Exposure - Statement on the effects of excess Vitamin A on maternal health

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Exposure

Population estimates

106 In many regions of the world, for example, regions of Africa and south-west Asia (Harika et al., 2017) the issue with vitamin A is deficiency and the deleterious effects this has upon the health of unborn children. However, in developed countries, many people regularly have an intake that exceeds EFSA's dietary reference value, with a range of values across European countries being reported, although values did not exceed the tolerable upper limit of 3,000 mg RE/day (Jenab et al., 2009). Allen and Haskell (2002) found that in the United States, for non-pregnant, non-lactating women aged 19 – 30 years, the median intake of vitamin A (retinol and provitamin A carotenoids) from food was 530 mg of RE/day, and the 95th percentile was 1,112 mg of RE/day. Reportedly, 17 % of this group took supplements. For these women, the median level of vitamin A in the supplements was about 1,422 mg of RE/day with a 95^{th} percentile of 2,543 m g/day. A woman who consumed the 95^{th} percentile of vitamin A from both diet and supplements would consume about 3,655 mg of RE/day, exceeding the UL of 3,000 mg/day.

107 Van den Berg et al. (1996) assessed the distribution of dietary vitamin A intake among Dutch women aged 16 - 50 and among pregnant women, and evaluated the effect of the use of a vitamin A (1,200 RE) containing multivitamin supplement in terms of nutritional and teratogenic risk. Data from the 2^{nd} Dutch national food consumption survey (1992) were used to calculate the vitamin A intake among 1,725 women aged 16 - 50 years and 58 pregnant women with and without simulation of the use of a supplement containing 1,200 RE vitamin A. Average vitamin A intake, based on a two-day dietary record method, was 850 RE for the 16 - 50 year old non-pregnant (NP) women (RDA: 800 RE), and 990 RE for the pregnant (P) women (RDA: 1,000 RE), respectively. Consuming liver on one of the survey days resulted in 60 % of the women in this subgroup exceeding 3,000 RE, and in 23 % of the cases intakes were >7,500 RE (the lowest dose found by EFSA (2006) to be hepatoxic) (Van den Berg et al., 1996). Those not consuming liver or liver products on the survey days had average intakes (NP: 540 RE; P: 720 RE]. About 70 % of the non-liver consumers had intakes below the RDA. Including the daily use of a vitamin A containing multivitamin supplement with 1,200 RE resulted in intakes >RDA, while only in 2 % (NP), and 3 % (P) of the cases did the intake exceed 3,000 RE but was still less than 7,500 RE/day. **The authors concluded that** the use of a vitamin A-containing multivitamin supplement (maximum 1,200 RE) could contribute to a controlled and adequate vitamin A intake and be considered as safe for pregnant women or women who wish to become pregnant, if the consumption of liver was completely avoided and a daily maximum limit of one liver product is consumed.

108 EFSA (2015) estimated the average dietary intake in adults as being between 816 and 1,498 µg RE/day (retinol and provitamin A carotenoids). Average daily intakes were in most cases slightly higher in males than in females, mainly due to the larger quantities of food consumed per day.

109 UK Government dietary advice, as communicated via the NHS.uk website recommends a daily vitamin A intake for adults aged 19 to 64 of 700 µg for men and 600 µg for women and that the diet should provide this. Pregnant women are warned about eating liver or liver products such as pate, or supplements that contain vitamin A to avoid potential harm to the unborn baby.

UK retinoid intake

110 Consumption data for the assessment of vitamin A intake were obtained from NDNS years 1-8 (Bates et al., 2014, 2016; Roberts et al., 2018). The NDNS is designed to collect detailed information on the diet, food consumption patterns and nutrient intake of the UK population on a rolling basis. The vitamin A content of foods consumed by NDNS respondents has been published (McCance and Widdowson's 'The Composition of Foods' – the UK food composition tables (FSA, 2019). The FSA uses CRÈME software to interrogate these dietary datasets to derive vitamin A intakes. The software derives a mean and high-level intake value from a distribution of vitamin A intakes among consumers of foods that have been reported in Appendix 1. The following data were extracted from Appendix 1. Table 2 gives the daily intake of RE in women aged 16 – 49.

Table 2. Chronic exposure of Vitamin A (retinol equivalents) in women from food sources only (Bates et al., 2014; 2016; 2018)**.

