Implementing Vitamin D guidance - Consultation on Draft Scope

Stakeholder Comments Table

7th Jan - 1st Feb 2013

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Birmingham Vitamin D Steering Group & Birmingham Public Health	General		In Birmingham, vitamin drops are given to all babies regardless of feeding method, due to local evidence of high rates of maternal deficiency which have led to hypocalcaemia fits in formula fed babies aged less than 6 months. We believe that this should be the national guidance, as stated by COMA and the CMOs letters (http://www.dh.gov.uk/health/2012/02/advice-vitamin-d/) rather than the Healthy Start guidance about not giving drops to formula fed babies aged less than 6 months. This evidence has been around since before the Healthy Start scheme was introduced so it is disappointing that it has not been considered. In addition, recommending vitamin supplements to only breast-fed babies undermines the "breast is best" message and is hard to explain to mothers.	Thank you for this comment and supporting information. The scope for this work covers the implementation of all existing evidence guidance, including that issued by SACN, the CMO and NICE. The specific issue that you raise is covered by existing NICE health guidance on maternal and child nutrition (2008).
Birmingham Vitamin D Steering Group & Birmingham Public Health	3 e)	4	It would be worth investigating whether the fact that not all the families health professionals deal with are eligible for free vitamins causes confusion about whether non-eligible women and children also need to take vitamins. I.e. clarify whether the national scheme confuses rather than informing professionals. A universal scheme would simplify this. It is not possible for them to keeps up to date with what Over the Counter supplements they can recommend. NHS Choices website does not distinguish between sites which take Healthy Start vouchers and sites which issue vitamins. Could the impact of this on how able professionals are to advise families be explored?	Thank you for raising this issue. Any unhelpful inconsistencies between existing sources of guidance or confusion about existing guidance (by health professionals or at risk groups) are likely to be considered as part of this work.
Birmingham Vitamin D Steering	3 d)		There seems to an assumption here that a high proportion of those suffering	Thank you for this

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Group & Birmingham Public Health			vitamin D deficiency would be eligible for the Healthy start scheme. Is there evidence for this?	comment – the text has been slightly amended for clarity. The issue is that healthy start includes at risk groups. However, we recognise that women and children not eligible for healthy start may be at risk and vice versa, and there are other at risk population groups not covered by healthy start
British Association of Dermatologists	4.2.2	7	We feel that the activities/measures that will not be covered may lead to limited relevance of the proposed guidance. While we appreciate that there is a paucity of available data and evidence regarding vitamin D, for example regarding the biomarkers for deficiency and insufficiency / optimal levels for vitamin D, this type of baseline data is needed to form the foundations of any available guidance. This also applied to the examination of all the various delivery methods for vitamin D, including: I. diet II. supplements III. fortification IV. sunshine, including all the variables (skin types, geographical location, UV levels etc)	Thank you for these comments. The areas listed in section 4.2.2 are excluded from the scope as they are being considered by SACN, not because of a lack of evidence.

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			We would like to stress the importance of ensuring that the guidance development process does indeed look closely at all barriers / obstacles to uptake by clinicians / the public, including those raised by various stakeholders at the May 2011 workshop: The Healthy Start vitamins for children, which may need to be reformulated for a longer shelf life in order to be taken up by stockists Lack of suitable, licensed supplementation products Supply chain issues and lack of profitability for pharmacists Pharmacists not incentivized to provide Healthy Start products We assume these issues will all be addressed but seek clarification.	Thank you for raising these issues, which will be considered, depending on the evidence available.
British Association of Dermatologists	4.1.1	5-6	The "population groups at increased risk of vitamin D deficiency" listed in "Groups who will be covered" by the guidance should include: Those who have been advised to avoid sun exposure, due to an increased risk of skin cancer, including those previously diagnosed with skin cancer. An extended list of such groups, for each of the most common skin cancer types, is as follows: Squamous Cell Carcinoma:	Thank you for raising this issue. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearc olleagueletters/DH 13250 9). People who have
			•Older people - even those who tend to avoid the sun •Builders, farmers, surfers, sailors and people who often are out in the sun, can develop a SCC when they are quite young.	been advised to avoid sun exposure would be covered by 'people how

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			Those with a fair skin are more at risk of developing SCC than people with a darker skin. Anyone who has had a lot of ultraviolet (UV) light treatment for skin conditions such as psoriasis will also be at increased risk of getting an SCC. Those whose immune system has been suppressed by medication taken after an organ transplant, or by treatment for leukaemia or a lymphoma.	have low (or no exposure) to the sun.' Please note that NICE is also developing guidance on 'sunlight exposure – benefits and safety'
			 People who burn easily in the sun are particularly at risk. Melanoma occurs most often in fair-skinned people who tan poorly. Often they have blond or red hair, blue or green eyes, and freckle easily. Melanomas are less common in dark-skinned people. Past episodes of severe sunburn, often with blisters, and particularly in childhood, increase the risk of developing a melanoma. However, not all melanomas are due to sun exposure, and some appear in areas that are normally kept covered. People with many (more than 50) ordinary moles, or with a very large dark hairy birthmark, have a higher than average chance of getting a melanoma. Some people have many unusual (atypical) moles (known as 'dysplastic naevi'). They tend to be larger than ordinary moles, to be present in large numbers, and to have irregular edges or colour patterns. The tendency to have these 'dysplastic naevi' can run in families and carries an increased risk of getting a melanoma. The risk is raised if another family member has had a melanoma. 	Thank you for this information.

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			 People who have already had one melanoma are at an increased risk of getting another one. People with a damaged immune system (e.g. as a result of an HIV infection or taking immunosuppressive drugs, perhaps after an organ transplant) have an increased chance of getting a melanoma. Basal Cell Carcinoma: People with pale skin who burn easily and rarely tan (generally with light coloured or red hair, although some may have dark hair but still have fair skin). Those who have had a lot of exposure to the sun, such as people with outdoor hobbies or outdoor workers, and people who have lived in sunny climates. People who use sun beds or sunbathe. People who have previously had a basal cell carcinoma. 	
British Medical Association	General		We are concerned that the scope is unnecessarily restrictive in its current form, and would suggest that the guideline also covers indicators of vitamin D deficiency and management of vitamin D deficiency.	Thank you for this comment. As a short, public health topic we are not able to extend the scope to include indicators of defiency and management. You may wish to submit these areas as topics for clinical guideline here

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				http://www.nice.org.uk/get involved/topicselection/to picselection.jsp
British Medical Association	Section 3 d), e) and f)	pp.4-5	We hope that the guideline development group will provide clarity and advice to GPs on the supply of and access to vitamin D supplements (and particularly Healthy Start supplements).	Thank you for these comments – these issues are likely to be covered by the guidance, depending on the evidence available.
British Medical Association	General		We hope that the guideline will also consider what advice health professionals should give to those who are concerned about vitamin D deficiency but who are not eligible for Healthy Start supplements – e.g. what supplements to advise those patients take and where to advise patients to buy from.	Thank you for these comments – these issues are likely to be covered by the guidance, depending on the evidence available.
British Medical Association	General		The aim of the guideline seems to be promoting public awareness of the dangers of vitamin D deficiency, rather than treatment of the deficiency. We are concerned that it is currently unclear from the scope how either of these aims would be achieved.	Thank you for comments. The guidance focuses on the implementation of existing guidance to prevent vitamin D deficiency. It does not cover treatment. It will cover the activities outlines in section 4.2.1 of the draft scope ie

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				awareness and uptake among at risk groups, provision of supplements in a range of settings and update of health start vitamins.
British Nutrition Foundation	general		We are supportive of the development of guidance on this topic and have nothing further to add to the scope.	Thank you for this comment.
British Paediatric & Adolescent Bone Group	General		"This document relates to the implementation of existing guidance for the prevention of Vitamin D deficiency in at risk groups as defined by the Department of Health. It is worth noting that the Scientific Advisory Committee on Nutrition (SACN) are due to publish revised recommendations on this topic in 2014. It is conceivable that these recommendations may differ from current guidance and therefore it would be sensible to await this publication before reviewing the implementation of current guidelines. "	Thank you for this comment. NICE are aware of the work of SACN and will aim to ensure that the guidance is complementary to the work of SACN. This guidance focuses on the implementation of guidance focused on eg update and awareness, provision of supplements and update of healthy start. These issues are not being considered by SACN.
British Paediatric & Adolescent	General		"The existing guidelines on supplementation of infants need to be simplified	Thank you for this

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Bone Group			and less ambiguous. Currently it is recommended that formula fed infants do not require Vitamin drops until they are receiving less than 500mls of formula per day. It would be easier to implement a policy that ensured that all infants regardless of mode of feeding received vitamin drops. This has been safely and effectively implemented in Birmingham (see Moy RJ et al, Successful public health action to reduce the incidence of vitamin D deficiency, Arch Dis Child 2012;97:952-4.) "	comment and supporting information. This guidance will be able to consider any inconsistencies with existing guidance. The scope for this work covers the implementation of all existing evidence guidance, including that issued by SACN, the CMO and NICE. You may also wish to refer to NICE public health guidance on maternal and child nutrition (2008).
British Paediatric & Adolescent Bone Group	General		"Existing guidance recommends that infants should take a daily Vitamin supplement from the age of 6 months although it is recognised that breast fed infants may need to receive drops from 1 month of age if their mother has not taken Vitamin D supplements during pregnancy. The age of 6 months is too late to introduce vitamin supplements and does not coincide with a routine contact with a health professional. Many eligible infants will be missed by advocating such a late age of starting supplements. It would be more effective to introduce supplements from the age of 2 to 4 weeks to coincide with a routine health visitor contact. See Moy RJ et al 2012 for evidence of	Please see above.

