Public Health Guidelines

Implementing Vitamin D guidance - Consultation on Draft guideline
Stakeholder Comments Table

13 May – 24 June 2014

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Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Association for Improvements in the Maternity Services	General		The use of language is important. Throughout this guideline the language used is prescriptive and directive. It would be good to bear in mind that the intention of this guideline is to inform and aid choice. Not to dictate what must be done. We agree that clarity is needed. However, we do have some reservations about the way in which this may be implemented. We are aware that this may be more relevant when it comes to putting the quality standard together as so ask that a note be made of this for us.	Thank you for this comment.
Association for Nutrition	General		AfN welcomes this guidance. Overall we consider the guidance to be clearly laid out with clear expectations of all those involved. AfN would have no issues in recommending compliance with this guidance to our UK based registrants.	Thank you for this comment.
Association for Nutrition	1	7	Reference to Health and social care professionals. Not all social care professionals are appropriately trained and competent to provide dietary advice to individuals and may not have the awareness of the potential problems which could be caused in doing so.	Thank you for this comment. Health and social care professionals have been re-named 'practitioners' throughout.
Association for Nutrition	1	8	It is suggested that health and social care professionals receive information on Vitamin D as part of their registration and CPD. Registration is normally provided by a regulator, whether one of the nine UK based statutory ones or the voluntary regulators. CPD can be provided by a combination of regulators, professional bodies or membership organisations. This recommendation needs tightening up to ensure it is clear to all who is responsible for providing this information. In our view, it is not the role of the regulator to provide registrants with advice on specific government policy, only to recommend, as part of	Thank you for this raising this issue. Provision of training and CPD is an implementation issue outside the remit of NICE.

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			ethical guidance that government policy is followed.	
Association for Nutrition	2	12	AfN would welcome Registered Nutritionists to be included by name in this list.	Thank you, the text has been amended in line with your comments
Association for Nutrition	3	13	The last sentence under the heading 'People at Risk' appeared to make an assumption without taking into account other lifestyle factors such as the number of people who live and work in London, who will therefore work inside, commute using public transport, ease and availability of that public transport reducing individuals physical activity, undertake entertainment activities largely based inside and have little access to open spaces in the same way those living outside of London generally do.	Thank you for raising this issue. The wording has been amended to state '…may reflect….'
Birmingham Vitamin D steering Group	General		There may be a risk that, because Healthy Start mothers' and children's vitamins contain vitamins A and C and folate, they are perceived as general vitamin supplements for, which may lead to resistance from some families who believe that their diet is good. If they were both vitamin D, the purpose of taking them would be more clearly defined and thereby uptake might be improved. For babies, this would also reduce any risk of exceeding safe recommended vitamin A dose if started from soon after birth. Starting early, with a bottle of children's vitamin's given by the heath visitor at post birth visit, is likely to lead to on going uptake.	Thank you for raising this issue. We did not identify any evidence on the content of the supplements impacting on uptake. However, recommendations 3 and 10 highlight the importance of communicating the benefits of a daily supplement. The content of the healthy start supplement per se is outside the remit of this guidance.
Birmingham Vitamin D steering Group	General		The Birmingham Vitamin D steering group members strongly believe that the only way to make the scheme simple enough for high uptake of vitamin D supplements for "at risk" groups is to make provision free and universal. This simplifies it sufficiently for professionals to remember to always give this message, and for issuing sites to be prepared to take	Thank you for this comment. As noted in the considerations for this guidance, no studies were identified that compared universal free provision of vitamin D supplements with universal provision of supplements that have to be paid for (albeit at a low

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			on the issuing role, and also removes stigma for families. We recommend that NICE looks in general at evidence of cost effectiveness of universal v targeted provision for health care interventions of a similar nature	cost. This prevented the committee from commenting on the relative benefits of these approaches and members felt that this is an important area for future research.'. NICE is undertaking a separate piece of work to consider the cost effectiveness of a universal compared with targeted approach for healthy start supplements (see here).
Birmingham Vitamin D steering Group	Draft recommendations: Recommendation 7	7	Apparently health visiting is not yet a statutory service, although midwifery is!	Thank you, the text has been amended to remove 'statutory'
Birmingham Vitamin D steering Group	Draft recommendations: recommendation 7	7	Include ensuring mention in electronic as well as hand held antenatal notes	Thank you, the text has been amended as suggested
Birmingham Vitamin D steering Group	General		It would simplify matters if vitamin D supplementation was not linked to the Healthy Start scheme. In our area, this confuses people as all families, including those **not eligible** for Healthy Start, **are eligible** for Healthy Start vitamins. The Healthy Start scheme does not necessarily reach those at highest risk of vitamin D deficiency. In addition, the Healthy Start logo may put off those who have applied to the national scheme, and found that they are not eligible, or those who consider Healthy Start stigmatising, or reinforce the notion that they are a non essential multi-vitamin for those who do not have a balanced diet.	Thank you for raising this issue. PHAC shared many of these concerns, as discussed in the considerations section of the guideline.
Breastfeeding Network	General		These comments are sent by Breastfeeding Network by Phyll	Thank you for raising these issues.

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			Buchanan. We welcome this guidance and recognise the need for clear, simple messaging. We think the approach should be based on assuming everyone needs vitamin D and some need it more urgently than others, instead of an opt-in based on target groups. [It may be out-dated but has been described as progressive universalism, to allow for a sliding scale of measures] In order to understand the difficulties of increasing uptake it may help to explain some of the barriers with the available preparations. *** Product differences** The two products are different, with their own strengths and weaknesses, and understanding these differences will help to increase uptake. **Maternal vitamin D**, combined with folic acid, has a long shelf life which means it could be stocked in a greater variety of places. Consider re-classification as a food supplement rather than a medicine to help reduce hurdles involved in storage and distribution systems – this would make it possible to reduce the costs of storage as the current system requires secure, separate medicine cabinet for storage. It needs to be available in places accessed by pregnant women such as: midwife led clinics, Children Centre's, scanning waiting room, GP surgeries.	No evidence was identified on weekly supplement preparations. Revisions to existing guidance. is outside the remit of this guidance. SACN is currently considering population recommendations on vitamin D. We did not identify any evidence on specific timing of vitamin D campaigns

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			We understand that the barrier for pharmacies is the need to keep the cost, and therefore profit, low. This is therefore unlikely to be the main solution. Wider availability through supermarkets is more likely and they gain already through the Healthy Start vouchers. One of BfN's volunteers stated: "My nearest [source of Healthy Start vitamins] is two bus rides away and would cost me £5 just to get there. It is cheaper to for me to go to my local pharmacy and buy my own." It should be marketed to women pre-conception, particularly for subsequent pregnancies. Could there be a weekly dose of the maternal vitamin? **Infant vitamin D** is a liquid preparation and therefore has a shorter shelf life. This restricts the distribution network probably to the health visiting team and a limited number of pharmacies who can predict a rapid turn-over. This probably means it needs to stay regulated as a medicine. Would availability in different forms help increase uptake eg: could the vitamin K injection given to babies at birth include vit D? And could it be available as granules to add to food as this would have a longer shelf life than liquid drops. [cf sprinkles]	

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			*** Increasing uptake** A variety of options are likely to increase uptake involving a multi-disciplinary approach to reach more families. This should include times of contact with health professions eg: the 6 week post-natal check and immunisation times. Could the recommendation change so that all women are encouraged to take vit D & folic acid for the first 6 weeks postnatally, irrespective of whether they breastfeed or not? This might help raise levels post-partum. Thinking especially here of women who unexpectedly conceive soon after the birth of a first child. We suggest a general winter campaign when the clocks change in October and at the start of the new year to join with keeping fit should be investigated. It could include a prompt to couples considering a new baby in the year. Although the best way to make sure women become pregnant with a normal level of vitamin D is for there to be greater awareness and uptake of vitamin D in the general population. We would urge you to avoid the option of maternal or infant fortified milks as this will be expensive and have unintended consequences such as undermine family meals and health eating habits. It is also unlikely to reach those most in need. Availability needs to be increased My nearest is two bus rides away and would cost me £5 just to get there.	

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Breastfeeding Network	Rec 2	P4	We welcome the recognition that the vitamins should be halal and suitable for vegans. They should also be kosher to ensure acceptability for orthodox Jewish community.	Thank you for raising this issue, the text has been amended to reflect your comment.
Breastfeeding Network	Rec 4	P5	Local coordination essential, available at every children's centre. Access often a barrier in terms of distance and availability.	Thank you, children's centres are flagged in recommendation 6.
Breastfeeding Network	Rec 5	P6	We welcome the recommendation to provide free supplements but targeting at-risk groups is not likely to be as effective as a universal and progressive approach. Please note that teenagers under the age of 18 and who are not eligible for healthy start are only able to get vit D while pregnant and not while breastfeeding [at least from 16 years]. This is a strange anomaly. Whatever decisions are made about provision, all those under 21 should be eligible for vitamin D in pregnancy, while breastfeeding and for their babies, irrespective of eligibility for Healthy Start.	Thank you for this comment. As noted in the considerations for this guidance, no studies were identified that compared universal free provision of vitamin D supplements with universal provision of supplements that have to be paid for (albeit at a low cost). This prevented the committee from commenting on the relative benefits of these approaches and members felt that this is an important area for future research. A research recommendation has been made on this point. NICE is also undertaking a separate piece of work to consider the cost effectiveness of a universal compared with targeted approach for healthy start supplements. Thank you for raising the issues re access to supplements for women under age 21.
Breastfeeding Network	Rec 6	P7	Noting comment above for recommendation 5, the recommendation in 6 to make the vitamin supplement available to all pregnant and breastfeeding women and children under 4 years is welcome and would	Thank you for these comments. Recommendation 2 focuses on the complexity of existing guidance.

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			be a lot simpler and therefore more effective than trying to target at-risk groups. We note that the upper age limit of 4 years was a reduction from 5 years in the previous welfare food scheme. It was introduce to keep within the budget - not based on clinical need. One way to introduce universal vitamins would be to use the same principle to reduce the upper limit of universal vitamins to two years, although uptake may already be much lower after this age. The addition of specific questions in the maternity notes is very welcome. It should also be added to the postnatal assessment at the first visit by the health visiting team, the 6 week check, and immunisations.	Recommendation 8 on prompts has been extended to include postnatal and health visitor appointments.
Bristol University	Recommendation 5	6	Recognising the importance of Children's Centres for families with young children, here and later we would suggest that 'health and social care professionals' is expanded to include other early years staff. Perhaps 'health, social care, and other relevant professionals' as used for recommendation 8	Thank you for this comment. The updated guidance uses the term 'health, social care and other relevant practitioners throughout. The list of who should take action for recommendation 10 includes early years staff (this list is not intended to be exhaustive). Early years staff would be included within 'health, social care and other relevant practitioners' within recommendation 9.
Bristol University	Recommendation 7	7	Consistent with the previous point and recommendation 8, could this be retitled "health, social care, and other relevant professionals"	Thank you, the text has been amended to 'health, social care and other relevant practitioners' as appropriate throughout.

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Bristol University	Recommendation 8	8	Here and elsewhere we would argue that increased awareness and knowledge among professionals is a necessary but not sufficient step since knowledge alone is seldom enough to change behaviours. We therefore need to ensure that other barriers (including attitudinal barriers) and also identified and addressed. In this section is it possible to add a recommendation that training should include a recommendation that training should address any barriers (including attitudinal barriers) to promotion of Vitamin D supplementation where appropriate?	Thank you for this comment. The evidence considered for the development of this guidance highlighted low levels of knowledge and awareness among health professionals and at risk groups. Recommendations aimed at increasing awareness should be read alongside the other recommendations in the guidance that address access and availability of supplements, consistency in messages to at risk groups and health professionals and improvements in monitoring and evaluation.
Bristol University	Recommendation 9	9	As with professional awareness, we believe it is important to recognise attitudinal as well as knowledge barriers to Vitamin D supplementation. Could the sentence “addressing any misconceptions” include “and attitudinal barriers”?	Thank you for this comment. The evidence considered for the development of this guidance highlighted low levels of knowledge and awareness among health professionals and at risk groups. Recommendations aimed at increasing awareness should be read alongside the other recommendations in the guidance that address access and availability to supplements, consistency in messages to at risk groups and health professionals and improvements in monitoring and evaluation.
Bristol University	Section 2 “Who should do what at a	11	Consistent with recommendation 8 and as noted previously, could “health and social care professionals” be amended to “health, social care, and other relevant professionals”	Thank you, the text has been amended to ‘health, social care and other relevant practitioners’ as appropriate throughout.

