature contains information on only four kits evaluated as they are intended to be used – by women testing their own urine. The results we have suggest that for every four women who use such a test and are pregnant, one will get a negative test result. It also suggests that for every four women who are not pregnant, one will have a positive test result.

Many important decisions will hinge on the results of a home pregnancy test – whether to see a doctor, decisions about termination, decisions about relationships. In the circumstances, the paucity and quality of published information could be regarded as a scandal. While results in the hands of experienced technicians may be adequate, it is clear that in the situation in which they are intended to be used, the tests do not work well enough. Women should know this.

Reference:
GOING TO WORK ON AN EGG

Bandolier did a quick survey of attitudes to and knowledge of the perceptions people have about egg consumption and the way it affects risk of heart disease. Responses varied from no effect at all, to just about lethal. What's the truth? Analysis of two large epidemiological studies tells us that eating up to one egg a day is unlikely to have any substantial impact on risk of heart disease or stroke [1].

Study

There were actually two prospective studies. One looked at just under 38,000 US male health professionals over eight years. The other collected data from 80,000 US nurses for 14 years. Both had obvious exclusions (hyperlipidaemia or diabetes where diet could radically be changed, prior heart disease or cancer), and both collected information from participants about their diets, including consumption of eggs.

Outcomes

The outcomes were fatal and non-fatal coronary heart disease and stroke (analysed separately) by using biennial questionnaires. They used sensible diagnostic criteria and had high (98%) follow-up rates. A wealth of additional information was collected about diet and lifestyle to adjust for risk factors other than egg consumption.

Results

At the beginning of the study men averaged 2.3 and women 2.8 eggs a week. At the end consumption had declined to about 1.5 eggs a week. There were still considerable numbers of men and women who consumed up to and above one egg a day.

There were 866 cases of coronary heart disease in men and 939 in women. Compared with eating less than one egg per week, eating up to and above one egg per day did not increase the risk of developing coronary heart disease (Table) for women or men.

There were 258 cases of stroke in men and 563 in women. Compared with eating less than one egg per week, eating up to and above one egg per day did not increase the risk of suffering a stroke (Table) for women or men.

When information from other groups was included, there did appear to be a higher risk of coronary heart disease for diabetic men eating more than one egg a day compared with those eating less than one a week. The relative risk was 2.0 (1.05 to 3.9).

Comment

The lesson seems to be that eggs may have cholesterol in them, but they probably have other important nutrients too. There is no evidence here that eating eggs has much effect on risks of heart disease or strokes, with the possible exception of diabetic men.

This does not mean that a daily ritual of fried bacon, fried sausage, black pudding and fried bread with plenty of toast and butter is advised. Rather it means that we can enjoy the occasional cooked breakfast, or enjoy a nice boiled egg and soldiers without feeling guilty. Bandolier intends to not feel guilty on a more regular basis.

Reference:

<table>
<thead>
<tr>
<th>Eggs per week</th>
<th>Relative risk for coronary heart disease</th>
<th>Relative risk for stroke</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Women</td>
<td>Men</td>
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<td>&lt;1</td>
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<td>1.0</td>
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<td>1</td>
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<td>1.06 (0.88 to 1.27)</td>
</tr>
<tr>
<td>2 - 4</td>
<td>0.99 (0.82 to 1.18)</td>
<td>1.12 (0.88 to 1.33)</td>
</tr>
<tr>
<td>5 - 6</td>
<td>0.95 (0.70 to 1.29)</td>
<td>0.90 (0.63 to 1.27)</td>
</tr>
<tr>
<td>≥7</td>
<td>0.82 (0.60 to 1.13)</td>
<td>1.08 (0.79 to 1.48)</td>
</tr>
</tbody>
</table>

Relative risks were obtained after adjustment for factors like age, body mass index, smoking, family history, vitamin supplements, alcohol, energy intake and other factors.

Pain – where’s the evidence?

Two conferences will take place on July 6th and July 8th in London and Manchester. In London the venue will be the Royal College of Pathologists. In Manchester we have booked a conference suite in Terminal 2 at Manchester Airport. Meetings start at about 9.30 am and finish by 5.00 pm.

For details please fax Eileen on 01865 226978, or write to her at the Bandolier address. If you want to book early, please send a cheque made out to Bandolier and tell us which venue you want.
**BENECOL AND LIPIDS**

Is having Carol Vorderman telling you that Benecol can reduce plasma lipids in TV advertisements enough to make you choose a different margarine at the supermarket? *Bandolier* thought not, so chose to examine a paper from a rival company that investigated the topic [1].

**Study**

The detailed study examined the effects of 30 g/day of five margarines, Flora, Benecol and spreads enriched with soybean, ricebran and sheanut oils over 3.5 weeks in a randomised, double-blind crossover study. The study appeared to be beautifully designed and conducted, and it was detailed in its measurement of diets, energy intake and blood chemistry. Blood samples were taken 2.5 and 3.5 weeks after starting on a margarine, and the average values of these two measurements were taken.

At baseline the 100 adults (50 men and 50 women) had a mean body mass of 24 kg/sq metre (allowable range 19 to 30 kg/sq metre), and a mean age of 45 years (allowable range 18 to 65 years). The mean values for lipids were:

- Total cholesterol 5.4 ± 1.1 (SD) mmol/L
- LDL cholesterol 3.5 ± 1.0 mmol/L
- HDL cholesterol 1.3 ± 0.35 mmol/L

**Results**

The mean reductions in total cholesterol were 0.37 mmol/L and 0.43 mmol/L, and in LDL cholesterol were 0.40 mmol/L and 0.44 mmol/L for Benecol and soybean sterol enriched spread. Compared with Flora, Benecol and a spread enriched with esterified soybean sterols significantly reduced total cholesterol and LDL cholesterol by about 8% and 13% respectively.

This effect was found in both men and women, and the same degree of reduction was found whatever the starting total and LDL cholesterol in the patient group (Figure). The margarines enriched with other plant oils were without effect. HDL cholesterol was unchanged.

**Comment**

This was a rigorous assessment of the effectiveness of margarine spreads enriched with sitostanol esters and their equivalent from soybean. It confirmed other studies demonstrating rapid falls in LDL and total cholesterol using spreads with these compounds. The magnitude of the reductions in cholesterol and LDL cholesterol is impressive, and while lower than reductions seen with statins in people with mild hypercholesterolaemia, is worthwhile.

For people who feel they want to reduce their own risks of heart disease, choosing a spread enriched with these esters would make sense. The effect on cardiovascular disease would be beneficial if small for an individual, but additive to effects of exercise, and use of daily folate.

Reference:


Figure: Plasma LDL cholesterol after 3.5 weeks using 30g/day of Flora, Benecol, and a Soybean oil spread for people with different initial LDL-cholesterol levels.