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			effectiveness of such a scheme in Birmingham. "	
British Paediatric & Adolescent Bone Group	3e		"The current Vitamin D supplementation scheme for infants, pregnant and breastfeeding women is too closely linked with the Healthy Start programme for which many families will not be eligible. Consideration needs to be made to separate the Vitamin D guidance from Healthy Start with a separate campaign with consideration of provision of free Vitamin supplements to all pregnant women and all infants for at least the first year of life. This is encouraged in the letter of Feb 2012 from the Chief Medical Officers of Health states "NHS organisations can choose to sell the vitamins or supply them free of charge to those who are not eligible for Healthy Start and we encourage this"."	Thank you for this comment. This issue is likely to be considered in the guidance, depending on the evidence available.
British Paediatric & Adolescent Bone Group	4.2.1		"Consideration needs to be made for the introduction of an incentive to encourage health care professionals to implement the current recommendations. For example the introduction of targets for GP's or Health Visitors to ensure that a certain percentage of their eligible population are receiving Vitamin D supplements. This may be suitable for the development of a CQUIN scheme."	Thank you for this comment. This issue may be considered in the guidance, depending on the evidence available.
British Paediatric & Adolescent Bone Group	3e		"Ongoing education of relevant health care professionals is important to ensure they continue to recognise the importance of ensuring Vitamin D supplementation is received by the at risk groups."	Thank you for raising this issue.
British Paediatric & Adolescent Bone Group	General		"A guidance on prevention of rickets has to include both calcium and vit D recommendations. Within the document there is no mention of calcium intake which has equal contribution to the risk of nutritional rickets than a 250HD level, although risk groups may differ. Rickets/osteomalacia can occur with 250HD levels between 50 - 100nmol/l and low ca intake, and equally no rickets with very low	Thank you for this comment. This guidance will not consider the substance of existing recommendations but focus on the

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			25OHD and high ca intake."	implementation of existing recommendations relating to vitamin D. Issues around vitamin D and / or calcium requirements are under the remit of SACN and also existing NICE guidance on maternal and child nutrition (2008).
British Paediatric & Adolescent Bone Group	3c and 4.1.1		"Target groups - I would not limit to babies and small children but children and young people of all age groups. (Although prisoners are mentioned specifically, I think there are far more people at risk in normal households)."	Thank you for raising this issue. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearc olleagueletters/DH_13250 9). Prisoners are given as an example of groups with limited exposure to sunlight; the list is not intended to be exhausted and other groups with

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				limited exposure may be included in the guidance, depending on the evidence available.
British Paediatric & Adolescent Bone Group	General		"I think there is no point discussing awareness and prevention if they are not defining a target serum 25OHD. How [can one answer] question 4.3.1. from a patient perspective, i.e. I am in a high-risk group- has my 25OHD been checked?"	Thank you for this comment. Indicators of vitamin D status and deficiency are under the remit of SACN and are outside the scope for this work. NICE will aim to work closely with SACN to ensure consistency.
British Paediatric & Adolescent Bone Group	2c		"NICE/DH directs this to everyone in the health sector (2c), rather than making it obligatory to neonatal units, GPs (6 weeks check) to identify at-risk patients and prescribe Vitamin D. Therefore, guidance is widely ignored, nobody takes the responsibilityThis is wrong and needs to be changed."	Thank you for this comment. As a short, public health topic we are not able to extend the scope to include indicators of deficiency and management. You may wish to submit these areas as topics for clinical guideline here http://www.nice.org.uk/get involved/topicselection/to

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				picselection.jsp. You may also be interested in existing NICE public health guidance on maternal and child nutrition (2008).
British Paediatric & Adolescent Bone Group	General		"The guidance should cover subjects with chronic diseases as well-which could simply be the recommendation to keep 25OHD above 50nmol/L."	Thank you for this comment. Indicators of deficiency among different population groups is outside the remit of this guidance and is covered by SACN.
Child-Nutrition.co.uk Ltd	3c	3	Vitamin D deficiency can occur at any age not just during periods of rapid growth, pregnancy and breastfeeding	Thank you for this comment; the text has been slightly amended for clarity.
Child-Nutrition.co.uk Ltd	3c	3	Infants who are born with low vitamin D levels because of their mother's low levels during pregnancy are at risk of deficiency in the early weeks of life whether breast fed or formula fed. They may suffer hypocalcaemic fits or tetany due to their low levels.	Thank you for this comment.
Child-Nutrition.co.uk Ltd	4.1.1	6	People at risk should also include adolescents who are going through their pubertal growth spurt	Thank you for raising this issue. The population groups listed in section 4.1.1 of the scope reflects

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				the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/ Publicationsandstatistics/ Lettersandcirculars/Dearc olleagueletters/DH 13250 9).
Child-Nutrition.co.uk Ltd	4.1.1		People at risk should also include: • children who have insufficient exposure to sunlight through lifestyle and clothing choices Bone length and/or density increases throughout childhood and satisfying calcium deposition in bone is dependent on their vitamin D status. Hence any children without sufficient sunlight exposure are also an at risk group.	Thank you for this comment. This group would be included in the guidance as noted in section 4.2.1 re 'People who have low (or no) exposure to the sun. For example, people who cover their skin for cultural reasons'.
Child-Nutrition.co.uk Ltd	4.1.1		People with dark skin should also Include people of middle eastern origin	Thank you, the text has been amended in line with your comment.
Danone Baby Nutrition	3a	3	The need for guidance indicates that dietary sources of vitamin D are limited. Infant formula is listed after margarines and breakfast cereals. Infant formula and growing up milks for toddlers contain significant amounts of vitamin D (1.2-1.7mcg/100ml) and depending on the age of the child and whether a child follows the recommended intake advised, they can provide 100% of their daily	Thank you for this information.

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Danone Baby Nutrition	31	3	reference nutrient intake of vitamin D. Definition of low vitamin D status may well be conservative. Even though previous research has used this cut off to define low vitamin D status, more recent research refers to a cut off of below 50nmol/l and therefore may greatly affect the population level of deficiency.	Thank you for this comment. Issues around vitamin D status are under the remit of SACN and are outside the scope for this work.
Danone Baby Nutrition	3d	4	In most instances, an intake above the RNI can only be guaranteed by taking a vitamin D supplement. As highlighted above in comment from section 3a, if a child is consuming infant formula or growing up milk, it is in fact quite likely that they will be receiving an intake of their RNI.	Thank you for this information. The inclusion of 'In most instances' in this sentence addresses this point.
Danone Baby Nutrition	3e	4	All at-risk groups should be made aware of how they can obtain the vitamins locally This wording is inappropriate because not all "at risk" groups are eligible for the healthy start vitamins. The vitamins should be seen as a separate initiative to healthy start and be made universal to all. One caveat is there is no evidence to suggest that vitamins A & C are deficient in the general population and so a supplement sole comprising of vitamin D together with the dietary inclusion of fortified foods, would be more appropriate for ubiquitous intervention.	Thank you for this comment. The guidance will consider the provision and availability of supplements (not just healthy start) in a range of settings for the different population groups at risk.