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	glance"			
Bristol University	Section 4.2	17	As noted previously, we agree that the evidence such as exists suggests that professionals do now always know or communicate correct information about Vitamin D. We believe it is worth noting that the reviews did not identify studies which also looked at attitudinal and motivational barriers beyond knowledge alone. Since much behavioural evidence from other topics suggests knowledge alone is insufficient to change behaviour, we would suggest this is acknowledged as a gap in the evidence here (as well as in section 5.2) noting it is likely to be important alongside increased knowledge in increasing promotion of Vitamin D.	Thank you for this comment. Specific issues relating to attitudinal and motivational issues were not identified in the evidence considered for this guideline, though are obviously important within wider literature on behaviour change. The guideline notes links to existing NICE guidance on behaviour change.
Bristol University	Section 5.5	25	We would like to add to these research gaps "attitudes to vitamin supplementation"	Thank you, the text has been amended in line with your comments.
British Association of Dermatologists	1, recommendation 1	4	Ideally, clarification should be given here to the term 'older people' (i.e. over-65s as per the at risks groups section)	Thank you for this comment, the guidance has been updated to flag people over age 65, in line with the CMOs letter 2012.
British Association of Dermatologists	1, recommendation 3	5	Messaging advocating sun exposure will have to be managed very carefully and in conjunction with skin cancer experts. The guidance from the current NICE skin cancer reviews as mentioned in Consideration 4.1, page 17, may not be sufficient to guide the vitamin D messaging. As outlined. exposure to ultraviolet B (UVB) radiation in sunlight is the most efficient way to boost vitamin D supply but it is still unclear how much sunlight is required to produce a given level of 25(OH)D. Environmental and personal factors greatly affect vitamin D production in the skin, making it difficult to recommend a one-size-fits-all level of exposure for the general population. The amount of UVB in sunlight changes substantially with season, latitude and time of day. Physical characteristics can also affect vitamin D production, with	Thank you for this comment. Sun exposure is outside the scope for this guidance but is being addressed in a parallel piece of public health guidance on sunlight exposure – benefits and risks. A reference to sun exposure (as a source of vitamin D) has been added to recommendation 3.

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			darker skin requiring longer UV exposures to produce the same amount of vitamin D. Older people have a reduced ability to make vitamin D through their skin. Obese people have lower 25(OH)D levels, which may be due to less sun exposure or greater uptake of vitamin D in fat tissue, which may be more inaccessible. The area of skin exposed will also influence the amount of vitamin D made after sun exposure as will other factors including posture, time of day, outdoor activities, and the presence of shading structures. All of these variables need to be accounted for in public messaging.	
British Association of Dermatologists	4, consideration 4.4	17	We agree that there is no definition of what constitutes 'a low exposure' to sunlight, or how many hours spent indoors equates to being 'housebound'. These issues will have to be managed carefully in public messaging to avoid over-exposure to sunlight, thereby increasing skin cancer risk.	Thank you for this comment.
British Medical Association	Recommendation 1	4	Increased awareness amongst health professionals about which groups are at-risk of vitamin D deficiency would be worthwhile. Redrafting the British National Formulary section would also be worthwhile as this section is not currently easy to use. The clarification that older adults with an adequate calcium intake from a balanced diet require vitamin D-only supplements, rather than a combined vitamin D and calcium supplement (which some people may find difficult to swallow) is helpful. Clarity on the relationship between vitamin D and calcium supplements would be welcomed.	Thank you for these comments. The amended guideline is in line with your comments.

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British Medical Association	Recommendation 6	7	We believe all pregnant and breast feeding women should have access to free supplements but it is important that they are also encouraged to increase dietary rich foods.	Thank you for this comment. Section 3 of the guidance notes that dietary sources of vitamin D are limited in the UK. Diet during pregnancy and breastfeeding is addressed in NICE public health guidance PH11.
British Medical Association	General	12	We are surprised there is little mention of fortified foods as a means of delivering Vitamin D. Cereal companies could be encouraged to target groups at-risk of vitamin D deficiency. Similarly Asian foods could be targeted at fortification.	Thank you for this comment. The guideline focuses on the implementation of existing guidance, particularly recommendations for certain population groups to take supplements. Fortification is outside the remit of the guidance and is under the remit of SACN.
British Medical Association	General		As this is primarily a public health issue, the benefits of good diet and adequate sunlight exposure ought to be dealt with on a population basis. We are generally supportive of raising awareness in target high risk groups but these groups need to be directed to supermarkets and pharmacies rather than to their GP. This guidance should be implemented with as minimal GP prescribing as possible.	Thank you for this comment. The recommendations focus on the implementation of existing guidance for at risk groups. PHAC recognised that access to and availability of supplements – for example from pharmacies and supermarkets - was a key issue and have made a range of recommendations on this point.
Consilient Health Ltd	General		At multiple points in the draft guidance, reference is made to a 'daily' vitamin D supplement. The recent National Osteoporosis Society (NOS) guidelines state that in the case of treatment doses, vitamin D may be given as daily or weekly split doses and for maintenance that vitamin D supplements may be given either daily or intermittently at a higher equivalent dose1. This is a reflection of the evidence generated by Ish-Shalom et al which demonstrated that vitamin D supplementation could	Thank you for this comment. The guidance focuses on the implementation of existing recommendations on vitamin D to prevent deficiency. Treatment is outside the scope of this work.

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			be achieved equally well with daily, weekly or monthly dosing2. We would like to see the wording within this guideline changed to reflect this as the current wording suggests that only a daily regimen is an appropriate approach most notably in recommendations 1, 3, 7 and 9. 1. *Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management; April 2013, version 1.1* 2. *Ish-Shalom S et al. Comparison of daily, weekly, and monthly vitamin D3 in ethanol dosing protocols for two months in elderly hip fracture patients. J Clin Endocrinol Metab 2008 93(9):3430-3435.*	
Consilient Health Ltd	General		This version of the guideline does not make clear any differential between products that have been granted a marketing authorisation by the MHRA (licensed products) and those that do not have a licence whether they are 'specials' or food supplements. Of particular concern is the issue of food supplements as they generate the same medico-legal issues for prescribers and dispensers as 'specials' but require no registration or authorisation prior to going on sale in the UK1. Multiple professional bodies have stated that where a licenced medication is available it should be prescribed in preference to an unlicensed medicinal product notably, the MHRA2, the General Medical Council (GMC)3 and the Royal Pharmaceutical Society3. We would urge you to amend this draft guideline to make it explicitly clear that licensed medicines should be used wherever possible. 1. *Department of Heatlh. Summary information on legislation relating to the sale of food supplements* 2. *MHRA Guidance note 14. The supply of unlicensed medicinal products ("specials")*	Thank you for this comment. Updated recommendation 1 notes that supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D. It also states that licensed products containing the recommended reference nutrient intake for at risk groups are available on prescription and are listed in the British National Formulary. To note that this guidance is focused on prevention rather than treatment and it is appropriate to recommend food supplements, in line with existing guidance. PHAC were of the view that it is important to minimise prescription costs wherever possible, both for the individual and NHS / LA; availability of low

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			3. *General Medical Council. Good practice in prescribing and managing medicines and devices. 2013.Available at http://www.gmc-uk.org/guidance. Accessed April 2014.* 4. *4. Royal College of Paediatrics and Child Health policy statement produced by the joint RCPCH/NPPG Standing Committee on Medicines. December 2013.*	cost food supplements to increase uptake is key.
Consumers for Health Choice (CHC)	Section 1 Recommendation 2	Page 4	CHC would like to thank NICE for the opportunity to comment on this draft guideline on the implementation of existing NICE guidance to prevent vitamin D deficiency. CHC welcomes NICE's recommendation that the Department of Health should work with manufacturers to ensure that vitamin D supplements that provide the reference nutrient intake recommended by the scientific advisory committee on nutrition (SACN) are made widely available for adults and children. CHC would like to note, however, that proposed plans by the European Union to introduce maximum permitted dose levels (MPLs) in vitamin and mineral supplements under Article 5 of the Food Supplements Directive (2002/46/EC) may undermine this aim.	Thank you for this comment. To note that the guideline focuses on existing recommended intakes for the prevention of vitamin D deficiency, as SACN 2007. Issues around maximum permitted doses of vitamin D supplements are outside the remit of this work.
Consumers for Health Choice (CHC)			Proposals to set potentially low, harmonised MPLs for supplements across Europe will result in safe, higher-potency supplements being banned. This will inhibit access to higher potency, safe vitamin D	Thank you for this comment. To note that the guideline focuses on existing recommended intakes for the prevention of vitamin D deficiency, as SACN 2007. Issues around

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			supplements which certain groups may need or benefit from. The implementation of low-level MPLs will also result in manufacturers having to produce supplements which are weaker and fall short of providing SACN's reference nutrient intake. CHC urge NICE to make it clear within this guidance that the safety of higher-potency supplements, which may beneficial to some individuals within some key groups, is not in question. Therefore there is no need for further legislation or regulatory change to the laws surrounding food supplements on the basis of safety.	maximum permitted doses of vitamin D supplements are outside the remit of this work. Safe upper limits of vitamins and minerals is under the remit of the Committee on Toxicity and SACN.
Consumers for Health Choice (CHC)	Section 1 Recommendation 3	Page 5	CHC welcomes NICE's recommendation that Public Health England lead the development of a national campaign to raise awareness of the importance vitamin D, with campaign resources that are easily adaptable for local use. CHC believes it is important that messages seeking to raise awareness of the need to take vitamin D supplements are made in a variety of settings - including stores in the health food sector - as many consumers may be unaware of the importance of vitamin D for good health. The provision of easily adaptable campaign material will enable such retail stores to participate in raising awareness about this issue.	Thank you for this comment.
Consumers for Health Choice (CHC)	Section 1	Page 6	CHC would like to reiterate that the introduction of MPLs may negatively	Thank you for this comment. To note that the guideline focuses on existing recommended

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	Recommendation 5		impact on the availability of effective supplements at a local level too.	intakes for the prevention of vitamin D deficiency, as SACN 2007. Issues around maximum permitted doses of vitamin D supplements are outside the remit of this work.
Consumers for Health Choice (CHC)	Section 1 Recommendation 9	Page 9	CHC welcomes NICE's recommendation that local shops and businesses are also used to help disseminate messages and information about the importance of vitamin D to local groups.	Thank you for this comment.
Department of Health	General		There are inconsistencies with the format of the document. Sections 1 to 4 have bullet points and sub points. Section 4 has numbering, and then it reverts back to bullet points.	Thank you for this comment; the format of the guidance follows a standard template.
Department of Health	Recommendation 1 2nd point	4	We consider the guidance is clear for children under 6 months of age as stated in the CMO's letter of 2 February 2012.	Thank you for this comment. PHAC considered evidence that there is on-going confusion among practitioners and users about existing guidance (see evidence statement 1.8) and PHAC discussed that this was particularly the case in relation to guidance for children under age 6 months. PHAC are concerned that the complexity of existing advice may hinder uptake. The updated guideline recommends that PHE and DH consider whether there are any risks in formula fed infants also taking a supplement containing the RNI.
Department of Health	Recommend	4	We consider that it is clear that children aged 4 to 5 years require a	Thank you for this comment. PHAC