(µg/person/day)*	(µg/person/day)*	(µg/person/day)*	(µg/kg bw/day)*	(µg/kg bw/day)*
Age group	Mean	97.5th percentile	Mean	97.5th percentile
16 – 49 yrs	760	2,600	11	39
19 – 64 yrs	830	2,800	12	43

*Rounded to 2 significant figures.

**Based on total populatio.

111 Liver and liver products in the diet constitute a major source of dietary pre-formed RE. As shown in Table 3, only a small number of such consumers was recorded in the NDNS. The small number of liver consumers creates uncertainty surrounding the data. However, the Exposure Assessment Team cross referenced the data from NDNS with online sources of intake (from supermarkets and recipes) and found from these sources that the amounts consumed were similar to those in the Survey.

Table 3. Chronic exposure of Vitamin A from Liver (with recipes) in women aged 16 -49 (Bates et al., 2014; 2016; 2018)^.

(µg/person/day)*	(µg/person/day)*	(µg/person/day)*	(µg/kg bw/day)*	(µg/kg bw/day)*
Consumers**	Mean	97.5^{th} percentile	Mean	97.5^{th} percentile
25	3500	7500	50	97

*Rounded to 2 significant figures.

**Consumption or exposure estimates made with a small number of consumers may not be accurate. The number of consumers is less than 60, and estimates should be treated with caution and may not be representative for a large number of consumers. However, data are consistent with those from other sources.

^Based on food consumers on all types of liver

112 Heat-clarified butter, known as ghee, also contains appreciable amounts of vitamin A. Ghee forms a staple part of the cuisine of some Asian cultures and thus contributes to vitamin A intake in these population groups. The FSA Analytics Team investigated whether this potential, ethnicity-based dietary component, might lead to a small “hot spot” of the population being exposed to a disproportionately high intake of vitamin A. The ethnicity of ghee consumers is presented in Table 4 below. The total number of ghee consumers was 123. Only eight and two of these consumers were exposed to vitamin A from ghee above

the mean of 9.5 µg/day and 97.5th percentile of 120 µg/day, respectively (Table 4).

Table 4: Ethnicity and number (percentage) of ghee consumers.

Ethnicity	**Total ghee consumers (n=123)***	**Consumers above the mean (n=8)***	**Consumers above the 97.5th percentile (n=2)***
White	103 (84)	3 (38)	0 (0)
Black or Black British	4 (3.3)	1 (13)	0 (0)
Asian or Asian British	15 (12)	4 (50)	2 (100)
Mixed ethnic group	1 (0.8)	0 (0)	0 (0)

*Rounded to 2 significant figures.

113 Although Asian and Asian British women of childbearing age are more likely to consume ghee than those in other ethnic groups, the majority of ghee consumers were found to be White (84%). This is because White people account for the majority of the survey population. However, the highest consumers of ghee are more likely to be Asian or Asian British (Table 4). Given that Asian/Asian British, Black/Black British and white respondents represent 5.4%, 2.7% and 88%, of the total NDNS respondents, respectively it is assumed that ethnic groups likely to consume above average amounts of ghee are represented. However, the low numbers of consumers of ghee within ethnic groups in NDNS is acknowledged as an important source of uncertainty.

114 Appendix A, Table 16 gives a list of food products fortified with vitamin A. On the basis of one of these products being consumed once daily, the highest contribution for any one of them, would be an extra 432 µg RE/day (Dr

Witt Multivitamin drink).

115 Appendix A Table 17 gives a list of food supplements containing b-carotene or vitamin A. The supplements containing 1 – 7 mg of b-carotene do not have warnings against their use by pregnant women because of the accepted low risk of this provitamin, but the supplements containing various esters of preformed vitamin A (300 – 906 mg RE/serving) are not recommended in pregnancy.

116 An internet search reveals that in Norway at least, the processing of raw cod liver oil to produce the refined product for sale to the public leads to a reduction in the vitamin A and D content and these vitamins are then added back to the product so that the recommended dose to the consumer is 1,100 to 4,600 IU (330 – 1,380 mg RE) vitamin A per teaspoon. At the maximum level, 2 teaspoons of the oil would result in an intake of 2,760 mg RE per day, which is below the maximum level set by EFSA but exceeds the “appropriate” level set by EVM. Cod Liver Oil and Vitamin A: Notes | Acubalance Wellness Centre (This link is no longer live).