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Danone Baby Nutrition	4.2.2	7	The fortification of food and drinks with vitamin D will not be included in this guidance Given the above comments of how fortified milks can help ensure the under 5's get appropriate amounts of vitamin D, this could be an effective strategy to prevent deficiency in this "at-risk" population group. The child's intake of such a product should be considered even when advice is given on supplementation.	Thank you for raising this issue. SACN is considering the relative contribution of diet to status.
Department of Health	General		I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you.
Feeding for Life Foundation	1	1	This work will concentrate on <i>existing</i> guidance about the prevention of vitamin D deficiency and in particular the role and implementation of vitamin D supplementation, ie relating to those recommendations contained in the CMOs letter of 2012 and the NICE Public Health Guidance 11 "Improving the nutrition of pregnant and breastfeeding mothers and children in low-income families". However it must be noted that the Scientific Advisory Committee on Nutrition (SACN) is currently also reviewing the evidence base for vitamin D supplementation and is due to publish a report in September 2014 (ie after the conclusion of the NICE work). On the basis of new information and a much wider scope, SACN may well make <i>new</i> recommendations about vitamin D supplementation and other means of prevention of vitamin D deficiency (such as extended food fortification). Subsequently this new NICE guidance may become rapidly out of date.	Thank you for this comment. NICE are aware of the work of SACN and will aim to ensure that the guidance is complementary to the work of SACN. This guidance focuses on the implementation of guidance focused on eg update and awareness, provision of supplements and update of healthy start. These issues are not being considered by

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			NICE may therefore wish to consider delaying this work on implementation of guidance until after the publication of the SACN report (or at least in collaboration and at the same time as SACN).	SACN.
Feeding for Life Foundation	2	1	The stated focus of the new NICE guidance is on <i>at risk population groups</i> for vitamin D deficiency. However the concept of "at risk groups" is an inherent contradiction to the recommendations in the CMOs letter highlighting that ALL pregnant, breastfeeding and children under 5 years and older people aged 65 and over should receive supplementation as these population groups living in the UK are unlikely to get their vitamin requirement from sunlight exposure and food sources. Not only are new at risk groups being recognised such as adolescents (see Absoud M et al. Prevalence and predictors of vitamin D insufficiency in children: a Great Britain population based survey. PLoS ONE 2011;6:e221279:1-6) but it is becoming increasing clear that the whole UK population is deficient in vitamin D especially given current climatic conditions. Additional new evidence currently being evaluated in detail by SACN points to the likely association between low vitamin D status and a wide range of adult diseases. The focus therefore needs to shift from the prevention of vitamin D deficiency in at risk groups only to prevention in the whole population.	Thank you for raising this issue. This guidance focuses on the implementation of existing recommendations. The published guidance will be reviewed after 3-5 years. If there is new evidence or guidance at that point a decision may be taken to update the guidance.
Feeding for Life Foundation	3a	3	The importance of vitamin D and dental and oral health	Thank you for raising this

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Feeding for Life Foundation	3a	3	Sunlight synthesis of vitamin D is only sufficient to supply daily needs during the summer months. Adequate amounts cannot be stored in fat to last 6 months of winter without additional exogenous supplies (Scientific Advisory Committee on Nutrition 2007).	issue. Thank you for raising this issue. The scope states that 'Existing evidence suggests that from October to April in the UK, there is no ambient ultraviolet sunlight of the appropriate wavelength.' Sun exposure is outside the remit of this guidance. However, DH has asked NICE to develop public health guidance on 'Sunlight exposure: benefits and safety. NICE public health guidance'
Feeding for Life Foundation	3 subnote	3	Definition of low vitamin D - many surveys of vitamin D population status have used a blood level cut off of less than 25nmol/l to define deficiency. More recently a higher cut off of <50 nmol/l has been used thereby greatly increasing the numbers with states of insufficiency or deficiency.	Thank you for this comment. Vitamin D status is being considered by SACN and is outside the remit of this guidance.
Feeding for Life Foundation	3d	4	SACN is also reviewing the evidence base for setting the RNI for vitamin D that has so far directed the current level of dosage for supplementation. The RNI may well be increased which would then justify a higher supplementation	Thank you for this comment. Any changes to the dosage of

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			dosage. Supplementation doses higher than the 7-8.5µg recommended for children in the UK are currently used in the USA (10µg) and Canada (20µg during the winter months for areas on a similar latitude to the UK). Furthermore significantly a higher supplementation dosage (100µg) is recommended for pregnant and lactating women in the USA (Hollis B et al. Am J Clin Nutr 2004;80:S175-8, Hollis B et al. J Bone and Mineral Research 2011;26:2341-57) Therefore along with the possibility of the RNI being raised, recommendations for the supplementation dosage may need to changed.	supplements is unlikely to change the substance of recommendations in the guidance which is focused on awareness and uptake of advice, availability and provision of supplements and uptake of healthy start.
Feeding for Life Foundation	3d	4	The USA also recommends supplementation starting soon after birth (rather than at 6 months in the UK) and continuing to adolescence (Wagner C et al. Prevention of rickets and vitamin D deficiency in infants, children and adolescents. Pediatrics 2008;122:1142-52) Consideration needs also be given to the timing of starting supplementation.	Thank you. This guidance is focused on the implementation of existing guidance rather than the substance of existing guidance.
Feeding for Life Foundation	3e	4	Surveys of health professionals have revealed a low level of awareness of vitamin D recommendations and policy and of the Healthy Start scheme (Jain V et al. Arch Dis Child 2011;96 (Suppl 1) A16-17), Feeding for Life Foundation 2011). There is therefore a need for greater education of health and social care	Thank you for raising this issue and providing relevant references. Awareness and uptake of recommendations is a key aspect of this

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			professionals including GPs, Health Visitors, Health Visiting Teams, Midwives, Practice nurses, Obstetricians and Early Year Practitioners (EYPs) in social and day care settings etc. HV's and EYPs have the opportunity to promote this, as they continue to deliver a universal service.	guidance.
Feeding for Life Foundation	3e	4	The DH Healthy Start programme is primarily about the provision of food vouchers for low income families in receipt of state benefits. The vitamin supplementation component for pregnant women and young children has had a poor rate of uptake nationally (see DH Healthy Start coverage statistics). Many "at risk" families by virtue of being of dark skinned Asian origin will not be eligible for Healthy Start vitamins if they are in employment. Surveys have shown that they may have low levels of knowledge about vitamin D and may not receive advice from health professionals to purchase supplements themselves (Sharma V et al. Arch Dis Child 2011;96 (Suppl 1) A62, Feeding for Life Foundation 2011) To specifically prevent vitamin D deficiency diseases, the vitamin supplementation component of Healthy Start needs to be separated from the food voucher programme and re-launched as a national vitamin D deficiency prevention programme through universal supplementation of the whole population.	Thank you for this comment. Uptake of healthy start among those eligible and provision of supplements for those not eligible is likely to be a key issue for consideration during the development of this guidance.

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Feeding for Life Foundation	3f	5	Health and Wellbeing Boards/ CCG's need to consider options for increasing the availability and uptake of Healthy Start and supplementation. Uptake will not increase without a multi- focused approach. Training of HCP's is required alongside some form of social marketing directed at consumers.	Thank you for raising this issue.
Feeding for Life Foundation	3f	5	As clinical vitamin A and C deficiency are not conditions seen in the UK and that dietary intake and blood levels of these vitamins are generally satisfactory, a vitamin D only supplement needs to be considered instead of the existing Healthy Start A, C and D combinations or the various commercially available vitamin supplement preparations. It may be possible to reduce the cost of Healthy Start vitamins if they only contained vitamin D.	Thank you for raising this issue.
Feeding for Life Foundation	4.1.1	6	Although the CMOs letter has particularly highlighted the needs of the elderly and housebound, there has been no national programme to raise awareness amongst health professionals and the general population about the needs of this very vulnerable group.	Thank you for raising this issue.
Feeding for Life Foundation	4.2.1	6	The existing targeted national Healthy Start programme has failed to reduce the prevalence of vitamin D deficiency disease in children as evidence by continuing publication of case reports (Ahmed S et al. Arch Dis Child 2011;96:694-6) However a unique programme of universal vitamin D supplementation of pregnant women and young children in Birmingham combined with increased public awareness has significantly reduced clinical cases (Moy R et al.	Thank you for these comments and references.

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			Successful public health action to reduce the incidence of vitamin D deficiency. Arch Dis Child 2012;97:952-4). This study lends support to the concept of whole population supplementation.	
Feeding for Life Foundation	4.2.2.	6	Although there are quite a few areas not in the remit they are all relevant and need to be considered, to give guidance and direction to practitioners, in particular "length and intensity of sun exposure for different population groups." People are very uncertain about this because of conflicting messages over time.	Thank you for this comment. As a short piece of public health guidance the scope needs to be tightly focused. For info, DH has also asked NICE to develop public health guidance on Sunlight exposure: benefits and safety.
Feeding for Life Foundation	Appendix A	11	The statement could be misleading "the safe implementation". This statement should be made clearer. It seems to mean safe with regard to ensuring people do not receive sub optimal levels of vitamin D. However the statement could give the impression that there is a tight window of safety with regard to dosage and that it is easy to overdose. The evidence shows that it is very difficult to over dose.	Thank you for this comment. This was the original referral from DH. We consider that we have improved the clarity with the stated title of Vitamin D: implementation of existing guidance to prevent deficiency. For information, NICE has had a series of clarification meetings

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				with DH.
Go-Kyo Science Ltd	General	General	Consideration should be given to help provide clarity between insufficiency and deficiency. Insufficiency should be mentioned as a specific issue separated from deficiency	Thank you for this comment. Identification and assessment are outside the remit of this work which is focused on implementing existing guidance.
Go-Kyo Science Ltd	3a	3	Consideration should be given to how the recommendations here are aligned or not to the sun safe strategy	Thank you for this comment. DH have also asked NICE to develop public health guidance on Sunlight exposure: benefits and safety. We will ensure consistency with this work. For info, SACN is considering thresholds for deficiency and excess http://www.sacn.gov.uk/meetings/working_groups/vitamin/index.html
Go-Kyo Science Ltd	3b	3	With regards to discrimination issues it should be highlighted that individuals with darker skin have ahigher propensity to both being Vitamin D deficient and insufficient	Thank you – we are of the view that the existing text makes clear that individuals with darker skin

