What risks do women face when seeking advice during pregnancy from pharmacies and natural health retailers?

Sarah Jefferies, Bridget Healy, Mark Weatherall, Richard Beasley, Philippa Shirtcliffe

Abstract

**Aim** Potential risks to mother and foetus exist with the incorrect use of complementary and alternative medicine (CAM) products during pregnancy. This study aimed to identify the risks that a woman may face when seeking advice during pregnancy from pharmacies and health food stores (HFS) in Greater Wellington (New Zealand).

**Methods** 21 HFS and 21 geographically-matched pharmacies were visited by a researcher who sought advice regarding vitamin supplementation and nausea in early pregnancy using a standardised scenario. Any advice given, including details of recommended products, was documented immediately upon leaving the premises. Proportions were obtained and paired contingency table analysis was used to examine the agreement between the matched pairs.

**Results** A minority of pharmacies (5/21, 23.8%) and HFS (1/21, 4.8%) made primary recommendations for nausea which were supported by Ministry of Health (MOH) guidelines, and both pharmacies (14/21, 66.7%) and HFS (7/21, 33.3%) recommended products contrary to these guidelines. A greater proportion of pharmacies gave advice consistent with MOH recommended dosage of folic acid supplementation than HFS (20/21, 95.2% vs 10/21, 47.6%). 2/21 (9.5%) of pharmacies and 4/21 (19%) of HFS gave advice with a potential risk of vitamin A overdose.

**Conclusions** Pharmacies and HFS in Greater Wellington provided potentially hazardous advice, recommending products, often branded for pregnancy, which contradicted NZ MOH guidelines. Regulatory reform of CAM products and those who sell them is called for in New Zealand.

Natural health products are popular among pregnant women in Australasia, yet potential risks of exposure to teratogenic herbs, vitamins and other substances raise concerns regarding the present lack of effective regulation of the complementary and alternative medicine (CAM) industry in New Zealand.

Natural health (or CAM) products, including herb, mineral and vitamin supplements, are marketed for pregnancy on the basis of health promotion as well as to remedy pregnancy-associated ailments such as nausea and vomiting of pregnancy (NVP).

Consumers may use them with the belief that they are ‘natural’ and therefore safe; attracted by the autonomy of self-care; or wary of conventional medicines and their adverse effects. However, not only is there little evidence of the efficacy or safety of CAMs promoted for pregnancy in New Zealand, but there are risks of toxicity from...
herbal ingredients and supplement overdosing, product contamination and adulteration, as well as interactions with conventional drugs. CAMs are widely available from advertisements, pharmacies, health food stores, supermarkets, on the Internet and from medical practitioners. In New Zealand the CAM industry is substantial, with manufacturers’ annual turnovers ranging from $100,000 to >$20M.

CAM use in pregnancy is specifically addressed by the New Zealand Ministry of Health (MOH) in the Food and Nutrition Guidelines for Healthy Pregnant and Breastfeeding Women which sets out evidence-based recommendations regarding the use of vitamins, minerals and herbs.

The guidance explicitly states that there is no requirement for a healthy pregnant woman to take multi-vitamin supplementation; and that a balanced diet is sufficient. It also states that ‘all herbs should generally be avoided’. It advocates discussion with the lead maternity carer regarding taking any supplements and herbs prior to their commencement. Unfortunately, research shows that CAM use is often not discussed with a primary care physician.

NVP is a common and distressing ailment of early pregnancy and the use of the herb ginger (Zingiber officinale) and vitamin B₆ (pyridoxine) are popularly promoted. However, a recent Cochrane review of randomised controlled trials of therapies for mild-moderate NVP concluded that the evidence for a beneficial effect of ginger or pyridoxine supplementation was inconsistent and/or limited.

Matthews et al. found that while adverse effects had not been reported in trials using short courses of low dose ginger 1g daily or 30-75mg pyridoxine daily for NVP, this research was insufficient to prove safety. There are also concerns regarding potential toxicity of these substances: pyridoxine is neurotoxic at high doses and ginger is considered an emmenagogue (induces menstrual bleeding) in traditional medicine and its constituents have been shown to inhibit thromboxane synthetase activity and exhibit antiplatelet and cytotoxic properties although there is conflicting evidence.

NZ MOH guidelines recommend that pregnant woman choosing to use ginger for NVP do not exceed a daily dose of 1g and also advise an upper limit of 50mg pyridoxine daily.