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	ation 1 3rd bullet point		vitamin D supplement as stated in the CMO's letter of 2 February 2012.	considered evidence that there is on-going confusion among practitioners and users about existing guidance (see evidence statement 1.8) and PHAC discussed that this was particularly the case for children age 4 to 5. The updated guidance notes in recommendation 3 re activities to increase awareness that 'Explain existing advice as clearly as possible, particularly if this may be misinterpreted……(note that children aged 4 to 5 years are not usually eligible for Healthy Start supplements).'
Department of Health	Recommend ation 2 1st bullet point	4	It would be helpful if there is a glossary link providing a definition and description for what are acceptable sources of vitamin D for vegans.	Thank you for this comment. A glossary definition of vegan has been added
Department of Health	Recommend ation 2 3rd bullet point	4	The guide for health professionals 'Help pregnant women, new mothers and children get their free healthy start vitamins' (www.healthystart.nhs.uk) states that these charging regulations are being considered. Regulations are being drafted to allow their sale again, we anticipate this process will be completed by the end of 2014.	Thank you for this clarification.
Department of Health	Recommend ation 2 3rd bullet point	4	We would prefer the sentence to read 'There should be arrangements in place so that pharmacies can purchase Healthy Start vitamins'. This is because the Department of Health does not have arrangements directly with the manufacturers.	Thank you for this comment, the wording of this recommendation has been amended.
Department of Health	Recommend ation 6	7	The Healthy Start scheme is for pregnant women, new mothers and children over 6 months and under 4. However in the context of this	Thank you for this comment. The guidance has been checked for consistency in relation

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	2nd bullet point		guideline and in line with CMO recommendations should this say 'children over 6 months and under 5?	to age groups at risk and age for eligibility to Healthy Start.
Department of Health	Recommendation 6 2nd bullet point	7	Would it be appropriate to flag to Local Authorities the specific piece of work that NICE are undertaking in response to the CMO's recommendation that NICE reviews whether it is cost effective to ensure every child receives Healthy Start vitamins?	Thank you for this comment. The considerations section states no studies were identified that compared universal free provision of vitamin D supplements with universal provision supplements that have to be paid for (albeit at a low cost). This prevented the committee from commenting on the relative benefits of these approaches and members felt that this is an important area for future research'. The additional work that NICE are undertaking on the cost effectiveness of universal versus targeted provision of healthy start supplements will be published as a stand-alone report rather than guidance and therefore not appropriate to flag as suggested (see here).
Department of Health	Recommendation 6 2nd bullet point	7	To be aware that if the central hub is distributing to sites outside its own organisation (e.g. NHS owned facilities such as health clinics or children's centres run by charitable organisations) we believe the central hub will need a wholesale dealers licence. We suggest NICE seek clarification from the MHRA regarding this to assist readers.	Thank you for this comment. As licenses are currently obtained by all issuing sites, we consider this a specific implementation issue rather than for inclusion in the recommendation.
Department of Health	Recommendation 7 1st Bullet	7	Should this read Clinical Commissioning Groups?	Thank you, the wording of the recommendation has been amended.

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	point			
Department of Health	Recommendation 7. 1st Bullet point, 3rd indent	7	'statutory Health Visitor appointments for infants and children' is not factually correct. Within the context of the point we would prefer it to say 'Universal Healthy Child Programme health visitor contacts for infants and children.'	Thank you for this comment, the text has been amended to state 'health visitor appointments…..'
Department of Health	3 Context How to get vitamin D supplements 2nd paragraph, last sentence	16	Manufacturers cannot make Healthy Start vitamins directly available to pharmacies. This is because the arrangement is for direct supply between the manufacturer and supplier/distributer. We anticipate the process for pharmacies to purchase vitamins will be in place by the end of 2014	Thank you for this clarification.
Department of Health	3 Context How to get vitamin D supplements 4th paragraph	16	The word 'entitled' implies that a person has the right to buy the supplements. The regulations used to enable the sale of the Healthy Start vitamins designated it a 'facility'. As a consequence NHS organisations could choose whether to sell them. DH is drafting regulations to allow NHS organisations to sell the vitamins again	Thank you for this clarification. The wording has been amended in line with your comment.
Department of Health	4.13	21	We wonder whether the phrase 'prohibitively expensive' is appropriate. It would be helpful to have some evidence to support the comment.	Thank you for this comment, the wording has been amended.
Department of Health	`4.13	21	The Department is in discussions with the supplier that should mean they are more widely available.	Thank you for this information.
Department of Health	4.13	21	The Department is in discussions with the supplier that should mean they will be available in high street outlets.	Thank you for this information.
Department of Health	4.13	21	The Department is in the process of making new regulations to allow the sale of vitamins again by organisations providing child health clinics	Thank you for this information

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			and maternity clinics.	
Department of Health	7 Glossary Healthy Start	28	Factual corrections (underlined) Healthy Start is a UK-wide scheme that provides a nutritional safety net for	Thank you, the wording has been amended in line with your comment.
Department of Health	7 Glossary Healthy Start	28	Women who are at least 10 weeks pregnant and families with children younger than 4 years qualify if they receive the relevant benefits	Thank you, the wording has been amended in line with your comment.
Department of Health	7 Glossary Healthy Start	28	Children over 1 and under 4 years old get 1 voucher	Thank you, the wording has been amended in line with your comment.
Department of Health	7 Glossary Healthy Start	28	They can be spent on …. at retail outlets registered to accept them, these include supermarkets, grocery stores, chemists and milk rounds	Thank you, the wording has been amended in line with your comment.
Department of Health	7 Glossary Healthy Start	28	In England, as a consequence of the Health and Social Care Act 2012 the regulations changed. It is the responsibility of: NHS England (commissioning children's services 0-5 years until October 2015, Clinical Commissioning Groups (commissioning maternity services) and/or Local Authorities (commissioning from October 2015 /providing child health clinics/maternity services) to provide or arrange the provision of Healthy Start vitamins to those registered on the scheme. (Responsibilities in Scotland and Wales have not changed)	Thank you, the wording has been amended in line with your comment.
Department of Health	General		Healthy Start vitamins women's tablets and children's drops contain the reference values recommended by SACN. The Department is already taking steps to improve access and increase awareness and uptake amongst Healthy start families.	Thank you for this comment.
Department of Health	General		We understand that NICE have agreed to review the cost effectiveness of extending the provision of free Healthy Start vitamins to every child under 5	Thank you for this comment. NICE is considering the cost effectiveness of universal versus targeted provision of healthy start supplements (see here).
Office of Public Health, Dudley Metropolitan	1	4	Clarify if women's Healthy Start tablets contain vitamin D	Thank you for this comment; a definition of the healthy start vitamins is given in the

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Borough Council				glossary.
Office of Public Health, Dudley Metropolitan Borough Council	1	4	Highlight the direct impact between intake of vitamin D on pregnant women and their unborn baby.	Thank you for this comment; this would be addressed under recommendation 3, bullet point 'emphasise the importance of vitamin D for good health' and recommendation 5 on local availability.
Office of Public Health, Dudley Metropolitan Borough Council	1	4	The voucher exchange process should be streamlined. Increase the number of stores that accept vouchers and stock vitamins.	Thank you for these comments. Wider distribution and sale is dealt with in recommendation 2.
Office of Public Health, Dudley Metropolitan Borough Council	1	5	Pharmacies and other outlets should also stock Healthy Start vitamins.	Thank you for these comments. Wider distribution and sale is dealt with in recommendation 2.
Office of Public Health, Dudley Metropolitan Borough Council	1	5	Emphasis lack of dietary influence of vitamin D	Thank you for this comment. The wording of recommendation 3 has been revised to more strongly emphasise the limited dietary sources for vitamin D.
Office of Public Health, Dudley Metropolitan Borough Council	1	5	Who is the lead agency referred to in Recommendation 4?	Thank you for this comment. Recommendation 4 has been re-drafted to make clear that Directors of public health should ensure a multiagency approach.
Office of Public Health, Dudley Metropolitan Borough Council	1	6	Include the use of Healthy Start vitamins when talking about providing free supplementation for at-risk groups.	Thank you for this comment. Consultation recommendation 6 states 'consider offering free healthy start supplements…..'

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Office of Public Health, Dudley Metropolitan Borough Council	1	7	Suggest Universal Provision when recommending free healthy Start supplements to breastfeed women and children under 4.	Thank you for this comment. Recommendation 6 states 'Consider offering free healthy start supplements to all pregnancy and breastfeeding women and children under 4 years.
Office of Public Health, Dudley Metropolitan Borough Council	1	7	Include MECC when talking about healthcare professionals recommending vitamin supplementation.	Thank you for this comment. Updated recommendation 7 highlights the broad range of settings where health practitioners may be prompted to raise the issue of vitamin D.
Office of Public Health, Dudley Metropolitan Borough Council	1	7	Include antenatal appointments are included in the computerised prompts for vitamin D.	Thank you, the text has been amended in line with your comment.
Office of Public Health, Dudley Metropolitan Borough Council	1	8	MECC should be included in the list of information health professionals receive upon registration.	Thank you for this comment. This recommendation focuses on specific information on vitamin D for practitioners rather than general information about policies such as MECC.
Office of Public Health, Dudley Metropolitan Borough Council	1	9	Raise awareness that vitamin D is scarcely found in the diet.	Thank you for this comment. The revised text more strongly emphasises limited dietary sources.
Office of Public Health, Dudley Metropolitan Borough Council	2	11	Public Health already do recommendations 2, 4, 5, 6, 7, 8, 9 and 10. Public Health should be involved with all points relating to Healthy Start.	Thank you for this comment. Who should take action attributes responsibility, rather than listing all staff who may be involved.
Office of Public Health,	3	14	Newborns/ neonatal babies should be mentioned when referring to	Thank you for this comment. The list reflects

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Dudley Metropolitan Borough Council			those at a particular risk.	existing guidance from SACN and the CMOs. P15 of the consultation document states that 'Infants who are exclusively breastfed, particularly for more than 6 months, or have an infant formula intake less than 500ml, are at increased risk because the amount of vitamin D in their milk will not meet their needs.'
Office of Public Health, Dudley Metropolitan Borough Council	3	14	The links to vitamin D and obesity should also be highlighted.	Thank you for this comment. The list of groups at risk reflects existing guidance from SACN and the CMOs.
Office of Public Health, Dudley Metropolitan Borough Council	3	16	The cost of treating rickets should mentioned in the paragraph about cost effectiveness.	Thank you for this comment. The cost of treating rickets is mentioned in the context on page 19. As discussed in section 4.16 the main question for the cost effectiveness was 'What is the most cost-effective way of providing vitamin D supplements to at-risk groups?' It is also included in 4.19 as the cost per deficiency averted.
Office of Public Health, Dudley Metropolitan Borough Council	4	21	The difference in frequency of voucher distribution (4 weeks and 8 weeks) also causes confusion.	Thank you for raising this issue.
Office of Public Health, Dudley Metropolitan Borough Council	1	6	Local Public Health teams need clear and concise data regarding Healthy Start eligibility and actual uptake in their localities. This will help in seeing how accessibility and uptake can be improved.	Thank you for this comment – this is reflected in consultation recommendation 10 on monitoring and evaluation.