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				are at greater risk of deficiency, as stated in existing guidance.
Go-Kyo Science Ltd	3e	4	It is suggested that health professionals could make 'a significant difference' if they ensure those at risk of vitamin D deficiency understand how important the vitamin is. With this in mind it is suggested that reference is made to health professionals providing good and consistent advice to sun exposure and therefore safe sun exposure rather than covering up or over using sun creams.	Thank you for this comment. DH have also asked NICE to develop public health guidance on Sunlight exposure: benefits and safety. We will ensure consistency with this work.
Go-Kyo Science Ltd	3e	5	The cost effectiveness of implementing existing guidance on Vitamin D remains unclear- this point should be elaborated upon since prescription data is widely available as is consumer sales data.	Thank you – given the limited space in the standard scope template we are of the view that the information provided on cost effectiveness, the availability and cost of supplements is clear and sufficient. This issue may be expanded on in the final guidance depending on the evidence available and economic modeling undertaken.
Go-Kyo Science Ltd	3f	5	Secondary care costs should be included. The primary care costs include unlicensed medicines used and the need for licensed preparations should be highlighted. Also it is not clear if this cost relates to both insufficiency and	As above.

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			deficiency combined or deficiency alone.	
Go-Kyo Science Ltd	4	6	The report should consider insufficiency as a distinct group	Thank you for this comment. Identification and assessment are outside the remit of this work which is focused on implementing existing guidance.
Go-Kyo Science Ltd	4.2	6	It is recommended that a further activity be considered with regards to 'safe sun exposure'. Since most people can get adequate Vitamin D from sunlight exposure, this guideline should be clear and consistent with regards to the advice to ensure this is consistent with aspects of overexposure (i.e. cancer risk) and sun cream usage.	Thank you for this comment. DH have also asked NICE to develop public health guidance on Sunlight exposure: benefits and safety. We will ensure consistency with this work.
The Infant & Toddler Forum is supported by an educational grant from Danone UK. The views and outputs of the group, however, remain independent of Danone UK and its commercial interests	3c	3	Vitamin D deficiency can occur at any age not just during periods of rapid growth, pregnancy and breastfeeding	Thank you for this comment; the scope has been amended for clarity.
The Infant & Toddler Forum is supported by an educational grant from Danone UK. The	3c	3	Infants who are born with low vitamin D levels because of their mother's low levels during pregnancy are at risk of deficiency in the early weeks of life whether breast fed or formula fed. They may suffer hypocalcaemic fits or	Thank you for this comment

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views and outputs of the group, however, remain independent of Danone UK and its commercial interests			tetany due to their low levels.	
The Infant & Toddler Forum is supported by an educational grant from Danone UK. The views and outputs of the group, however, remain independent of Danone UK and its commercial interests	3e	5	Those who are at a higher risk of vitamin D deficiency may not be eligible for Healthy Start vitamin supplements.	Thank you for this comment.
The Infant & Toddler Forum is supported by an educational grant from Danone UK. The views and outputs of the group, however, remain independent of Danone UK and its commercial interests	4.1.1	6	People at risk should also include • adolescents who are going through their pubertal growth spurt.	Thank you for raising this issue. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearc olleagueletters/DH 13250 9).
The Infant & Toddler Forum is	4.1.1	6	People at risk should also include:	Thank you for this

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supported by an educational grant from Danone UK. The views and outputs of the group, however, remain independent of Danone UK and its commercial interests			children who have insufficient exposure to sunlight through lifestyle and clothing choices. Bone length and/or density increases throughout childhood and satisfying calcium deposition in bone are dependent on their vitamin D status. Hence any children without sufficient sunlight exposure are also an at risk group.	comment. This group would be included in the guidance as noted in section 4.2.1 re 'People who have low (or no) exposure to the sun. For example, people who cover their skin for cultural reasons'.
The Infant & Toddler Forum is supported by an educational grant from Danone UK. The views and outputs of the group, however, remain independent of Danone UK and its commercial interests	4.1.1	6	People with dark skin should also include people of middle eastern origin.	Thank you, the text has been amended inline with your comments.
The Infant & Toddler Forum is supported by an educational grant from Danone UK. The views and outputs of the group, however, remain independent of Danone UK and its commercial interests	4.2.2	7	In line with recommendations outlined in RCPCH's position statement in December 2012, fortification of foods is a strategy for prevention of vitamin D deficiency used in several countries outside the UK. Further scoping into the role of the food industry "in regards to the fortification of foods and milk with vitamin D" is recommended.	Thank you for this comment. Fortification of foods is outside the remit of this guidance.

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Internis Pharmaceuticals Ltd	General		The document should mention that there are licensed medicines available for the prevention of vitamin D deficiency and treatment of insufficiency. The difference between these licensed medicinal products and unlicensed food supplements and the risks associated with the unlicensed products, particularly in certain populations, needs to be addressed throughout the guidance note.	Thank you for raising this issue. The scope notes that the guidance will consider the provision of supplements. Management of deficiency is outside the remit of this work.
Internis Pharmaceuticals Ltd	3f)	5	The guidance note should distinguish between licensed medicinal products that are available and unlicensed food supplements. The public needs to be aware that unlicensed vitamin D3 food supplements are subject to a very wide potency range (65% to 160%) so care should be taken with these. Licensed vitamin D3 products are controlled to much tighter potency tolerances and subjected to impurity controls. It would also be worth differentiating between activity of vitamin D2 and the pro-hormone vitamin D3 since vitamin D2 is about one third as active as vitamin D3 (weight for weight).	Thank you for raising this issue. The scope notes that current provision will be considered.
Internis Pharmaceuticals Ltd	3f)	5	The phrase 'Pharmacies may sell other commercially available supplements containing vitamin D at a higher price' is too general as product prices vary. Also this clause does not state that vitamin D is available on prescription (and prescriptions are free in Scotland and Wales and to many patient groups in England)	Thank you for raising this issue. A note about the availability of supplements at pharmacies or on prescription has been added to the scope.
Internis Pharmaceuticals Ltd	4.1.1	6	The safety implications for the certain patient groups (e.g. elderly, renally impaired, those suffering with hepatic and cardiac insufficiency) need to be	Thank you for this comment. The

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			addressed. The effect of concomitant medicines may also be an issue in some patient groups and supporting plasma levels may need to be monitored.	management of other conditions is outside the remit of this work. However, any potentially adverse outcomes identified in evidence will be considered.
Internis Pharmaceuticals Ltd	4.1.1	6	People with malabsorption should be added as a group as they are at risk of vitamin D deficiency.	Thank you for this comment. People with diseases or conditions which may be associated with an increased risk of vitamin D deficiency are excluded from the scope for this work.
Internis Pharmaceuticals Ltd	4.1.1	6	People living in northern latitudes should be added as a group at risk.	Thank you for this comment. Thank you for raising this issue. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/Publicationsandstatistics/

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				<u>Lettersandcirculars/Dearc</u> <u>olleagueletters/DH 13250</u> <u>9</u>).
Internis Pharmaceuticals Ltd	4.3	7	Professional training is mentioned. Internis Pharmaceuticals Ltd provide training sessions to healthcare professionals on the use of Vitamin D3. This could be extended further.	Thank you for this information.
Internis Pharmaceuticals Ltd	4.3	8	Question 3 – Many people are treated for Vitamin D deficiency (or prevention of vitamin D deficiency) with unlicensed food supplements. There is an inconsistency of the potency of these unlicensed food supplements and this can cause problems. Dietary differences (cultural and socioeconomic), latitudinal public health differences and education all cause inconsistency.	Thank you for raising this issue. The scope notes that the guidance will consider the provision of supplements. A note has been added to the scope re the variation in content and cost of products available.
Internis Pharmaceuticals Ltd	4.3	8	Indicators of product available – This should list licensed products first. It needs to be highlighted that the quality and safety of licensed products is assured following assessment of the data supporting the product by the Medicines and Healthcare products Regulatory Agency, manufacture according to Good Manufacturing Practice and Pharmacovigilance.	Thank you for this comment – products available could include those listed as medicines and those listed as food supplements.
Internis Pharmaceuticals Ltd	4.3	8	There is a new NHS guideline (East & South East England Specialist Pharmacy Services; "Vitamin D deficiency and insufficiency – Using appropriate available products", January 2013) which categorises products into risk categories based on their licensing status)	Thank you for providing this information