The key issue that this study sought to investigate was the risks which a woman may face when seeking advice regarding NVP, and vitamin supplementation during pregnancy from pharmacies and health food stores (HFS) in Greater Wellington.

Methods

A search of The Yellow Pages telephone directory in February 2010 identified 26 Health Food Stores (HFS) in the Greater Wellington region. Of these, 5 were excluded: 3 were no longer in operation, 1 was a residential property, and 1 specialised in sports supplements. Twenty-one HFS and 21 geographically-matched pharmacies (on the basis of closest location to the HFS) were visited by the same researcher between the months of February to July 2010.

With each visit, the researcher commenced a conversation with a retail assistant by saying she was 6–8 weeks pregnant, having problems with morning sickness, and enquiring about any herbal products which the retail assistant could recommend to help reduce nausea. The researcher would then ask what
the retail assistant could recommend with regards to vitamin supplementation. Finally she asked which vitamins were important during pregnancy and if there were any to avoid.

If questioned by the retail assistant, the researcher would reply, as appropriate, saying she was: 30 years old, married, excited about her first pregnancy, currently working in a clerical office job, and otherwise fit and healthy with no previous medical history.

During each interaction, the researcher would take note of the products recommended and their prices, and upon leaving immediately complete a standardised data collection form to document the advice received. The ingredients of each recommended product were later confirmed by searching for the product on the Internet.

The NZ MOH Food and Nutrition Guidelines of Healthy Pregnant and Breastfeeding Women (revised 2008) was the standard against which all advice was compared. For ingredients not noted therein, a database search using Medline was performed for evidence of safety during the first trimester of pregnancy.

The following criteria were used to evaluate advice given:

**Products recommended for nausea in the first trimester of pregnancy**

**Safe**—Product contains ingredients which are not absolutely contraindicated in pregnancy or their daily dose does not exceed the upper limit recommended by NZ MOH guidelines, or, if the ingredient is unknown, there is no evidence that it may be unsafe by Medline search of the literature.

**Unsafe**—Product contains ingredients which are absolutely contraindicated in pregnancy or the daily dose exceeds the upper limit recommended by NZ MOH guidelines, or, if the ingredient is unknown, there is evidence that it may be unsafe by Medline search of the literature.

**Advice regarding vitamin supplementation in early pregnancy – folic acid advice**

**Correct**—Dose advised corresponds with NZ MOH guidelines for supplementation with 800 mcg/day in low-risk pregnancy.

**Incorrect**—Folic acid not recommended or dose advised was less than 800 mcg/day.

**Advice regarding vitamin supplementation in early pregnancy – Vitamin A overdose risk.**

**Safe**—Advice given did not pose risk of vitamin A overdose. This includes recommendation of a multivitamin product marketed for pregnancy which did not contain doses of vitamin A exceeding 3000mcg/day of retinol, even without demonstrating explicit vitamin A overdose awareness.

**Unsafe**—Advised that there is no limit to vitamin dosing during pregnancy or recommended a product containing >3000 mcg/day of retinol or advised to take any generic multivitamin.

**Statistical analysis**

Paired contingency table analysis was used to examine the agreement between the matched pairs in advice between pharmacies and HFS. Statistical analysis was by an exact McNemar’s test and a confidence interval for the difference in marginal proportions, representing the proportion of pharmacies that gave particular advice versus the proportion of matched HFS that gave advice. A statistically significant McNemar’s test means the marginal proportions of the contingency table are different. In the analysis McNemar’s test is based on an exact test whereas the confidence interval is based on asymptotic (large sample) assumptions. Where more than one product was recommended for nausea, the primary recommended products were compared in one analysis, and then the secondarily recommended products compared separately.

The number of matched pharmacies/HFS was based on an earlier study comparing the advice from HFS assistants with that of pharmacy assistants given to an individual presenting with symptoms suggestive of moderate to severe asthma who should be referred to a medical practitioner. Based on this, it was calculated that the study would need to have 19 store/pharmacy pairs to have 80% power to detect the difference.
The study was approved by the Central Regional Ethics Committee.

**Results**

Data was collected from 21 HFS and 21 geographically-matched pharmacies in the Greater Wellington region. The investigator was advised by retail assistants in all the HFS, with 6/21 (28.6%) HFS advising further discussion with a naturopath (n=2) or GP (n=4).

In 7/21 pharmacies, advice was indirectly (n=3) or directly (n=4) from the pharmacist. 9/21 (42.9%) of pharmacies referred the researcher to a GP (n=7) and/or midwife (n=2) during the interaction.