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First Steps Nutrition Trust	General		The policy on supplementation for infants and young children does need to be clearly specified, but it would also be helpful if it could be highlighted that there is no benefit, and potential risk, associated with the provision of vitamin D to children through fortified growing up milks. The European Food Safety Agency (EFSA) have recently stated that there is no need for these milks in the diets of children in the EU and this is also specified on NHS Choices. There are potential risks associated with consumption of flavoured, sweetened milks which have very high amounts of some nutrients and lower amounts of others compared to whole animal milk. This may also be relevant as commercial companies seek to expand the market for expensive fortified milks to pregnant and lactating women and potentially older people, and a clear statement that current UK policy relates only to vitamin D supplements should be considered.	Thank you for this comment. Fortification issues are outside the scope of this work. Issues around infant formula are covered by existing guidance on maternal and child nutrition (PH11).
First Steps Nutrition Trust	1. Draft recommendation 2	4	We fully support the need for supplements to be made available which are suitable for all population groups	Thank you for this comment.
First Steps Nutrition Trust	1. Draft recommendation 3 and 4	5	There should be some clarity over potential risk of Vitamin D overdose if national campaigns are to stress importance of vitamin D for good health. Whilst very high does may be rare, a clear Upper Level should be specified.	Thank you for this comment. The upper limit is under the remit of SACN. Updated recommendation 1 states that supplements should provide the reference nutrient intake.
First Steps Nutrition Trust	1. Recommendation 8	8	As above – clear advice on UL should be specified for health professionals in training	Thank you for this comment, we are of the view that the existing wording 'supplement recommendations for different groups' would

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				cover this issue.
Foodtalk CIC	General	2	Guidance should also be aimed at those working with “at risk” groups such as early years workers, midwives, health visitors and other health professionals.	Thank you for this comment. Those working with at risk groups are highlighted in the section ‘who should take action’.
Foodtalk CIC	Recommendation 2	4	Include Kosher	Thank you, the text has been amended in line with your comment.
Foodtalk CIC	Recommendation 2	4	Work with manufacturers to increase the shelf life of Healthy Start vitamins	Thank you for raising this issue.
Foodtalk CIC	Recommendation 3	5	Campaign material should be “picture-based” or simple English as vitamin D deficiency often effects those with English as a second language. Translation the resources to other languages should also be recommended.	Thank you for this comment. The specific details or methods used for a campaign or awareness raising activity is beyond the remit of this guidance.
Foodtalk CIC	Recommendation 6	6	Research shows that the primary reason for low HS uptake is that those most in need do not know where or how to access them. All Public Health teams should be required to keep a list of Healthy Start distribution centres that is updated regularly. This should then be either posted electronically and/or distributed to children’s centres, pharmacies and GP clinics so that the general population knows how and where to access. All boroughs should be encourage to also upload their list of HS distribution centres online as a way of making it accessible to all.	Thank you for this comment. Awareness of local sources is covered in updated recommendation 9.
Foodtalk CIC	Recommendation 6	7	Consider offering Healthy Start vitamins to children up to the age of 5 to align with the Department of Health’s recommendations.	Thank you for this comment. Suggested amendments to the Healthy Start benefit is outside the remit of this guidance. Updated recommendation 3 notes the importance of clarifying any confusion around at risk groups,

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				noting that children age 4 to 5 are not eligible for healthy start.
Foodtalk CIC	Recommendation 7	7	Add statutory appointments with midwives for pregnant women	Thank you, the wording of this recommendation has been amended.
Foodtalk CIC	Recommendation 8	8	Ensure health and social care professionals also receive information on how and where families can access Healthy Start supplements in their areas and how to go about signposting.	Thank you, this is covered in the recommendation as it stands, stating 'local sources of healthy start supplements'
Foodtalk CIC	Recommendation 10	10	Use a standardised tool with when developing and evaluating awareness-raising interventions to support high quality, effective and consistent evaluation of vitamin D awareness-raising interventions.	Thank you, this is covered in the recommendation as it stands, stating 'develop a standardised too ……'
Foodtalk CIC	Who should do what at a glance	11	Voluntary and community organisation with healthcare professionals as part of their teams could also take action for: - Recommendation 3 by developing local campaigns or support Public Health in developing wider vitamin D campaigns. In addition voluntary and community organisations could develop resources recommended by the guidance. - Recommendation 8 by developing and delivering awareness-raising training programmes to health and social care professionals.	Thank you for this comment . Who should take action highlights key responsibility rather than listing all those involved. A broad range of health and social care professional are listed in recommendation 9.
Foodtalk CIC	Who should take action Recommendation 8	12	Recommend that "voluntary and community groups" be included on who should take action for recommendation 8	Thank you for this comment . Who should take action highlights key responsibility rather than listing all those involved. A broad range of health and social care professional are listed in recommendation 9.
Foodtalk CIC	Paragraph 3	14	Could "particularly for more than 6 months" be changed to "particularly after 6 months of age". Also, it seems to state that those on less then	Thank you, the wording has been amended.

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			500ml of formula milk per day are at risk in both the first and second sentence. These 2 sentences could be simplified to "infants greater than 6 months of age and on less than 500ml of Infant formula per day are at increased risk…"	
Foodtalk CIC	General	17	Could this section be titled "considerations when developing the above recommendations" or something similar? As right now, it is a bit confusing as to what the considerations are for.	Thank you for this comment, the guidance follows a standard template.
Foodtalk CIC	4.2	17	I don't feel that recommendations stressed the order in which action should be taken as stated in this paragraph. This needs to be made clearer.	Thank you for this comment , the wording has been amended.
Foodtalk CIC	4.14	22	Could the need for training be made clearer as part of recommendation 8. Or, if all PHAC members agree, potentially the need for training of HCPs and those working with "at-risk" groups should be a recommendation on its own.	Thank you for this comment. We are of the view that the importance of training and professional development is made strongly within updated recommendation 9.
Foodtalk CIC	5. Recommendations for research	23	1. Would screening for vitamin D deficiency in all pregnant women with darkly pigmented skin be cost effective? 2. Is 10ug vitamin D sufficient to prevent deficiency of a new born infant whose mother was deficient during pregnancy? 3. (A clinical research question- What is a safe dose to treat vitamin D deficiency in pregnant woman?)	Thank you for this comment. Screening is outside the remit of NICE. The dietary reference values are currently being considered by SACN. Treatment is outside the remit of this guidance.
Foodtalk CIC	5.1	24	It can be extremely challenging to receive ethical approval to conduct studies where vitamin D status in children needs to be collected. Measuring effectiveness and cost effectiveness of awareness raising and uptake can be done without the need of measuring vitamin D status and would encourage more researchers to complete studies that can	Thank you for this comment, the research recommendations have been amended.

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			answer the research question. We kindly ask you to reconsider the opening paragraph presented before section 5.1.	
Foodtalk CIC	5.5	25	Similar to previous comment we question whether measuring vitamin D status is a must to answer the research question. We kindly ask you to reconsider the opening paragraph presented before section 5.1.	Thank you for this comment , the research recommendations have been amended.
Health and Social Care Board, Northern Ireland	Section 1 Recommendations/ General Comment		Healthy Start Vits are suitable for children/mothers/mothers-to-be. These groups will be take the supplements for a time limited period and with widely varying levels of compliance. A potentially much larger group in the CMO letter is people aged 65 and over, who will potentially been supplemented daily from age 65 until death. Compliance with taking tablets in some over 65s may be much less of an issue, for a number of reasons including familiarity with taking medications for other conditions, monitored dosing systems, being within a residential or nursing care facility. The guidance needs to address this issue. A suitable (licensed?) product is needed and definitive advice on whether this should be prescribed by GP, supplied by another non-prescription route but at NHS cost, or purchased by the individual/carer	Thank you for this comment. A limited amount of evidence was identified for adults over age 65. Updated recommendation 1 notes the importance of suitable supplements containing the RNI being available for at risk groups.
Health and Social Care Board, Northern Ireland	Section 1 Recommendation 2	Page 4	Should a licensed medicine product be available?	Thank you for this comment. Updated recommendation 1 notes that DH should work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.

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Health and Social Care Board, Northern Ireland	Section 1 Recommendation 2 and Recommendation 3	Page 5	Could consideration be given to a recognised cross-manufacturer endorsement, logo or labelling system for products available to purchase, similar to food labelling?	Thank you for this comment. No evidence was identified on endorsement, logo or labelling schemes for vitamin D supplements.
Health and Social Care Board, Northern Ireland	Section 1 Recommendation 5	Page 6	Minor Ailments schemes would not suitable for this purpose; please consider removing it as an option/example Minor Ailments is for acute self-limiting conditions, and is primarily about advice; product supply should be secondary to this and only if necessary. Supply of Vitamin D through the scheme could distort the image of Minor Ailments both to patients and pharmacy staff. It may also be a costly option given a payment would be made for each consultation; bar maybe the first issuing there will be virtually no interaction and it will be purely a supply role. Exploring alternative methods for distribution through community pharmacy would be welcomed. One option could be issuing of vouchers for reimbursement at pharmacy or other outlet of choice. The outlet would be reimbursed for the vouchers, similarly to existing arrangements for infant formula, cow's milk etc.	Thank you for this comment, the text has been amended.
Health and Social Care Board, Northern Ireland	Section 1 Recommendation 6 and Recommendation 7	Page 7	Consider providing a 'starter pack' of Healthy Start vitamins at routine vaccinations together with information on accessing locally, or include first voucher in the 'Red Book'.	Thank you for this comment, no evidence was identified on 'starter packs' of healthy start vitamins. The recommendations as they stand would not prevent this type of activity.

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Health Food Manufacturers' Association	General	5, 8, 9	Reference to the importance of vitamin D for 'good health' should be more specific in explaining the actual benefits of vitamin D e.g. for bone health, calcium absorption, the immune system – in order to engage the public by giving them more tangible information	Thank you for this comment. The specific information provided by health professionals or in awareness raising are beyond the scope of this guidance.
Health Food Manufacturers' Association	Section 1	4	Recommendation 1, 4th sub bullet – Public Health England to clarify how older adults would know that they have an adequate calcium intake – e.g. by reference to already taking calcium supplements, or number of portions of dairy foods per day	Thank you for this comment , the wording of this recommendation has been revised.
Health Food Manufacturers' Association	Section 1	4	Recommendation 2, regarding provision of the RNI – if people have a particularly low status of vitamin D they are likely to benefit from a supplement providing an intake that is above the RNI to return to optimum vitamin D status. Hence supplements providing above the RNI should also be available, particularly in view of the wide safety margin between the RNI and the upper safe level.	Thank you for this comment. The recommendations are focused on prevention rather than treatment.
Health Food Manufacturers' Association	Section 1	4	Recommendation 2 – It is important in the interests of cost effectiveness that the guidance should apply to dietary supplements as well as to prescription/licensed products. The Chief Medical Officers for the United Kingdom recognise the role of vitamin D food supplements in raising vitamin D status in groups at risk of low status and vulnerable groups. Long-standing advice the UK Health Departments is for at-risk groups to take a daily dietary supplement containing vitamin D. A food supplement is the ideal product to help maintain optimum status or restore low status in at-risk groups. Vitamin D is a nutrient and thus low status should be restored by a nutritional supplement. There is no evidence of adverse effects from people consuming vitamin D dietary supplements.	Thank you for this comment. The guidance applies to both dietary supplements and products available on prescription. The aim of the guidance is to increase access through a variety of sources. The recommendations address both food supplements and licensed products. PHAC members were keen to ensure that options remained low cost both for the individual and NHS / local authorities.