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Liverpool Primary Care Trust	Section 4.3 Q1	7	From Liverpool PCT (Dr Katy Gardner lead clinician) please see below for general comments: In Liverpool we plan to publicise/ launch our universal supplementation plan with both the public and health professionals. We have already done a much work on increasing awareness locally of risk factors for Vitamin D deficiency. Steps we have taken so far include: Putting guidelines for Vitamin D prevention, detection and treatment on Map of Medicine for all local GPs including identifying those at risk. They are also on the Mersey Medicines management website (2012). Education sessions for GPs at neighbourhood, practice and locality level. Ensuring that medicines management team had Vitamin D deficiency prevention and treatment guidelines as part of their programme working with practices in 2012. This counts towards practice QOF so meetings have been well attended by GPs. Giving information to all GPs and health visitors about prevention of Vitamin D deficiency and Healthy Start as part of the Baby Friendly/breast feeding campaign. Most GPs in Liverpool attended these sessions as this was given high priority by the PCT.	Thank you for providing this information.
Liverpool Primary Care Trust	4.3 Q2	8	In Liverpool we have costed out our Healthy Start provision with public awareness and health professional awareness campaigns. Despite maximum effort (see above) uptake of Healthy Start is very poor. We have decided that it would be more cost effective to implement city wide free supplementation based on the Healthy Start scheme for pregnant women	Thank you for this information – it would be helpful if you could submit this data as part of any call for evidence to

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			and infants and young children. (There have been several documented cases of rickets in young children in Liverpool in last few years resulting in unnecessary suffering and needing expansive treatment. I personally dealt with 2 as a GP (both before GP guidelines were issued) and neither would have qualified for Healthy Start. In our view the existing Healthy Start Scheme is not currently effective and not targeted necessarily at women at risk. We are working with local maternity providers (Liverpool Womens Hospital trust) as universal supplementation is likely to result in decrease in testing for deficiency in pregnant women which could be a cost saving. We strongly feel that a universal supplementation is the only way forward to address this issue effectively, equitably and cost effectively.	support the economic modelling for this guidance. Data of this type will be vital to consider, for example, the proportionate uptake of healthy start and of free supplementation citywide, and possibly also the costs involved. There may be variations in the magnitudes of the proportions between locations.
Liverpool Primary Care Trust	Q3	8	The current voucher system for Healthy Start hinders the implementation of the guidance as it is complex and confusing to both at risk groups/ pregnant women and women with young children and health professionals. We need to move to universal supplementation and this is what we plan in Liverpool Vitamin D supplementation should be available through a national programme for all children under 5, following the recent recommendation by the CMO. This should be available without forms being completed for eligibility, and via health workers at community level (HVs, midwives, children's centres). This is what we plan to do locally.	Thank you for raising this issue. For info, while existing NICE guidance on maternal and child nutrition (2008) had a particular focus on disadvantaged groups, many of the recommendations are aimed at all women and children (as appropriate).

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			The original NICE guidance should have not have been restricted to low income households, but applicable to all children.	
Liverpool Primary Care Trust	Q4		Despite a huge amount of effort we in Liverpool have not managed to have anything approaching a reasonable uptake of HS. Healthy Start vitamins should also be available at the least in pharmacies and on FP10. They are not at present. We currently have them available in some health centres and chilrdens centres but there is waste as they are not all used and shelf life not very long. We plan to deliver our universal supplementation scheme through Childrens centres, health centres and the Liverpool Womens Hospital and decrease waste through increased uptake.	Thank you for raising this issue and information about your practice. Please also refer to the response to the item which is 2 comments above this one.
· · · · · · · · · · · · · · · · · · ·	Outcomes/gen eral	8	The only way to obtain the outcomes you wish to achieve is to have a well publicised universally free supplementation scheme form pregnant women and children under 5. This would be the logical conclusion form CMO letter to clinicians in Feb 2012.	Thank you for this comment and a name to contact.
National Osteoporosis Society	General		In June 2011 the All-Party Parliamentary Osteoporosis Group (APPOG) reported on its 'Inquiry into the role of nutrition in preventing osteoporosis and promoting good bone health' (http://www.nos.org.uk/document.doc?id=894). This inquiry found that official guidance is being used inconsistently and is inadequately promoted and it recommended that existing guidance on dietary supplementation must be implemented more effectively. The National Osteoporosis Society welcomes the development of Public	Thank you for this reference.

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			Health Intervention Guidance on Implementing vitamin D guidance which addresses this recommendation.	
National Osteoporosis Society	4.1.1	6	We agree that the population groups listed should be included in the scope. We would like to see the addition of vegans and vegetarians who choose not to consume eggs or fortified spreadable fats	Thank you for this comment. Thank you for this comment. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearc olleagueletters/DH 13250 9).
National Osteoporosis Society	4.3	8	With the expected outcomes measures of 'reported barriers' and 'indicators of product availability' it is important to ensure that appropriate dosage formulations of vitamin D for all groups, both with and without calcium supplements are considered.	Thank you for raising this issue. The scope notes that the guidance will consider the provision of supplements. A note has been added to the scope re the variation in content and cost of products available.

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National Osteoporosis Society	General		We would like to alert NICE to the National Osteoporosis Society is due to publish 'Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management' which • provides clear recommendations on treatment of vitamin D deficiency in relation to bone health and fracture prevention for primary, secondary and social care health professionals • aids in the identification of people at risk of vitamin D deficiency; propose effective measurement techniques and reference ranges	Thank you for alerting us to this publication. Please note that identification of deficiency / insufficiency and management are outside the scope of this work.
NHS Greater GIsgow and Clyde			Throughout the document it is clear that the focus is on Engand, its systems and the DOH and whilst NICE produce for the DOH, it may be a more collaborative with the 4 Health Departments and systems (as the CMO's did in their joint letter). This would save save us time from having to adapt the final document for the 4 countries. Having been involved in translating CEL 36 for Scotland, it was hugely time consuming. Since Scotland has no control over Healthy Start it would be additionally appropriate to produce a joint document.	Thank you for this comment. NICE public health guidance only applies to England.
NHS Greater Glsgow and Clyde			The document refers to the supply chain as embedded and it is far from it in many areas. There are practical supply and distribution issues and integrity of the supply chain varies considerably. The proposed scope makes assumptions about this and it's not equitable across the UK.	Thank you for this comment. NICE has been made aware that there are problems with supply and provision, and that uptake of healthy start varies markedly between areas. These issues are likely to be considered during the development of

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NHS Greater Glsgow and Clyde			We would suggest that HA'S and HB's need some guidance on mapping the processes and care pathway from recommendation to compliance with vitamin taking. This document would be a good place to really make some practical difference.	the guidance. Thank you for this comment.
NHS Greater Glsgow and Clyde			The scope appears unwilling to acknowledge that the current supplementation method and actual preparation may not be the most effective, cost effective and sustainable method of doing this. On the ground, we are aware of this and would like this document to be open to including some evidence reviews and discussion in the scope. Other EU countries have been much more successful and these methods should be explored.	Thank you for this comment. The scope notes that the guidance will consider the provision of supplements. The revised scope notes that there is wide variation in vitamin content and cost and some products may not be suitable for particular at risk groups. A note has been added to the scope re the variation in content and cost of products available.
NHS Greater Glsgow and Clyde			There is no opportunity to review the actual supplement preparations for normal supplementation. Additionly, it's not always specialists who are prescribing traeatment doses and some guidance would be helpful or a referral pathway suggested for more severe cases.	Thank you for this comment. Please see above. Legislative issues around supplements is

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				outside the remit of this guidance.
NHS Greater Glsgow and Clyde			We are clear that there is more to this and having the a group of Profs involved in past campaigns they recommend that we review the actual cases of rickets and cardiomyopathies including reviewing the diet histories of those affected. There are likely to be lessons to be learned.	Thank you for this comment.
NHS Greater Glsgow and Clyde			We would recommend that the document provides guidance on risk managing cases, monitoring and audit, measuring population incidence and prevalence.	Thank you for this comment. The scope, as it stands, does not preclude consideration of these issues and the guidance may consider these, depending on the evidence available.
NHS Greater Glsgow and Clyde			Whilst it mentions higher risk groups, the scope directs you to socioeconomic deprivation targeting. HS vitamins don't target high risk groups necessarily. Deprivation is not the highest risk	Thank you for this comment. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearc olleagueletters/DH 13250

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				g). NICE is aware that those eligible for healthy start may not be considered at risk and vice versa, and the final guidance is likely to reflect this. The draft scope notes that it is possible for those not eligible for Healthy Start to buy Healthy Start supplements and this has been encouraged in some areas (DH 2011b).
NHS Greater Glsgow and Clyde			There is no mention of disadvantaged groups such as Asylum seekers and how we support them. This is a major inequality issue. They are extremely poor but not entitled to HS benefit. They also have a high proportion of at risk groups.	Thank you for raising this issue. Asylum seekers from one of the at risk groups highlighted in section 4.1.1. of the draft guidance would be covered.
NHS Greater Glsgow and Clyde			In general, we feel that the scope of the document simply concurs with the conclusions of previous working groups with minimal discussion of the epidemiology of vitamin D deficiency, rickets or osteomalacia or of current issues relating to optimum vitamin D intakes. There are no references to the	Thank you for these comments. The guidance is focused on the implementation of existing