Table 1 lists the products recommended for nausea and Table 2 summarises other recommendations made, including multivitamin supplementation.

**Table 1. Products recommended for nausea by Health Food Stores (HFS) and pharmacies (P), their retail price, ingredients and adherence with MOH guidelines**

<table>
<thead>
<tr>
<th>Recommended products: Name, manufacturer (recommended by)</th>
<th>Price range of products offered ($)</th>
<th>Daily doses if maximum dose taken as directed on packet/otherwise directed</th>
<th>MOH recommendation (Y/N)</th>
<th>Safe/Potentially unsafe (S/PU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ginger+Vitamin B6: Morning Sickness Formula, Blackmores (8HFS, 10P)</td>
<td>17.50–23.00</td>
<td>Ginger root 1.2g B6 75mg</td>
<td>N</td>
<td>PU</td>
</tr>
<tr>
<td>Ginger: Travel Calm Ginger, Blackmores (10P)</td>
<td>16.50–18.60</td>
<td>Ginger root 5.6g</td>
<td>N</td>
<td>PU</td>
</tr>
<tr>
<td>Ginger syrup/ capsules, Lifestream (4HFS)</td>
<td>17.00–17.40</td>
<td>Ginger rhizome 1–3g</td>
<td>1g=R (1HFS) &gt;1g=N (3HFS)</td>
<td>PU</td>
</tr>
<tr>
<td>Crystallised ginger (3HFS)</td>
<td>4.10–7.30</td>
<td>Not directed</td>
<td>N</td>
<td>PU</td>
</tr>
<tr>
<td>Ginger drops, Botanicals (1HFS)</td>
<td>14.00</td>
<td>‘Ginger veg glyceride’ 1g</td>
<td>Y</td>
<td>S</td>
</tr>
<tr>
<td>Ginger from a general store e.g. Raw ginger/ ginger beer/ale (3HFS, 5P)</td>
<td></td>
<td>Not directed</td>
<td>N</td>
<td>PU</td>
</tr>
<tr>
<td>Ginger tea, Planet Organic (2HFS)</td>
<td>4.60–7.85</td>
<td>Not directed</td>
<td>N</td>
<td>PU</td>
</tr>
<tr>
<td>Raspberry leaf: Raspberry leaf, Blackmores (1P)</td>
<td>12.79</td>
<td>Rubus idaeus (Raspberry) leaf powder/equivalent 6g</td>
<td>N</td>
<td>PU</td>
</tr>
<tr>
<td>Vitamin B6 supplements: From multivitamins (1HFS, 2P)</td>
<td></td>
<td>Varying levels in multivitamins - all &lt;50mg</td>
<td>N</td>
<td>S</td>
</tr>
<tr>
<td>Other vitamins: Morning</td>
<td>29.99</td>
<td>Vit B6 75mg</td>
<td>N</td>
<td>PU</td>
</tr>
</tbody>
</table>
Wellness Support, Clinicians (1P)

**Homeopathy:**

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Vitamin C 75mg</th>
<th>Vitamin K1 270mcg</th>
<th>P</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morning medrelief, Naturopahm (11HFS)</td>
<td>19.60–21.30</td>
<td>N/A</td>
<td>N</td>
<td>S</td>
</tr>
<tr>
<td>Nausyn, Weleda* (3HFS, 2P)</td>
<td>14.00–18.90</td>
<td>N/A</td>
<td>N</td>
<td>S</td>
</tr>
<tr>
<td>Nausmed relief, Naturopahm (2HFS)</td>
<td>20.30–20.80</td>
<td>N/A</td>
<td>N</td>
<td>S</td>
</tr>
<tr>
<td>Saccharum/Mel complex, Weleda (1HFS)</td>
<td>17.50</td>
<td>N/A</td>
<td>N</td>
<td>S</td>
</tr>
</tbody>
</table>

**Other:**

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Vitamin C 75mg</th>
<th>Vitamin K1 270mcg</th>
<th>P</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupressure wrist bands (11P)</td>
<td>22.50–23.99</td>
<td>N/A</td>
<td>Y</td>
<td>S</td>
</tr>
<tr>
<td>Frequent snacking (2HFS)</td>
<td>N/A</td>
<td>Y</td>
<td>S</td>
<td></td>
</tr>
</tbody>
</table>

In brackets = Number of HPS and P recommendations for the product. *Also contains herb mixture called cardiodoron 250mg/15 drops = Digestion, equiv. fresh plant juice: Hyoscyamus niger, herb 1mg; onopordon acanthium, flower 25mg; Primula veris, flower 25mg. Nausyn is licensed by Medsafe as a Medicine.