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Health Food Manufacturers' Association	Section 1	7	Recommendation 6, regarding provision of Healthy Start supplements to pregnant women – pregnant women may require more specific advice to reassure them that it is safe to take supplements during pregnancy and what supplements are suitable to take.	Thank you for raising this issue. Updated recommendation 10 highlights the importance of tailoring advice.
Health Food Manufacturers' Association	Section 1	7	Recommendation 7, 1st bullet point – suggest adding oncology appointments, which would be particularly helpful for skin cancer patients who may be avoiding exposure to the sun	Thank you for this comment. Management of conditions that may increase risk of deficiency is outside the remit of this guidance. 'Screening appointments' is included within the updated recommendation.
Health Food Manufacturers' Association	Section 1	8	Recommendation 8 – 1st bullet point, include educational information about the RNI, the upper safe level, and advice specifically or vitamin D supplements during pregnancy as well as the other areas listed.	Thank you for this comment. This is covered by the bullet 'supplement recommendations for different groups'
Internis Pharmaceuticals Limited	General		**Panel of authors** The current panel of authors is an eminent group of experts. Internis recommends that a licensed prescribing physician is also invited to join the panel in order to complete the 360° perspective.	Thank you for this comment. PHAC can request expert testimony or co-opt an expert to the committee if they feel that they are lacking expertise or evidence in a particular area. General licensing issues are outside the remit of this guidance. However, NICE did seek advice from MHRA and DH post consultation.
Internis Pharmaceuticals Limited	Recommendation 1	4	**Clarify existing guidance on, and which groups are at risk of, vitamin D deficiency – at-risk groups** Internis notes that vitamin D dietary reference value nutrient intake is currently the subject of a Scientific Advisory Committee on Nutrition (SACN) reappraisal.[1] Definitions of 'at-risk' groups should reflect the	Thank you for this comment and references. The guidance focuses on the implementation of existing guidance but the introduction notes that it should be considered alongside SACN's report when published. The guidance

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			vitamin D dietary reference value nutrient intake levels as re-defined by the SACN. 1. SACN, Call for evidence – SACN review of vitamin D http://www.sacn.gov.uk/news_press_releases/latest_news/call_for_evidence_-_sacn_review_of_vitamin_d.html last accessed 09/06/14 The British Geriatric Society, American Geriatric Society and National Osteoporosis Society all recommend a 800 iu vitamin D in a daily dose for most at risk groups.[2, 3] 2. American Geriatric Society / British Geriatric Society Clinical Practice Guidelines for Prevention of Falls in Older Persons http://www.bgs.org.uk/index.php?option=com_content&view=article&id=320:bgsagsfalls2010&catid=47:fallsandbones&Itemid=307 3. National Osteoporosis Society (NOS) Guidelines published April 2013, Vitamin D and Bone Health: A Practical Clinical Guideline for Patient Management http://www.nos.org.uk/document.doc?id=1352 To date all calcium / vitamin D combined therapies have included 800iu vitamin D in each daily dose. Internis recommends that the Guideline Development Group aligns its recommendations with the generally accepted[1, 2] dose of 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and	is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.

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			5 years and the over 65s). There is an increasing, and therefore competitive, number of fully MHRA licensed D_3 products on the market. The MHRA licensed vitamin D_3 products have all been granted authorisation where the products are only available as POM. No P or GSL licences have been granted to date. Internis recognises that there is a place for food supplement products with nutritional levels of D_3 but Internis does believe that treatment prescribed by doctors should always be given using licensed medicinal products. Internis asks the Guideline Development Group to note that, for elderly patients receiving treatment for dementia, only MHRA licensed, prescription products are permitted in the 'Nomad' box (a system intended to make drug regimen compliance simpler for this group of patients).	
Internis Pharmaceuticals Limited	Recommendation1	4	**Clarify existing guidance on, and which groups are at risk of, vitamin D deficiency – at-risk groups** Much of the UK and Europe's medicines control legislation can be traced back to the tragic consequences of the use of thalidomide by pregnant women. MHRA licensing of products exists to protect vulnerable groups, like pregnant woman and their children, from the unacceptably high human cost associated with drug errors.	Thank you for this information.
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements – working with manufacturers** There are significant differences between pharmaceutical manufacturers and health food manufacturers, based on the different regulations that govern them. The more rigorous regulation applied to manufacturers of MHRA licensed, prescription medicines includes the inspection of manufacturing facilities and standards as well as	The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI

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			monitoring of the quality and consistency of their products via batch testing. Regulation of MHRA licensed, prescription products means that quality and safety reporting are guaranteed by the existing 'yellow card'[4] system. 4. https://yellowcard.mhra.gov.uk/ last accessed 02/06/2014 A prescription route also allows more accurate monitoring of the impact of the Public Health Guideline. Internis believes that vitamin D3 supplementation should be provided in a consistent, regulated dose which meets generally accepted dose of 800iu for most at-risk groups – using an MHRA licensed, prescription (POM) or pharmacy (P) or General Sales List (GSL) product.	for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** Only pharmaceutical companies supplying licensed medicinal products are obliged to operate pharmacovigilance on their products. There is no requirement for suppliers of food supplement products without an MHRA licence to monitor any adverse events reported in relation to the products that they distribute. In addition to the drug safety review procedures embodied within pharmacovigilance, pharmaceutical companies, including Internis, also provide important medical information support services to healthcare professionals and patients. Through the first 5 months of 2014 the Internis medical information service has been dealing with an average of more than two enquiries per day relating to Vitamin D treatment. This important back-up service is not provided in relation to food supplement products, without an MHRA licence.	Thank you for this information. The guidance is focused on the prevention of deficiency; treatment is outside the scope. The guidance focuses on the implementation of existing guidance and focuses on the RNI. SACN are currently considering the dietary reference values, including safe upper limits. General licensing issues are outside the remit of the work.

Public Health Guidelines

Implementing Vitamin D guidance - Consultation on Draft guideline
Stakeholder Comments Table

13 May – 24 June 2014

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted. If comments forms do have attachments they will be returned without being read. If the stakeholder resubmits the form without attachments, it must be by the consultation deadline

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** Vitamin D is a fat soluble secosteroid, sometimes referred to as a prohormone (a hormone precursor).[5, 6, 7] This is very different from a relatively simple molecule like ascorbic acid (vitamin C). Internis believes that such complex products should be considered medicines, not supplements, and should be subject to regulation and licensing via the MHRA, with all the quality control, measurement and accountability that this implies. 5. Vitamin D, Third Edition by Feldman D, Pike JW, Adams JS. Elsevier Academic Press, 2011. 6. Coen G. Vitamin D: an old prohormone with an emergent role in chronic kidney disease. J Nephrol. 2008 May-Jun;21(3):313-23. http://www.ncbi.nlm.nih.gov/pubmed/18587719 last accessed 19/06/2014 7. Holick,M. Vitamin D: the underappreciated D-lightful hormone that is important for skeletal and cellular health. Current opinion in endocrinology and diabetes 2002, 9:87-98	Thank you for this issue. Whether vitamin D is a food supplement or medicinal product is outside the remit of NICE and under the remit of the MHRA borderline products.
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** Internis recommends that the Guideline Development Group aligns its recommendations with the generally accepted[1, 2] dose of 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	Thank you for this comment. The guidance is focused on the prevention of deficiency and the implementation of existing guidance. The introduction notes that the guidance should be read alongside any new SACN recommendations on dietary reference values.
Internis Pharmaceuticals	Recommend	4	**Increase access to vitamin D supplements**	Thank you for this information. The specific

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Limited	ation 2		Strict vegans may have difficulty accepting vitamin D_3 in any form. All vitamin D_3 comes from animal derivatives. Internis recommends that the Guideline Development Group is less specific and amends its recommendation to 'suitable formulations for all at-risk groups', in order to reduce the potential for creating unnecessary concern. Internis is working closely with the MHRA to correctly manage the removal of peanut oil from the Fultium D_3 product formulation. By the time the Guideline is published, this Autumn, we expect the entire Fultium D_3 supply chain to be free of peanut oil. However, the allergic response risk associated with the use of peanut derived oil depends on the quality of the oil. Highly refined versions of the oil, like that used in Fultium D_3 capsules do not present a high risk to potentially allergic patients. Individual patients could suffer from other allergies as well as those associated with the consumption of peanuts so Internis considers that wider, more balanced guidance is presented with regard to potential allergies. To date no allergic/anaphylactic reaction has been reported in any patient treated with Fultium D_3.	form of vitamin D is outside the remit of this guidance.
Internis Pharmaceuticals Limited	Recommend ation 2	4	**Increase access to vitamin D supplements** The draft NICE Guidance makes no distinction between vitamin D_2 (ergocalciferol) and vitamin D_3 (cholecalciferol). Evidence suggests that, while both forms may be beneficial, vitamin D_3 is more effective in humans [8,9]The National Osteoporosis Society also recommends vitamin D_3.[3] 8. Armas LA, Hollis BW, Heaney RP. "Vitamin D2 is much less effective than vitamin D3 in humans." J Clin Endocrinol Metab. 2004 Nov;89(11):5387-91.	Thank you for this comment. The specific form of vitamin D is outside the remit of this guidance.

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			9. Houghton LA, Vieth R. "The case against ergocalciferol (vitamin D2) as a vitamin supplement." Am J Clin Nutr. 2006 Oct;84(4):694-7. Internis recommends that the Guideline Development Group note that vitamin D_3 is the preferred option in most circumstances.	
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** Food supplement products are not licensed by the MHRA and are not subject to strict control. Products without an MHRA licence have shown large variation in the percentage label claim of vitamin D content (between 8% and 201% of the labelled amount).[10] Another study identified dose variations in pills from the same bottle (52-136% of stated dose) and between separate preparations (9-140% of stated dose).[11] Only a third of the pills tested were within 10% of the stated dose, with licensed products proving the most accurate.[12] 10. Garg S, et al. Evaluation of vitamin D medicines and dietary supplements and the physicochemical analysis of selected formulations. The Journal of Nutrition, Health & Aging. 2013; 17(2), 158–61. doi:10.1007/s12603-012-0090-4 11. Leblanc ES, Perrin N, Johnson JD, Ballatore A, Hillier T. Over-the-Counter and Compounded Vitamin D: Is Potency What We Expect? JAMA Intern Med. 2013 Apr;173(7):585–6. 12. Khadgawat R, Ramot R, Chacko KM, Marwaha RK. Disparity in cholecalciferol content of commercial preparations available in India. Indian J Endocrinol Metab [Internet]. 2013 Nov [cited 2014 Jan 14];17(6):1100–3. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3872693&tool=pmcentrez&rendertype=abstract	Thank you for this comment. Updated recommendation 1 states that 'Supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D.'

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			The European Commission (EC) stipulates that vitamin products, not licensed by the MHRA, should contain between +50% and -35% of the stated dose,[13] however, this is not currently enforced by the FSA or by Trading Standards. By contrast the MHRA stipulates that licensed products must contain more strictly control drug contents around the stated dose; limits which are subject to strict and active legal enforcement. 13. EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL GUIDANCE DOCUMENT FOR COMPETENT AUTHORITIES FOR THE CONTROL OF COMPLIANCE WITH EU LEGISLATION ON: Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to	

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			consumers, amending Regulations (EC) No 1924/2006 and EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 and Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling of foodstuffs and Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements with regard to the setting of tolerances for nutrient values declared on a label, December 2012. The European Food Safety Authority recommends the following upper safe limits on dietary intakes of vitamin D: 25mcg (1,000iu) per day for infants 0–12 months and 50mcg (2,000iu) per day for children 1–10 years.[14] 14. EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2012. Scientific Opinion on the Tolerable Upper Intake Level of vitamin D. EFSA Journal 2012;10(7):2813, 45 pp. doi:10.2903/j.efsa.2012.2813 Vitamin D toxicity has been reported in a subject using a 600iu vitamin D formulation, which actually contained 52,800iu.[15] A separate incident involved 7 paediatric cases of toxicity where a fish-oil supplement contained vitamin D at 4,000 times the stated dose.[16] Multiple studies	

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			have reported similar instances of toxicity associated with poorly controlled or miss-stated vitamin D content.[17, 18, 19, 20, 21, 22, 23] 15. Benemei S, Gallo E, Giocaliere E, Bartolucci G, Menniti-Ippolito F, Firenzuoli F, et al. It's time for new rules on vitamin D food supplements. Br J Clin Pharmacol [Internet]. 2013 Dec [cited 2013 Oct 31];76(5):825–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23594340 16. Kara C, Gunindi F, Ustyol A, Aydin M. Vitamin D intoxication due to an erroneously manufactured dietary supplement in seven children. Pediatrics [Internet]. 2014 Jan 2 [cited 2014 Apr 1];133(1):e240–4. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24298009 17. Koutkia P, Chen TC, Holick MF. Vitamin D intoxication associated with an over-the-counter supplement. N Engl J Med [Internet]. 2001 Jul 5 [cited 2013 Dec 24];345(1):66–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/11439958 18. Klontz KC, Acheson DW. Dietary supplement-induced vitamin D intoxication. N Engl J Med [Internet]. 2007 Jul 19 [cited 2013	