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			role of dietary factors or patterns of dietary intake {lactovegetarianism, high fibre intakes, low calcium intakes} as risk factors for rickets. Apart from late weaning, no references to the success or failure of past rickets campaigns in the UK, and no references to the problems of promoting supplement uptake with the current range of preparations.	recommendations rather than focusing on the substance of existing recommendations. The effectiveness of interventions to reduce the risk of rickets or problems around increasing update of supplements is within this scope, as reflected in the draft questions in section 4.3 of the draft guidance.
NHS Greater Glsgow and Clyde			As regards the rickets prevention programme in Scotland is concerned, our needs are slightly different as compaired to those of England and Wales. We know the problem of Vitamin D exists in people in Scotland irrespective of their age and ethnicity.	Thank you for raising this issue. NICE public health guidance applies to England only.
NHS Greater Glsgow and Clyde			We fear that the possible outcome, based on the current scope, of this exercise, whilst it may appear authoritative, is for it to make recommendations which will be little different from those made over 30 years ago. There may be subsequent improvements in uptake in some of the target groups for a year or two and then there will be a return to vit D deficiency states. Recommendations for the south-east of England would not necessarily be	Thank you for this comment. The guidance will be focused on the implementation of existing guidance and depending on the evidence available may be able to make

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			appropriate for the west of Scotland because of latitudinal, cloud cover, dietary and other differences. One particular target group for "Nice" to emphasise would be young pregnant women aged less than 19 years. The Ruston, Hoare and Henderson 2004 diet and nutrition survey covered only the 19-64 yr age spectrum. They reported that a quarter of non-pregnant women aged less than 19 yrs were vit D deficient. When women younger than 20 years, also likely to be vit D deficient and with their own bone growth incomplete, become pregnant there is competition between the fetus and young mother for the limited amount of available "free" Calcium, Magnesium and Phosphorus. This results in maternal hyperparathyroidism with osteoclastic release of these elements from maternal bone and can cause adverse events in the mother, embryo, fetus and young infant. The report due in 2014 from SACN may provide a little more information and guidance on which to base future advice.	useful recommendations on cost effective interventions to increase uptake and improve provision. As noted above, NICE public health guidance applies to England only. Thank you for raising the issue of young pregnant women and associated references. NICE will ensure that the guidance is consistent with the SACN work.
NHS Sheffield	General comments		Disappointing remit in that the subject is being considered from the point of view only of nutritional supplements NOT ensuring we all have adequate sun exposure. Vit D fdeficiency is essentially a lack of sunshine - not a nutritional deficiency as 90% of our vit D comes from sunshine. What we need therefore is much wider public health awareness of this and guidance about appropriate sun exposure - including for different degrees of skin pigmentation - to give us the vit D we need whilst not overdoing it and risking skin cancer. This is quite	Thank you for this comment. Please note that DH has also asked NICE to develop guidance on 'sun exposure: benefits and safety' (publication date

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NHS Sheffield	General comments in relation to Question 1		simple advice and should be part of NICE guidance. The Sheffield guidelines are clear and available to all. A well attended PLI was held last year to raise awareness amongst medical professionals	to be confirmed). Thank you for alerting us to these references. The NICE guidance is focused on improving the implementation of existing guidance.
NHS Sheffield	General comments in relation to Question 2		We have a range of simple patient leaflets available through the Medicines Management Team /PCT internet.	Thank you for alerting us to these resources.
NHS Sheffield	General comments in relation to Question 3		It would help planners and Health and Wellbeing Boards make policies about the benefits of being outdoors. The advice is available - it doesn't need more research.	Thank you for this comment. NICE has also issued guidance on physical activity, the physical environment and walking and cycling. However, this guidance is about the implementation of existing guidance on vitamin D, with key questions around how best to increase awareness and how best to improve provision and

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				access to supplements (healthy start or otherwise).
NHS Sheffield	General comments in relation to Question 3		Vit D advice is given by health profession. Healthy Start vits are provided by the LA. The two don't connect. Most GPs considering vit d deficiency will offer blood testing then feel obliged to offer prescription products - at considerable expense.	Thank you for this comment.
NHS Sheffield	General comments in relation to Question 3		Of those at risk or symptomatic for vit D deficiency - a large percentage have severe deficiency. Healthy Start doesn't provide enough for this group. Not all have symptoms. I would estimate 60% have severe deficiency. So simple advice to at risk groups will miss large numbers of people who need higher doses. If we identify deficiency, ProD3 20,000u for 12 weeks advised, gelatin free	Thank you for this comment. The guidance is focused on prevention; management of deficiency is outside the scope of the work.
			etc/good value (* or desunin licensed product)	
NHS Sheffield	General comments in relation to Question 4		Pregnant women have to prove eligibility for Healthy Start which takes some weeks therefore they wouldn't get access unless prescribed by the GP.	Thank you for raising this issue.
NHS Sheffield	General comments in relation to Question 4		Only a few childrens centres in Sheffield give out the vitamins - access again. Pregnant women, breast fed and children under 5 should be encouraged by their GP to buy these vitamins.	Thank you for raising this issue.

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NHS Sheffield	General comments		This is an area which is purely lifestyle related which looks set to consume ever more medical resources in terms of time, testing, prescribing, chasing up non- compliers, retesting	Thank you for this comment.
NHS Wakefield District	3.c	4	Not just those who are housebound or prisoners, but also those living in care homes who are less able to influence their health and may not always be able to get outside.	Thank you, the scope has been amended in line with your comments.
NHS Wakefield District	3.e	4	Not only how people can apply for Healthy Start but also support them to apply. This will reduce inequalities of literacy.	Thank you for raising this issue. The scope as it stands does not preclude consideration of this issue.
NHS Wakefield District	4.2.1	6	Ensure that the range of settings includes care homes and guidance for staff.	Noted, thank you.
NHS Wakefield District	4.1 Question 1	7	Important target groups are midwives and health visitors. Both found to be very hard to organise training for due to workforce issues.	Thank you for raising this issue.
NHS Wakefield District	4.1 Question 1	7	Important to include guidance for staff working in care homes. It's good that awareness is raised, but often influencing Vit D intake is out of the control of care home staff unless it has been prescribed by the residents GP.	Thank you for raising this issue
NHS Wakefield District	4.1 Question 2	8	Cost effectiveness of implementing the Healthy Start scheme to those eligible is hindered by the short shelf life of the children's vitamins and wastage	Thank you for raising this issue.
NHS Wakefield District	4.1 question 3	8	The new requirement for a wholesale licence to supply to locations outside supplying organisation hinders commissioners. This will cause further inequality locally as more acceptable and innovative options are needed to	Thank you for raising this issue.

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			target the south asian population who have low attendance at our children's centres yet these will be costly to provide.	
NHS Wakefield District	4.1 question 3	8	Healthy Start being available to eligible families to 4 years yet recommendations for supplementation are to 5 years. Understanding of the need for supplementation is poor yet explaining vitamin requirements is complicated, especially where Healthy Start and vitamin D recommendations differ such as above.	Thank you for raising this issue.
NHS Wakefield District	4.1 question 3	8	The reporting basis of data on Healthy Start uptake based on the child's economic status hinders commissioners	Thank you for raising this issue.
NHS Wakefield District	4.1 question 3	8	Lack of allocated budget hinders.	Thank you for raising this issue.
NHS Wakefield District	4.1 question 3	8	In a local focus group of new mums with vitamin D literature too much information on the effects of vitamin D deficiency was felt to be too scary and they wanted messages to advise on the option of supplementation not recommend, explaining that during pregnancy and birth they have so many decisions to make it can be overwhelming. This can make explanations of vitamin D difficult.	Thank you for raising this issue.
NHS Wakefield District	4.1 Question 3	8	There is a lack of clarity re vit D advice for older adults living in institutions. Care home staff can only administer what is prescribed to them by a GP. Although Vit D supplements can be bought over the counter, this control is taken away from residents in care homes.	Thank you for raising this issue.
NHS Wakefield District	4.1 question 4	8	Healthy Start does not make provision for 4-5year olds	Thank you for raising this issue.