**Advice given for nausea in the first trimester of pregnancy**—5/21 (23.8%) of pharmacies and 1/21 (4.8%) of HFS made primary recommendations for nausea which were supported by the NZ MOH guidelines, with a non significant difference in marginal proportions of 19.1% (95% CI -2.3% to 40.4%), p=0.10.

Both pharmacies (14/21, 66.7%) and HFS (7/21, 33.3%), made primary recommendations which were contrary to NZ MOH safety guidance. The difference in marginal proportions was 33.4% (95% CI 5.9% to 60.8%), p= 0.07. With regards to recommendations of second-line products which were contrary to MOH safety guidance, this occurred in 7/21 (33.3%) of pharmacies and 10/21 (47.6%) of HFS with a non significant difference in marginal proportions of -14.3% (95% CI -41.6% to 13.0%), p=0.51. The most common reason for a product being considered unsafe was that it provided >1g ginger ± >50 mg pyridoxine in the maximum daily dose as directed (Table 1).

7/21 (33.3%) of pharmacies and 0/21 (0%) of HFS advised GP consultation if nausea did not settle. Due to two zero cell counts in the paired contingency table, it was not possible to calculate McNemar’s test or a confidence interval for the difference in paired proportions.

**Advice promoting a balanced diet with folic acid supplementation**—1/21 (4.8%) of HFS and 0/21 (0%) of pharmacies correctly advised that a balanced diet, along with folic acid supplementation, was recommended during pregnancy in otherwise healthy young women. However, 0/21 of HFS and 18/21 (85.7%) of pharmacies primarily recommended Elevit by Bayer, a multivitamin product which is licensed by Medsafe. Due to zero cell counts in the paired contingency tables, it was not possible
to calculate McNemar’s test or a confidence interval for the difference in these paired proportions.

Table 2. Summary of other products/advice given. Numbers represent the total number of pharmacies (P) or Health Food Stores (HFS) giving recommendation (whether primary or secondary)

<table>
<thead>
<tr>
<th>Multivitamin supplements</th>
<th>Other supplements</th>
<th>Miscellaneous advice for nausea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevit, Bayer (20P)</td>
<td>Folic Acid, Blackmores, Red Seal, Solgar, NFS, or via GP (17HFS, 20P)</td>
<td>Acupuncture (1P)</td>
</tr>
<tr>
<td>Prenatal Nutrients, Solgar (10HFS)</td>
<td>Omega 3 Fish oil (Efanatal, Prenatal DHA)/Flaxseed oil (Waihati Bush)) (13HFS, 2P)</td>
<td>Spiritual healer (1HFS)</td>
</tr>
<tr>
<td>Pregnancy and Breast Feeding Gold, Blackmores (5HFS, 4HFS)</td>
<td>Iron, Solgar (1HFS)</td>
<td>Referred to the local HFS for advice as the pharmacy too busy (1P)</td>
</tr>
<tr>
<td>Multipregnancy Essentials, NFS (2HFS)</td>
<td>Spirulina, Lifestream (3HFS)</td>
<td></td>
</tr>
<tr>
<td>Meta B Multivits, Metagenics (1HFS)</td>
<td>Probiotics, brand not specified (1HFS, 1P)</td>
<td></td>
</tr>
<tr>
<td>Pregacare, Thomsons (2HFS, 4P)</td>
<td>Pregnancy Tea, Artemis Contains: Raspberry leaves, Lady's Mantle, Nettle, St John's Wort, Lemon Balm, Horsetail, Yarrow (1HFS)</td>
<td></td>
</tr>
<tr>
<td>NFM Professional Multi (2HFS)</td>
<td>Eczema Shield, Ethical Nutrients Contains: Lactobacillus rhamnosus (GG) organisms (LGG®) (1HFS)</td>
<td></td>
</tr>
<tr>
<td>Multi for Pregnancy, Radiance (1HFS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PregaVit, Clinicians (1P)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Advice regarding folic acid—The majority of those promoting folic acid supplementation advised that this was for the prevention of neural tube defects (14/20 pharmacies and 13/17 HFS). 20/21 (95.2%) of pharmacies and 10/21 (47.6%) of HFS correctly gave dosing recommendations on the basis of national standards, with a difference in marginal proportions of 47.6% (95%CI 22.5% to 72.7%), p=0.006. 1/21 (4.8%) of pharmacies and 4/21 (19.0%) of HFS did not actively recommend taking folic acid supplementation.
Advice regarding Vitamin A overdose risk—2/21 (9.5%) of pharmacies and 4/21 (19.0%) of HFS vitamin recommendations were unsafe due to the potential risk of vitamin A overdose, with a non significant difference in marginal proportions of -9.5%, p=0.69.