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			Dec 24];357(3):308–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17634473 19. Lowe H, Cusano NE, Binkley N, Blaner WS, Bilezikian JP. Vitamin D toxicity due to a commonly available “over the counter” remedy from the Dominican Republic. J Clin Endocrinol Metab [Internet]. 2011 Feb [cited 2013 Dec 24];96(2):291–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21123442 20. Bell DA, Crooke MJ, Hay N, Glendenning P. Prolonged vitamin D intoxication: presentation, pathogenesis and progress. Intern Med J [Internet]. 2013 Oct [cited 2013 Dec 24];43(10):1148–50. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24134173 21. Anık A, Çatlı G, Abacı A, Dizdarer C, Böber E. Acute vitamin D intoxication possibly due to faulty production of a multivitamin preparation. J Clin Res Pediatr Endocrinol [Internet]. 2013 Jan [cited 2013 Dec 24];5(2):136–9. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3701922&tool=pmcentrez&rendertype=abstract 22. Granado-Lorencio F, Rubio E, Blanco-Navarro I, Pérez-Sacristán B, Rodríguez-Pena R, García López FJ. Hypercalcemia, hypervitaminosis A and 3-epi-25-OH-D3 levels after consumption of an “over the counter” vitamin D remedy. A case report. Food Chem Toxicol [Internet]. 2012 Jun [cited 2013 Dec 24];50(6):2106–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22426357 23. Araki T, Holick MF, Alfonso BD, Charlap E, Romero CM, Rizk D, et al. Vitamin D intoxication with severe hypercalcemia due	

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			to manufacturing and labeling errors of two dietary supplements made in the United States. J Clin Endocrinol Metab [Internet]. 2011 Dec [cited 2013 Dec 24];96(12):3603–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21917864 There is no age restriction on purchasing vitamin products which are not licensed by the MHRA. A child of any age could purchase a product which claims to contain 30,000iu vitamin D, one hundred times the recommended paediatric dose of 300iu and fifteen times the European Food Safety Authority upper safe limit for children between 1 and 10 years old (at the time of writing). Given the dose variation which characterises this product category[24] the actual dose could be significantly higher. 24. Company-led drug recall: Dekristol/Dektristol Capsules - Jumbogate Ltd. (Quvera livery) - CLDA(12)A/10 http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/DrugAlerts/Company-ledrecalls/CON172253 Internis recommends that the Guideline Development Group aligns its recommendations with the generally accepted[1, 2] dose of 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and	

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			5 years and the over 65s). This is particularly important as a public health and safety issue because of the current regulatory inconsistency in, on the one hand the regulator (MHRA) demanding a fully supported package of data to demonstrate adequate quality, safety and efficacy for a licensed product but at the same time allowing the distribution and supply of highly variable, potentially dangerous, unregulated products.	
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** Internis has sponsored its own analysis of vitamin D supplement products marketed for dosing to infants and children but available without an MHRA licence in the UK.[25] The analysis has been conducted by an independent laboratory certified for the analysis of medicines within the European Union. The amount of drug (versus the label claim) and the uniformity of the delivery system were examined. Three products failed to provide an adequate vitamin D content (BabyD 400iu syringe contained 19.6% of the stated dose, Nature's Aid Vitamin D_3 drops 200iu contained 13.6% of the stated dose and ProD_3 400iu drops contained 48.8% of the stated dose). The analysis of these products was repeated and the first results were substantiated in each case. Two products failed to deliver consistent doses. While testing Dlux 400iu it was found that the atomiser used for one batch did not operate properly (giving 13 out of 20 doses outside of 90 to 110 % of the dose and 5 of these doses fell outside of the 80 to 120 % limits) while a second batch performed satisfactorily. During testing of ProD_3 400iu drops the dropper failed to deliver the correct drop size / dose for each of two tests performed (9 of 20 samples were outside of the 90 to 110	Thank you for this comment. Quality control issues are outside the remit of this guidance. The draft guidance highlights throughout that supplements should contain the RNI. The guidance is focused on prevention; treatment is outside the remit of the guidance. Licensing issues are outside the remit of NICE. Updated recommendation 1 states that 'Supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D.'

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			% limits and 3 of 20 samples were outside of the 80 to 120 % limits). 25. Internis Pharmaceuticals Ltd, data on file	
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** The Medicines and Healthcare products Regulatory Agency (MHRA) assesses all data related to medicinal products to ensure that products taken by patients in the UK meet the correct requirements for quality, safety and efficacy. While reviewing the data packages prepared by pharmaceutical companies the MHRA will ensure that the products being licensed have a positive benefit: risk balance. Part of this assessment process includes setting tight specifications that both ensure the high quality of medicinal products but also insist on a testing regimen where deviations (including in-specification trends) can act as a signal of something going wrong with either the manufacture or quality control testing. Such regulatory safety checks provide a significantly higher degree of control on the medicinal products and as such result in a significantly reduced risk to all patients receiving vitamin D supplementation than they will receive if they are being prescribed or otherwise taking unlicensed supplements purporting to be medicinal products.	Thank you for raising this issue.
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** Is it the authors' intention that food supplements with MHRA licence are included in the British National Formulary (BNF)? If so this is likely to prove controversial. Alternatively, do the authors intend that existing food supplement products pursue GSL, P or POM licences through the MHRA, along with the significant improvements in quality, consistency and scrutiny of manufacturing facilities and processes that this implies? Existing food supplement products do not meet the standards required of any legal	Thank you for this comment. The introduction to the updated guidance notes that the guidance definition of supplements includes food supplements and licensed products. The updated recommendation 1 more clearly separates recommendations for all supplements and licensed products. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			classification of medicines. Internis recommends that the Guideline Development Group clarifies its meaning with respect to vitamin D products with no MHRA licence and BNF listing.	intake for at-risk groups are available on prescription and are listed in the British National Formulary.
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** The MHRA recommends that where an MHRA licensed prescription product (GSL, P or POM) option is available it should be used in preference to less well-regulated alternatives.[26] 26. http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990 The General Medical Council (GMC) states that: *When prescribing an unlicensed medicine you must:* *"a. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy* *b. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so* *c. make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine."* When prescribing a product without an MHRA licence, GMC members	Thank you for this comment. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			should be satisfied that an alternative, licensed POM medicine would not meet the patient's needs. Prescribing a product that has not been licensed by the MHRA may leave doctors open to an increased threat of litigation.[27] 27. General Medical Council, Prescribing guidance: Prescribing unlicensed medicines http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp. Last accessed 22.05.14 Internis recommends that the Guideline Development Group advises the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** 'Healthy Start' is a brand name, albeit one owned by the Government. It is not appropriate for the NICE Guidance to support a single brand without a clearly stated, evidence-based, rationale for doing so. Internis recommends that 'Healthy Start' is replaced with the generally accepted[1, 2] daily dose of 200iu - 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	Thank you for this comment; NICE considers it appropriate to refer directly to the Healthy Start benefit or Healthy Start vitamins.
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** The paediatric formulation of 'Healthy Start' includes vitamin A.	Thank you for this comment. The overall formulation of the healthy start supplement is

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			Although the vitamin A dose is below the recommended daily intake for children, additional high doses may be provided by certain foods, combining to exceed the recommended paediatric dose of 250-350µg per day.[28] Overdose of vitamin A can have serious consequences.[28] 28. Dr Richard Draper. Patient.co.uk, Hypervitaminosis. Doc ID: 1650 (v23). 20/04/2011 http://www.patient.co.uk/doctor/Hypervitaminosis.htm last accessed 19/06/2014 Internis recommends that the Guideline Development Group includes appropriate cautions when recommending multivitamin products to treat vitamin D deficiency.	beyond the scope of this guidance.
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** The Guideline Development Group recommends improvements in the provision of 'Healthy Start' vitamin D supplements to pharmacies. The majority of vitamin D prescriptions are dispensed by community pharmacists, often on the basis of a 'generic' prescription. Pharmacists should be alert to their responsibilities should they choose to dispense a vitamin D supplement without an MHRA license in response to a generic prescription (a prescription that does not specify a named/branded product). In this case pharmacists must ensure that the prescriber is aware that an unlicensed product is being dispensed and that the prescriber is aware of the possible consequences of dispensing an unlicensed product.[29, 30, 31] 29. Medicines information ebulletin [Internet]. UK Medicines Information. 2011 p. 52. Available from: http://www.merseycare.nhs.uk/Library/What_we_do/Clinical_Services/Pharmacy/MI_e-bulletin_Issue_52.pdf	Thank you for this comment. The draft guidance highlights throughout that supplements should contain the RNI. The guidance is focused on prevention; treatment is outside the remit of the guidance. General licensing issues are outside the remit of NICE.

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			30. Stevenson R. Guidance on unlabelled and off license medicines [Internet]. NHS Wirral. 2010 [cited 2014 May 23]. p. 1–31. Available from: http://mm.wirral.nhs.uk/document_uploads/guidelines/WirralSpecialsMar11.pdf 31. GPhC. Standards of conduct, ethics and performance [Internet]. London; 2010 p. 1–15. Available from: http://www.pharmacyregulation.org/sites/default/files/Standards of conduct, ethics and performance.pdf Use of products without an MHRA license, in place of available licensed alternatives, has tragically had fatal consequences in the past.[32] 32. GPhC. Fitness to Practice Committee; GPhC vs Patel [Internet]. London: GPhC; 2013. p. 1–23. Available from: http://pharmacyregulation.org/sites/default/files/Patel, Manhar Prabhubhai 2018623 - 05-12-2013.pdf Internis recommends that the Guideline Development Group aligns its recommendations with the generally accepted[1, 2] dose of 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	
Internis Pharmaceuticals Limited	Recommendation 2	4	**Increase access to vitamin D supplements** Internis is concerned about low uptake of/compliance with non-prescribed regimens. Evidence shows that compliance with prescribed	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work.

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			regimens exceeds compliance with non-prescribed regimens.[33] 33. Amanda B. Bower, Stacy Landreth Grau and Valerie A. Taylor Over-the-counter vs. prescription medications: are consumer perceptions of the consequences of drug instruction non-compliance different? International Journal of Consumer Studies Volume 37, Issue 2, pages 228–233, March 2013 http://onlinelibrary.wiley.com/doi/10.1111/j.1470-6431.2011.01093.x/abstract Last accessed 23.05.14 Prescription products offer improved uptake measurement, versus other less regulated delivery arrangements. Internis recommends that the Guideline Development Group aligns its recommendations with the generally accepted[1, 2] dose of 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.
Internis Pharmaceuticals Limited	Recommendation 3	5	**Develop a national campaign** Internis supports the recommendation for a national campaign aimed at achieving wider awareness of the importance of maintaining vitamin D sufficiency in at-risk groups. Internis recommends that at-risk groups should be encouraged towards the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.
Internis Pharmaceuticals Limited	Recommendation 4	5	**Co-ordinate local action to increase use of vitamin D supplements in line with existing guidance** Internis supports recommendation 4. Internis recommends that the Guideline Development Group aligns its recommendations with the generally accepted[1, 2] dose of 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.
Internis Pharmaceuticals Limited	Recommendation 5	6	**Increase local availability of vitamin D supplements for at-risk groups** The Guideline Development Group recommends local authorities consider providing free supplements to at-risk groups.	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work.