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NHS Wakefield District	4.1 question 4	8	Over the counter sales are available for under 5s and pregnant women	Thank you for raising this issue.
NHS Wakefield District	4.1 question 4	8	Over the counter sales are not clear for breastfeeding women	Thank you for raising this issue.
NHS Wakefield District	4.1 question 4	8	Over the counter sales are not clear for over 65s as no well known targeted product How is vit D promoted/recognised for over 65s? How can it be branded similar to healthy start?	Thank you for raising this issue.
NHS Wakefield District	4.1 question 4	8	Provision is not made through prescriptions for at risk groups except for people in care homes where GPs may prescribe. Responsibility for influencing prescribing and optimal dispensing is problematic.	Thank you for raising this issue.
NHS Wirral	3b	3	There has been some strong evidence about vitamin D deficiency and multiple sclerosis (maybe since this guidance was drafted). Should this be included?	Thank you for raising this issue. The guidance is focused on the impelementation of existing recommendations rather than 'making the case' for supplementation.
NHS Wirral	3c	3	Maybe an addition to this paragraph to recognise that exclusively fed breastfed infants may be at risk if their mother has not taken a supplement during pregnancy and whilst she is breastfeeding (reference to the UNICEF statement) http://www.unicef.org.uk/BabyFriendly/News-and-Research/News/UNICEF-UK-Baby-Friendly-Initiative-Statement-on-vitamin-D-supplementation-for-breastfed-babies/	Thank you for this comment. We are of the opinion that the scope as it stands covers this point. The scope states that 'Infants who are exclusively breastfed,

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				particularly for more than 6 months, are at increased risk because the amount of vitamin D in breast milk will not meet their requirements'.
NHS Wirral	3f	5	It may not be accurate to say that Healthy Start vitamins are usually available from health clinics, children's centres Sure Start centres outreach programmes or GP surgeries. More accurate to say that availability depends on local situations and that there may be limited availability as they can only be ordered through NHS Supplies chair. Uptake is low nationally and it is known that families are uncertain why they should take supplements, where they get them from and how they use the voucher, which they may not recognise.	Thank you for raising this issue. The text has been amended.
NHS Wirral	4.1.1.	5	As the Chief Medical Officers recognised that up to a quarter of the rest of the population could be vitamin D deficient, should there be some guidance about a recommended amount of supplement for all other groups, i.e. the over 5's and under 65s.	Thank you for this comment. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearc olleagueletters/DH_132509).

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NICE	General		This is a very comprehensible draft scope.	Thank you.
NICE	3b the need for guidance	3	Would it be possible to put in brackets after 'osteomalacia' soft bones so that all readers are aware of what it is?	Thank you, the scope has not been amended as to do so would result in having to explain all conditions listed, for which there is not space.
NICE	4.1.1	5	The inclusion of groups seems to be comprehensive. We are pleased to see them all included and hope none will be removed post consultation.	Noted, thank you.
NICE	4.3	7-8	We are pleased to see that questions 2, 3 and 4 include reference to the awareness and perspectives of at-risk groups as we believe that finding evidence on what these different groups perceive to be effective will be important for the recommendations.	Noted, thank you.
Proprietary Association of Great Britain (PAGB)	3	3	Paragraph b) PAGB is concerned that the data indicating the at risk status of vitamin D deficiency was derived from the National Diet and Nutrition Survey (NDNS) of 2004. There is more up-to-date data available, from 2011, which includes blood work. This clearly shows that vitamin D intake has fallen across all population groups, with approximately 75% of the population having intakes below the RNI levels; this holds true for data from food intake alone, and from food and supplement intakes. This would indicate that significantly more of the population are at risk than the conservative estimate in the draft scope.	Thank you for this comment. The NDNS data are given as an example. The guidance is focused on the implementation of existing guidance rather than making the case for intervention.
Proprietary Association of Great Britain (PAGB)	3	4	Paragraph d) Although guidance exists it is not implemented, and the distribution channels for Healthy Start supplements are inadequate. Industry	Thank you for raising this issue.

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			has offered to provide the Department of Health will guidance and support in establishing effective distribution channels, however the offer has not been taken up.	
Proprietary Association of Great Britain (PAGB)	3	5	Paragraph f) The primary care spending figures are based on prescription data only and do not take into account the cost of long term care of fracture resulting from vitamin D deficiency. In 2012 the National Osteoporosis Society estimated the annual cost of hospital and social care for patients with hip fracture alone at £2.3 billion a year.	Thank you for providing this information.
Proprietary Association of Great Britain (PAGB)	4.1.1	6	PAGB is delighted to note that NICE will be including an at-risk group that has been much neglected in relation to vitamin D: individuals with dark skins.	Noted, thank you.
Proprietary Association of Great Britain (PAGB)	4.2.1	6	The benefits of educating people on how to live as healthily as possible by encouraging more self-care are widely recognised. This includes ensuring people are aware of the need for supplementation if their diet is lacking the nutrients necessary to stay healthy. PAGB feels more can be done to educate the public to self-care in relation to vitamin D supplementation. Health professionals and public health agencies can raise awareness of the harm to people's health through lack of vitamin D, and how to help prevent this deficiency. Single ingredient vitamin D food supplements are widely available over the counter and the costs are not prohibitive, often cheaper than the prescription charge. Boots the chemist sell their own brand at £5.10 for 90 tablets of 25mcg (=1,000iu) whilst Holland and Barrett sell 100 tablets of an equivalent dose for £8.05. These are only two of many different products on the market; if at risk groups were provided with information it would not be unreasonable to suggest they accept responsibility for their own health.	Thank you for this comment.

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Proprietary Association of Great Britain (PAGB)	4.3	7	In response to Question 1 : More nutrition training is needed across all health professional groups.	Thank you for this comment.
Proprietary Association of Great Britain (PAGB)	4.3	8	In response to Question 2 there is very little evidence that at-risk groups are aware of issues around vitamin D, and this is not likely to change until such time as health professionals are more aware as they will need to fulfil the role of educator for these groups.	Thank you for this comment.
Proprietary Association of Great Britain (PAGB)	4.3	8	In response to Question 3 the following hinder the implementation of existing guidance on vitamin D: • Lack of awareness of the issues across all groups • Lack of nutrition knowledge • Lack of awareness of existing guidance which leads to failure of implementation • Lack of products available under UK licence for prescribing – many GP practices use special order products which can cost up to £50	Thank you for this comment.
Proprietary Association of Great Britain (PAGB)	4.3	8	In response to Question 3 the following may help the implementation of existing guidance on vitamin D: • Having information available at point of prescription – i.e. a note to doctors on vitamin D products available, both for prescription and for at-risk groups who are prepared to purchase their own products.	Thank you for this comment.
Proprietary Association of Great Britain (PAGB)	4.3	8	In response to Question 4 the British National Formulary states that there is no plain single ingredient vitamin D product available to prescribe to treat deficiency; the only product available for prescribing are combinations of vitamin D with calcium or other nutrients. GPs often resort to using special order products, at great expense to the NHS; the product of choice appears to	Thank you for this comment.

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			be Dekristol® which is licenced in Germany and can cost up to £50.00. As outlined above (section 4.2.1; page 6) there are multiple products available to buy over the counter at relatively low cost to the consumer.	
Proprietary Association of Great Britain (PAGB)	Expected outcomes	8	The guidance, as it currently exits, is primarily directed at health professionals; it is unlikely that this current exercise will be effective at raising awareness of the guidance to the at-risk groups.	Thank you for this comment. Section 2c of the draft guidance states 'This guidance will provide recommendations for good practice, based on the best available evidence of effectiveness, including cost effectiveness. It is aimed at commissioners, managers and other professionals with public health as part of their remit working within the NHS, local authorities and the wider public, private, voluntary and community sectors. It is also aimed at the suppliers and providers of vitamin D supplements. In addition, it may be of interest to people at risk of vitamin D deficiency, their families and carers and other members of the

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				public.'
Proprietary Association of Great Britain (PAGB)	Expected outcomes	8	Uptake of Healthy Start vitamins will only increase if the relevant health professionals are educated as to its importance, and the distribution channels are significantly improved.	Thank you for this comment.
Royal College of Nursing	General		There are no comments to submit on behalf of the RCN to inform on the draft scope of the above guideline	Noted, thank you.
Royal College of Paediatrics and Child Health (RCPCH)	General	General	The RCPCH has produced a position statement on Vitamin D deficiency and we are keen to work with NICE on this important public health issue. This can be read here.	Thank you for providing this information.
Royal College of Paediatrics and Child Health (RCPCH)	General	General	We are not sure how well this topic is addressed at the time of booking or birth for pregnant women, especially when promoting exclusive breastfeeding.	Thank you for raising this issue.
Royal College of Paediatrics and Child Health (RCPCH)	За	3	There is also evidence to suggest there are specific times when the strength of the sun can provide adequate exposure for vitamin D, but discussion is needed on this and on how skin types can affect these requirements.	Thank you for this comment. Sun exposure is outside the remit of this guidance but is covered by another referral from DH on 'sunlight exposure: benefits and safety'
Royal College of Paediatrics and Child Health (RCPCH)	3b	3	Should be "severe vitamin D deficiency MAY result in/cause rickets."	Thank you, text amended as suggested.
Royal College of Paediatrics and	3c	3	While the importance of the mother's level of vitamin D is stated, moving the	Thank you, text amended

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Child Health (RCPCH)			sentence "Infants who are exclusively breastfedrequirements" to follow the second sentence ending in "mother's level of vitamin D" would help emphasise that breastfeeding itself does not necessarily lead to vitamin D deficiency; rather, it is exclusive breastfeeding over an extended period of time, particularly if the mother is also deficient.	as suggested.
Royal College of Paediatrics and Child Health (RCPCH)	3 d & f	4-5	Healthy Start vitamin uptake is extremely low due to lack of availability in most areas; it is important to note that this option is not sufficient in providing supplements.	Thank you for raising this issue.
Royal College of Paediatrics and Child Health (RCPCH)	4.1.1	6	We think that the guidance could look at vitamin deficiency across childhood and adolescence, up to the age of 18. In particular, recent guidance from the Chief Medical Officer makes recommendations for supplementation for children aged 6 months to 5 years, but does not include guidance for those younger or older than these age ranges. Please find the guidance from the Chief Medical Officer here .	Thank you for this comment. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearc olleagueletters/DH 13250 9). To note that 5-18 year olds who fell within the other at risk groups listed would be covered by the guidance.
Royal College of Physicians	2a	Page 1	We feel that this section should explicitly refer to 'people with dark skin' as in 4.1.1 and women 'of South Asian, African, Caribbean and Middle Eastern	Thank you, text amended as suggested.