Discussion

Both pharmacies and HFS recommended products for nausea in early pregnancy which did not adhere with NZ MOH safety guidance.

A minority also provided potentially unsafe advice regarding vitamin supplementation. There were no statistically significant differences between stores in the majority of recommendations made, except pharmacies were more likely than matched HFS to advise correctly regarding folic acid dosing. While this difference is unsurprising taking into consideration that pharmacies promote Medsafe-approved folic acid products which only they can sell, it does demonstrate the positive influence of product approval.

This study supports the urgent introduction of regulatory reform of the CAM industry and the businesses which sell these products.

This study is the fourth in a series of surveys in New Zealand looking at the appropriateness of advice given by pharmacies and HFS for a range of medical conditions. Previous surveys have all raised concerns regarding the advice provided by HFS when compared with pharmacies.\(^{18-20}\) This is the first scenario to find that the standard of advice was, on the whole, similarly matched between both types of store.

In fact there was a trend towards the primary promotion of potentially unsafe products for NVP by pharmacies when compared with matched HFS. This is largely due to the primary promotion of homeopathy by HFS, which although only able to offer a placebo effect at best, is inherently safe.

There were several limitations of this study. One of these is the possibility of recall bias although advice was entered into a data collection sheet immediately following the interaction to minimize this. The study was limited by the sample size available to the researchers in the greater Wellington region and although no statistically significant differences were found the confidence intervals for the comparisons were quite wide.

While this is the first study in New Zealand examining advice given by CAM retailers for a scenario of pregnancy, the closest comparative is a survey carried out in 2003 in North America.\(^{21}\) In this study, advice was sought from HFS via telephone for the treatment of nausea and migraines in early pregnancy. They found that HFS readily made recommendations, 5% of which were for products contraindicated in pregnancy, and most stores primarily promoted ginger for NVP giving incorrect dosing instructions.

Since the 1990s the use of CAM has surged worldwide and the World Health Organization actively recommends the regulation of all complementary and herbal medicine products and practitioners.\(^{22}\) This is particularly so in situations where the practice of complementary medicine brings economic benefit. This is to ensure the quality of the service received and thus to protect the public from potential harm.
This study supports the introduction of the Natural Health Products Bill in New Zealand (currently before the Health Committee) which is aimed at improving regulation by making pre-marketing ‘product approval’ mandatory, establishing a database of permitted CAM ingredients, requiring product labeling and licensing of CAM product manufacturers.\textsuperscript{6} This proposed legislation would ensure that commercially available CAM products complied with national guidelines prior to appearing on the shelves. Furthermore it would help ensure the quality of the ingredients used.

Analysis of the contents of the recommended products was outside the scope of this study, but it would have been interesting to assess the accuracy of the listed ingredients.

Research has demonstrated a wide variation in the constituents of ginger present in commercially available ginger supplements.\textsuperscript{23} This not only has implications for the rights of the consumer, but lack of standardisation of the products used in research, as exemplified by the variety of preparations used in ginger studies, may create misleading results.

Further monitoring of the therapeutic claims made on product labeling is also appropriate; a number of products not registered as medicines by Medsafe, and therefore not permitted to make therapeutic claims, were found to do so.

Unfortunately the proposed bill will not address the issue of setting minimum staff training requirements for the promotion of health food goods. Although only a minority provided unsafe advice regarding vitamin supplementation (e.g. 4.8\% of pharmacies and 19.0\% of HFS did not recommend folic acid) in the context of a retailer presenting themselves as a source of health advice to the public, any unsafe practice is unacceptable.

In conclusion, this study found that both HFS and pharmacy staff made potentially unsafe recommendations for nausea and vitamin supplementation in early pregnancy.

Many of the pregnancy promoted products recommended often did not adhere to the safety guidance set out by the NZ MOH. This study supports the call for legislative change and high quality research to guide the practice of health care professionals and retailers who sell natural products which may exert both beneficial and harmful effects.

**Competing interests:** Nil.

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