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			Many of those in the at-risk categories qualify for free prescriptions*, meaning that a prescribed regimen will be the route of least resistance for them. Evidence suggests that the most effective way to ensure compliance is via prescription:[34] *The following groups qualify for free prescriptions: • 60 or over • Under 16 • 16-18 in education • Pregnant or had a baby in the last 12 months (maternity exemption certificate) • Certain low-income categories 34. Amanda B. Bower, Stacy Landreth Grau and Valerie A. Taylor Over-the-counter vs. prescription medications: are consumer perceptions of the consequences of drug instruction non-compliance different? International Journal of Consumer Studies Volume 37, Issue 2, pages 228–233, March 2013 http://onlinelibrary.wiley.com/doi/10.1111/j.1470 6431.2011.01093.x/abstract Last accessed 23.05.14 Internis recommends that the guidance specifies a licensed vitamin D_3 product via prescription, in the most vulnerable at-risk groups since this guarantees free supply (for most groups), provides monitoring of uptake and delivers a consistently high quality product.	In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.
Internis Pharmaceuticals Limited	Recommend ation 6	6	**Improve access to Healthy Start supplements** 'Healthy Start' is a brand name, albeit one owned by the Government. It	Thank you for this comment. NICE considers it appropriate to refer to the Healthy Start

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			is not appropriate for the guidance to support a single brand without a clearly stated, evidence-based, rationale for doing so. Internis recommends that 'Healthy Start' is replaced with the generally accepted[1, 2] dose of 200-800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	benefit or Healthy Start vitamins directly.
Internis Pharmaceuticals Limited	Recommendation 7	7	**Ensure health and social care professionals recommend vitamin D supplements** Internis recommends that health and social care professionals should encourage at-risk groups to seek an MHRA licensed form of vitamin D_3 supplementation, via prescription.	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.
Internis Pharmaceuticals Limited	Recommendation 8	8	**Raise awareness among health, social care and other relevant professionals of the importance of vitamin D** Internis welcomes recommendation 8. Internis recommends that health, social care and other relevant	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work.

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			professionals should be made aware of the importance of recommending a licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s). Please note that promotional activity should remain in line with existing promotional codes and that products with no MHRA licence cannot purport to be medicines, and cannot promoted as such even through educational activity. Pharmaceutical level regulation should be applied to all companies supporting education.	In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.
Internis Pharmaceuticals Limited	Recommendation 9	8	**Raise awareness of the importance vitamin D supplements among the local population** Internis supports the recommendation for local campaigns aimed at achieving wider awareness of the importance of maintaining vitamin D sufficiency in at-risk groups. Internis recommends that the Guideline Development Group aligns its recommendations with the generally accepted[1, 2] dose of 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	Thank you for this comment and references. The guidance is focused on the prevention of deficiency and references the RNI throughout. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.

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Internis Pharmaceuticals Limited	Recommendation 10	9	**Monitor and evaluate the provision and uptake of vitamin D supplements** Prescription products offer improved uptake measurement, versus other less regulated categories (yellow card system, PACT data, post-marketing surveillance). The yellow card system[4] is the ONLY means of monitoring safety. Internis recommends that the Guideline Development Group aligns its recommendations with the generally accepted[1, 2] dose of 800iu for most at-risk groups. This can be best achieved through the use of an MHRA licensed product in every case, and the use of an MHRA licensed prescription product in the most vulnerable at-risk groups (i.e. pregnant and breast-feeding women, babies and children between 6 months and 5 years and the over 65s).	Thank you for this comment. Updated recommendation 11 states 'Use a range of sources to assess local uptake, for example, orders for supplements and information collected in personal child health records, maternal antenatal notes and computerised prompts (see recommendation 8).'
Internis Pharmaceuticals Limited	General		**Quality, safety, efficacy, risk-benefit** Internis is concerned that the Guideline Development Group may seek to increase uptake of vitamin D supplementation without considering: 1. The quality and consistency of the products being used and the risks of under or overdosing at-risk groups 2. The availability of an appropriate (mono, i.e. non-multivitamin) dose option 3. The likely compliance with the different methods of bringing vitamin D supplements to at-risk groups (e.g. prescription, voucher, advice) 4. The potential legal liability to prescribers and dispensers arising from the use of products which have not been licensed by the MHRA	Thank you for this comment. The guidance is based on existing recommendations for the RNI and notes that is should be read alongside the forthcoming SACN report. The RNI of 10ug is well below the safe upper limit. The PHAC were aware of low uptake among at risk groups and have made a package of recommendations to increase awareness, availability and uptake.
Internis Pharmaceuticals	General		**Economic implications**	Thank you for this comment. In line with all

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Limited			A study demonstrates that, in lower doses, MHRA licensed (POM) preparations would save £325k per month.[35] Internis believes that the Guideline Development Group should consider the cost-effectiveness implications of its recommendations. 35. J Stephen Davies Vitamin D: too much of a good thing? British Journal of General Practice, January 2014 Despite the availability of licensed (POM) vitamin D supplementation products in the UK, prescription cost analysis shows that the average prescription cost of preparations with no MHRA licence is more than three times greater than for licensed POM products (£19.90 versus £6.53 respectively).[35] The recent Pharmaceutical Pricing Regulation Scheme (PPRS) agreement means that prescription prices will fall further over the next 5 years. Products without an MHRA licence are subject to VAT. Products without an MHRA licence are offered at prices which are neither fixed, nor guaranteed, unlike prescription product prices which are fixed in accordance with the provisions of the PPRS agreement. Many of those in the at-risk categories qualify for free prescriptions, meaning that a prescribed regimen will be the route of least resistance for them.	NICE guidance, economic modelling was undertaken. The economic report is published alongside the draft guidance here. An overview was given in the draft guidance sections 4.15 to 4.19. Please not that general licensing issues are outside the scope of this guidance. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. The draft guidance references the need for widespread availability of appropriate, low cost supplements. The committee were concerned that focusing on prescribed products (particularly for older adults) would increase the implementation cost of the recommendations. However, they were keen that an appropriate product containing the RNI should be available for prescribing for the prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary.

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Leeds City Council	General		The draft guidelines from NICE re "Vitamin D: implementation of existing guidance to prevent deficiency" are welcomed. For specific risk groups this is an important health issue which requires clarity of message, clear appropriate communication, and creation of systems to ensure availability of Vitamin D supplements at the right place in the most cost effective way.	Thank you for this comment.
Leeds City Council	Recommendation 2	4	There needs to be clear guidance about which Vitamin D preparations can be prescribed, there is a vast price difference between brands work with manufacturers could result in a generic preparation. Strongly agree that Healthy Start should be more widely available either free to all or available for sale. This does however carry a significant cost given the number of children and pregnant women involved. However realignment of budgets would part resolve this issue.	Thank you for this comment. NICE is unable to name specific brands but is clear throughout that low cost products containing the RNI should be widely available.
Leeds City Council	Recommendation 3	5	Definite need for national campaign using variety of different mediums and not just written information, in formats to ensure message connects with people. The need to take vitamins is a hard message to sell as individuals do not "feel" the impact of taking them compared with not doing so and are therefore more likely to stop taking them. Important to make obtaining the supplements easier for at risk groups – distribution by HCPs in contact with at risk groups including midwives, Health visitors and district nurses.	Thank you for this comment. The specific details of awareness raising initiatives are beyond the scope of this work. Supplement availability and training for practitioners are addressed in other recommendations.
Leeds City Council	Recommendation 4	5	There exists good links and partnerships regarding increasing the uptake of Vitamins – one potential area requiring clearer guidance is which budgets will be funding the various elements of the guidance.	Thank you for this comment. Local funding decisions are outside the remit of NICE.

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Leeds City Council	Recommend ation 5	6	Free supplements would have large cost implications where will the funding come from to ensure sustainability	Thank you for this comment. Local funding decisions are outside the remit of NICE. Recommendation 4 makes it clear that action should be based on local needs. Free supplementation (see updated recommendation 5 and 6) is only something that local areas should consider, rather than being a 'should do'. The understanding of NICE and PHAC is that implementation of existing recommendations, particularly healthy start is resource intensive and re-distribution of some costs may meet part of the cost of supplementation.
Leeds City Council	Recommend ation 6	7	Agree but needs to be closely linked with awareness campaign and certainly an easier system in terms of ordering, distribution and reimbursement. The costs to administer the scheme are substantial. Use of red book helpful – not only questions but possibly information too Make better use of the Start4Life materials	Thank you for this comment. No evidence was identified on start 4life. Recommendation 4 highlights the need for a consistent approach.
Leeds City Council	Recommend ation 10	10	Strongly agree – obtaining data locally and when compared to regional and nationally on a regular basis is arduous especially since reporting back from the issuing unit has changed	Thank you for this comment.
Leeds City Council	2	11	Helpful to see who be involved – but who should be ultimately responsible for co-ordinating the local response, programme?	Thank you for this comment. Updated recommendation 4 notes that DPH should ensure a consistent multiagency approach.

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Leeds City Council	4.2 Considerations	17	This is an important factor, along with the sheer quantity of other health information needed to be provided for families so information may get "lost"	Thank you for this comment.
Leeds City Council	4.3 Communications	18	Clarity around risk and exposure required to benefit from sunlight would be helpful	Thank you for this comment. The recommendations make clear that information on the sources of vitamin D should be provided (sun exposure, supplements and limited dietary sources). The risks and benefits of sunlight are outside the remit of this guidance but is addressed in a parallel piece of work on sunlight exposure.
Leeds City Council	4.9 Healthy Start	20	Regionally evidence that HCPs distributing vitamins especially to pregnant women are well received and adherence to taking them is high. Using specialist midwives to target vulnerable groups who do not qualify for the scheme is being piloted in Leeds. Needs to be regular refreshing of any scheme to remind HCPs and families about importance.	Thank you for this information.
Leeds City Council	4.11	21	Parents are unlikely to make a special specific trip to exchange their vitamin vouchers and as they do not see a consequence of not taking them for themselves or children may quickly ignore them when sent. This raises the importance of awareness campaigns being carefully developed to highlight the importance but acknowledging families will not necessarily see the benefits.	Thank you for raising this issue.
Leeds City Council	4.14	22	Important but agree needs to link to other recommendations being in place. Training should be part of initial courses attended by midwives and health visitors and then regularly topped up using different methods given other pressures of training commitments.	Thank you for this comment.

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Leeds City Council	4.18	23	The estimated cost per deficiency savings makes interesting reading. However the budget sources for prevention vs treatment are different and realigning budgets to make the savings is complex	Thank you for raising this issue.
Leeds City Council	5	24	In addition to the suggested areas for research conducting insight into what people know/think about vitamins and potential barriers to taking them long term could provide important information to shape awareness campaigns	Thank you for this comment.
Public Health, Leicester City Council	General		Although it is recognised that a separate sun exposure guideline will be produced, the importance of safe sun is not acknowledged appropriately in this draft. Sun exposure is free and the most effective method by which to obtain vitamin D – this should be considered as an option for addressing low levels at certain times of year.	Thank you for this comment. We disagree that the importance of sun exposure is not acknowledged. The second paragraph of the introduction to the guidance states 'The main natural source is from the action of sunlight on skin. The importance of safe sun exposure to prevent vitamin D deficiency is covered in a separate guideline (see related NICE guidance).' Updated recommendation 3 on raising awareness includes more reference to sunlight exposure.
Public Health, Leicester City Council	General		Why was the focus of the economic evaluation on what is the most cost-effective way to provide vitamin D supplements to at risk groups, opposed to whether or not they are cost-effective overall? This remit does not sufficiently support local decision making on whether or not to provide vitamin D supplements beyond Healthy Start.	Thank you for this comment. The approach to cost effectiveness reflects the scope of the work i.e. the implementation of existing guidance. NICE is undertaking an additional piece of work considering the cost effectiveness of healthy start.
Public Health, Leicester City Council	General		A pilot study is required to assess levels of deficiency in the UK across different at risk groups. We are looking into this for Leicester – for pregnant women. This is in the early stages as of yet but please	Thank you for providing this information.