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			descent' as in 3 c. It should be noted that susceptibility probably also depends on parity.	
Royal College of Physicians	General		We note that the scope explicitly excludes all the factors that seem to be of (non-public health) clinical relevance, including: · Management of vitamin D deficiency. · Management of conditions that may increase the risk of vitamin D deficiency. · Fortification of food and drinks with vitamin D. · Indicators of vitamin D status. · The relative contribution of dietary and cutaneous vitamin D synthesis to the vitamin D status of the UK population. · The association between vitamin D status and health outcomes. Our experts are concerned by this and feel these areas need to be covered by some form of guidance	Thank you. For information, clinical management is outside the remit of guidance developed by CPHE at NICE. The other areas listed are under the remit of SACN and will be covered by their report due in 2014. NICE is working with SACN to ensure consistency.
Royal College of Physicians	General		There is no discussion of the balance in public health benefits between protecting against skin cancer and ensuring adequate Vitamin D synthesis.	Thank you for this comment. Sun exposure is outside the remit of this guidance but is covered by another referral from DH on 'sunlight exposure: benefits and safety'.
The British Specialist Nutrition	General	All	The British Specialist Nutrition Association supports the development of public	Noted, thank you.

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Association (BSNA)			health intervention guidance by NICE which intends to implement existing guidance to prevent vitamin D deficiency among at risk groups of the population and advice to supplement inadequate dietary intakes and exposure to sunlight with vitamin D.	
The British Specialist Nutrition Association (BSNA)	General	All	Many foods for particular nutritional purposes, including foods for infants and young children (such as infant formula, follow on formula and milk based drinks for young children) and foods for special medical purposes, are fortified with vitamin D and can play an important and significant role in helping those who consume these foods to meet their vitamin D requirements. We believe that the role of fortified foods should also be included in any guidance developed.	Thank you for this comment. SACN is due to report on vitamin D in 2014. Their report will include comment on the contribution of fortified foods to status.
The British Specialist Nutrition Association (BSNA)	General	All	The BSNA would be happy to provide additional information to NICE on the levels of vitamin D in foods for particular nutritional uses in the UK and include information on the levels of other nutrients in these foods.	
The British Specialist Nutrition Association (BSNA)	General	All	The BSNA would welcome the opportunity for dialogue on how the specialist nutrition industry could support the Department of Health and NICE to implement existing guidance to prevent vitamin D deficiency among at risk groups of the population and advice to supplement inadequate dietary intakes.	Thank you, your continued involvement as a stakeholder in the development of this guidance is welcomed.
The British Specialist Nutrition Association (BSNA)	4.2.2	7	The draft scope suggests that activities/measures that will not be covered currently includes the fortification of food and drinks with vitamin D. Many foods for particular nutritional purposes, including foods for infants and young children (such as infant formula, follow on formula and milk based drinks for young children) and foods for special medical purposes, are fortified with vitamin D and can play an important and significant role in helping those who	Thank you for this comment. SACN is due to report on vitamin D in 2014. Their report will include comment on the contribution of fortified

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			consume these foods to meet their vitamin D requirements. We believe that the role of fortified foods should also be included in any guidance developed.	foods to status.
The British Specialist Nutrition Association (BSNA)	General	All	NICE should work closely with the Scientific Advisory Committee on Nutrition (SACN), given that the SACN review of Vitamin D is also currently underway.	Thank you. NICE is working with SACN to ensure consistency
The Royal College of Midwives	General		The Royal College of Midwives considers the scope of this guidance to be appropriate and has no further comments at this point.	Noted, thank you.
Centre of Paediatric Epidemiology and Biostatistics, UCL Institute of Child Health	2a,3c/4.1.1./gen eral	1,3-5	Review on vitamin D intake (both through diet and sunlight induced synthesis) should be used as guide for informing groups who are considered to be 'at risk' of insufficient intakes. It may be erroneous to start off with an assumption that intake is sufficient for the general population, or for population who do not fall within pre-defined 'at risk' groups.	Thank you for this comment. The population groups listed in section 4.1.1 of the scope reflects the letter from the CMOs 2012 (here http://www.dh.gov.uk/en/ Publicationsandstatistics/ Lettersandcirculars/Dearc olleagueletters/DH_13250 9). It is not that other population groups are assumed to have sufficient status, rather that existing guidance (which this work focuses on) identifies the listed

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Centre of Paediatric Epidemiology and Biostatistics, UCL Institute of Child Health	2a,3c/4.1.1./gen eral	1,3-5	There is evidence to indicate that overweight and obese individuals should be considered as an "at risk" group.	groups as at risk. Thank you, please see above. Existing guidance from NICE (Maternal and child nutrition and antenatal care highlights obese women before and during pregnancy. They would be covered by the list as it stands.
Centre of Paediatric Epidemiology and Biostatistics, UCL Institute of Child Health	3d	4	Evidence that intakes at RNI can be guaranteed by dietary intake without need of supplement should be reviewed.	Thank you for this comment. Dietary intakes and sources is under the remit of SACN. They are due to report on vitamin D in 2014.
Centre of Paediatric Epidemiology and Biostatistics, UCL Institute of Child Health	4.1.1	6	People who have low (or no) exposure to sun will include the whole UK population from October/November to March. Exceptions will arise from individuals who take holidays abroad in the sun.	Thank you for this comment. The wording has been amended.
Centre of Paediatric Epidemiology and Biostatistics, UCL Institute of Child Health	4.2.2.	7	It may not be necessary to establish in detail the relative contribution of sunlight/diet to total intake, however, lack of sunlight induced synthesis during a proportion of the year, is an important consideration for establishing the risk of vitamin D deficiency.	Thank you for this comment. Sun exposure is outside the remit of this guidance but is covered

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				by another referral from DH on 'sunlight exposure: benefits and safety'.

Document processed	Stakeholder organisation	Number of comments extracted	Comments
Birmingham Vitamin D Steering Group & Birmingham Public Health.doc	Birmingham Vitamin D Steering Group & Birmingham Public Health	3	
British Association of Dermatologists.doc	British Association of Dermatologists	3	
British Medical Association.doc	British Medical Association	4	
British Nutrition Foundation.doc	British Nutrition Foundation	1	
British Paediatric & Adolescent Bone Group.doc	British Paediatric & Adolescent Bone Group	11	
Child-Nutrition.co.uk Ltd.doc	Child-Nutrition.co.uk Ltd	5	
Danone Baby Nutrition.doc	Danone Baby Nutrition	5	
Department of Health.doc	Department of Health	1	

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Feeding for Life Foundation.doc	Feeding for Life Foundation	15	
Infant & Toddler Forum.doc	The Infant & Toddler Forum is supported by an educational grant from Danone UK. The views and outputs of the group, however, remain independent of Danone UK and its commercial interests	7	
Internis Pharmaceuticals Ltd.doc	Internis Pharmaceuticals Ltd	10	
Liverpool Primary Care Trust.doc	Liverpool Primary Care Trust	9	
National Osteoporosis Society.doc	National Osteoporosis Society	4	
NHS Greater Glsgow and Clyde.doc	NHS Greater Glsgow and Clyde	12	
NHS Sheffield.doc	NHS Sheffield	9	
NHS Wakefield District.doc	NHS Wakefield District	17	
NHS Wirral.doc	NHS Wirral	4	
NICE.doc	NICE	4	
Proprietary Association of Great Britain (PAGB).doc	Proprietary Association of Great Britain (PAGB)	12	
Royal College of Nursing.doc	Royal College of Nursing	1	
Royal College of Paediatrics and Child Health (RCPCH).doc	Royal College of Paediatrics and Child Health (RCPCH)	7	
Royal College of Physicians.doc	Royal College of Physicians	3	

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The British Specialist Nutrition Association (BSNA).doc	The British Specialist Nutrition Association (BSNA)	6	
The Royal College of Midwives.doc	The Royal College of Midwives	1	
UCL Institute of Child Health.doc	Centre of Paediatric Epidemiology and Biostatistics, UCL Institute of Child Health	5	