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			contact us if of interest.	
Public Health, Leicester City Council	Intro	1	The National Diet and Nutrition Survey (2001) quotes 14% of men and 15% of women with 'deficient' levels of vitamin D (<25 nmol/L). Only those sampled in winter had levels as suggested in the introduction – about one fifth. This should be amended.	Thank you for this comment. The figure is correct but the reference is the National Diet and Nutrition Survey for 2008-11, published in 2014. The context has been amended for clarity and a figure given for all adults age 19-64 rather than just women.
Public Health, Leicester City Council	Intro	1	The at risk groups do not include those on benefits, as identified in the National Diet and Nutrition Survey 2001. Surely this is why Healthy Start vitamins are provided to those on benefits? They are not a usual at risk group but perhaps NICE should review these groups and include deprived populations?	Thank you for this comment. The at risk groups are as identified by COMA, the CMOs and SACN. However, NICE has a particular focus on reducing inequalities in health and the recommendations raise any issues of relevance, for example, the consideration of availability of affordable, low cost supplements.
Public Health, Leicester City Council	1	5	Recommendation 3: a national campaign should include a safe sun element.	Thank you for this comment. Updated recommendation 3 on raising awareness includes more reference to sunlight exposure.
Public Health, Leicester City Council	1	6	Recommendation 5: 'consider providing free supplements' is not strong enough a recommendation – particularly for those making local decisions. If it is recommended please say so.	Thank you for this comment. Please see the considerations sections 4.4 and 4.12 in relation to the committee's deliberations on free provision of supplements.
Public Health, Leicester	3	13	The National Diet and Nutrition Survey (2001) states the general	Thank you for this comment. The figure is

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City Council			average levels of vitamin D as 14% and 15% (as mentioned previously). Surely this is more useful than women's levels only? Perhaps include both? Also amend the 'fifth' accordingly.	correct but the reference is the National Diet and Nutrition Survey for 2008-11, published in 2014. The context has been amended for clarity and a figure given for all adults age 19-64 rather than just women.
Public Health, Leicester City Council	3	15	The increased risk in London could be due to higher number of people with darker skin – does this make this the highest risk group? Should clearer recommendations be made for this group in particular, and so address the issue of Healthy Start being made available for those on benefits only?	Thank you for this comment. The at risk groups are as those identified in existing guidance (i.e. COMA, SACN and CMOs).
Public Health, Leicester City Council	3	16	Primary care spending rose but did the number of prescriptions? Could the increased cost be due to the use of 'specials' and other expensive treatment options? It should be eluded that the increase in spend on treatment is due to an increase in awareness (as demonstrated by the increase in testing) and possibly due to increasing drug costs, rather than an increase in prevalence.	Thank you for raising these issues. The details of changes to prescriptions has not been investigated as part of this work. The point being made in this section is that both testing and treatment spend has increased considerably, for whatever reason. The PHAC were keen that testing be reduced for people who do not show symptoms of deficiency, as addressed in updated recommendation 7)
Public Health, Leicester City Council	3	16	Healthy Start vitamins are only available to certain groups – this should be made more explicit. Also, distribution is locally arranged.	Thank you for this comment. Details of the healthy start scheme are given in the glossary.
Public Health, Leicester City Council	4.12	21	Uptake may treble with universal – does this take account of the actual numbers (the denominator is not the same) rather than just the percentage increase?	Thank you for this comment. The figures quoted are as stated in the paper by McGee and Shaw 2013 (full reference given in the guidance).
Public Health, Leicester	4.13	21	What changed in legislation to prevent the sale and distribution of	Thank you for this comment. The change was

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City Council			Healthy Start vitamins – and why?	due to health and social care legislation linked to wider changes to the NHS. Details are given on the healthy start website here http://www.healthystart.nhs.uk/for-health-professionals/vitamins/vitamins-in-england/
Public Health, Leicester City Council	4.13	21	Sentence stating with 'But'.	Thank you for this comment. The editors of this guidance considered it appropriate to start this sentence with but.
Public Health, Leicester City Council	4.15	22	This question does not answer what we need it to in order to make a local decision as to whether to provide wider / universal supplementation or not.	Thank you for this comment. The approach to cost effectiveness reflects the scope of the work i.e. the implementation of existing guidance. NICE is undertaking an additional piece of work considering the cost effectiveness of moving healthy start vitamins from a targeted to a universal approach
Public Health, Leicester City Council	4.16	22	We should be treating those who are deficient, not supplementing them.	Thank you for this comment. A supplement of vitamin D (at a higher level than is given to prevent deficiency) is the usual treatment for low vitamin D status.
Public Health, Leicester City Council	4.16	22	Does the cost-effectiveness analysis still stand if supplementation levels are applied to a deficient population? Leicester has a large population at risk of deficiency, if we just provided supplements would we actually reduce our level of deficiency?	Thank you for this comment. The analysis still stands if the population is vitamin D deficient. The more deficient people there are in the population the more likely it is to be cost effective as the capacity to benefit increases. For example, in the extreme case of the

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				whole population being deficient, it would not gain anything to test for deficiency.
Public Health, Leicester City Council	4.18	23	The cost of supplementation does not include associated costs, such as delivery, administration or assessment of need costs.	Thank you for this comment. The data for this analysis were based on an intervention carried out by the Heart of Birmingham Primary Care Trust, which promoted vitamin D supplementation and provided it universally within the at-risk groups that were not income assessed. The cost of implementing the intervention was included in the calculations. It includes the costs of both promotion and administration.
Public Health, Leicester City Council	4.19	23	By how much is the estimated cost of deficiency estimated to be overstated? To a level that overrides any benefit?	Thank you for this comment. The estimated costs of universal provision have almost certainly been overestimated, but in spite of this, universal provision was estimated to be cost effective. At a more realistic (and less conservative) cost, universal provision would be even more cost effective than was estimated when the costs had (almost certainly) been overestimated. Because the size of a bias is rarely known, we do not know the extent of the overestimation of costs, so we cannot answer your question. However, as stated above, at the conservatively-high level of costs assumed, universal provision was cost effective.
Mersey Care NHS	Recommend	4 of 43	Defining the “at risk population”:	Thank you for providing this information.

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Trust/Brain Injury Rehabilitation Centre	ation 1		We have started an audit of patients admitted to our unit with Acquired Brain Injuries. We have so far completed Vitamin D2/D3 levels on 12 patients, of which 4/12 have been severely deficient (<15 nmol/l) 3/12 have been deficient (15-30 nmol/l) 2/12 have been insufficient/low threshold (30-50 nmol/l) – including 1 patient who was on ADCAL D3 one tablet twice daily 3/12 have been adequate (>50 nmol/l) Ages of the patients without adequate Vitamin D levels have been 22 years-66 years, but 8/9 are younger than 55 years. Vitamin D levels were low both in patients admitted from home and in those admitted from hospitals/care homes.	
Mersey Care NHS Trust/Brain Injury Rehabilitation Centre	Recommend ation 1 cont.		The patients admitted from home with the lowest Vitamin D levels were not obviously housebound (i.e. not bedbound or in a wheelchair). Time since Brain Injury ranged from 29 months to 5 months in those without adequate Vitamin D levels. Most patients had normal blood levels for Adjusted Calcium and Inorganic Phosphate, meaning that routine “Bone Profile” screening would not have indicated deficient Vitamin D levels. Cause of Brain Injury included traumatic, anoxic, haemorrhagic. (As the audit is ongoing, we have not yet performed any statistical analysis). **We would therefore like to recommend that the population of individuals with Acquired Brain Injuries is included in the list of**	Thank you for this comment. The list of at risk groups is as identified by COMA, SACN and the CMOs and based on existing recommendations. SACN are currently considering population requirements for vitamin D and the introduction notes that the guidance should be read alongside the SACN report once published.

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			"groups at risk of low vitamin D status".	
Mersey Care NHS Trust/Brain Injury Rehabilitation Centre	3. Context/ Background	12-13/43	A study was performed on a group of 24 athletes/dancers, who had established Vitamin D deficiency. It was found that supplementing Vitamin D (2000 IU daily for 4 months) led to an improvement in muscle strength and reduction in injury risk. (Wyon MA et al, The influence of winter vitamin D supplementation on muscle function and injury occurrence in elite ballet dancers: A controlled study, Journal of Science and Medicine in Sport (2013) Vol. 17, Issue 1, Pages 8-12). As individuals who have experienced a brain injury commonly require intense rehabilitation of their strength and physical/motor skills, a factor such as supplementing Vitamin D after screening for its deficiency could contribute to a significant improvement in outcome. This effect might very possibly also apply to a large portion of the hospital population, as even short periods of immobility/illness can lead to loss of muscle strength, and many chronic illnesses (physical as well as mental) are associated with a lack of UV exposure (and resulting Vitamin D deficiency).	Thank you for providing this information. Treatment of deficiency is outside the remit of this guidance. Updated recommendation 7 notes that health and social care professionals should avoid vitamin D testing unless someone has symptoms of deficiency or is at very high risk.
National Osteoporosis Society	General		The advice given is clearly to guide Public Health in preventing vitamin D deficiency, as distinct from clinical guidance on appropriate testing and treating of deficiency. This is recognised with respect to the 'requirements for testing' shown on page 7.	Thank you for this comment.
National Osteoporosis Society	General		The document does not address the risks associated with supplementation and in particular those associated with high dose preparations. This is a consideration we feel needs to be addressed in public health advice	Thank you for this comment. The guidance notes throughout that supplements should contain the RNI.

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National Osteoporosis Society	General		There is variation in the units used within the document which could lead to confusion.	Thank you for this comment. A consistency check will be undertaken pre-publications.
National Osteoporosis Society	Section 1: draft recommendations	4	Recommendation 1: We welcome the recommendation to make it clear that older adults with adequate dietary calcium require vitamin D only supplements rather than a combined vitamin D and calcium supplement.	Thank you for this comment.
National Osteoporosis Society		4	Recommendation 1: Additionally, clear guidance is needed on which groups are considered to be at-risk of vitamin D deficiency, for example, should those suffering low vitamin D levels at the end of the winter be considered for supplementation?	Thank you for this comment. The list of at risk groups is as identified by COMA, SACN and the CMOs and based on existing recommendations. SACN are currently considering population requirements for vitamin D and the introduction notes that the guidance should be read alongside the SACN report once published.
National Osteoporosis Society		4	Guidance on how to assess calcium repletion easily is needed	Thank you for this comment. References to calcium have been amended in the updated guidance.
National Osteoporosis Society		4	Recommendation 2: We agree that it is important that there is access to vitamin D supplements. We would stress however, the following points in relation to this recommendation: • Supplements need to: ○ be the right dose, meeting the reference nutrient intake. However we are concerned that the availability of over the counter preparations which exceed the RNI may lead to people building up toxic levels of vitamin D.	Thank you for this comment. The updated recommendation states that supplements should undergo quality control checks to ensure they contain the correct dose. The updated recommendation states that suitable supplements should also be available for people with particular dietary needs.

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			○ be checked (licenced) in some way to ensure that the stated levels of vitamin D are met by the product. • While preparations which are halal/avoid certain oils etc. do need to be available for the minority that need them, we feel that making these products available to the whole population could unnecessarily increase costs.	
National Osteoporosis Society		5	Recommendation 3: Public health campaigns should also include information about lifestyle and safe sun exposure. The National Osteoporosis Society has been leading a public health campaign about safe sun exposure for 7 years having recognised the importance of information that allows individuals to balance risks associated with sun exposure with their need to produce sufficient vitamin D. This work includes national media work built around a consensus statement which represents the unified views of the British Association of Dermatologists, Cancer Research UK, Diabetes UK, the Multiple Sclerosis Society, the National Heart Forum, the National Osteoporosis Society and the Primary Care Dermatology Society. This statement is available on our website at: http://www.nos.org.uk/document.doc?id=945 We would welcome opportunities to explore ways to work with Public Health to promote messages around safe sun exposure.	Thank you for this comment. The recommendation has been updated to include a reference to sun exposure.
National Osteoporosis Society		6	Recommendation 5: We welcome the recommendation that Local Authorities (LA) consider providing free supplements to at risk groups. However, this needs to be done consistently and we would urge the use of daily supplements that meet the RNI rather than high dose products.	Thank you for this comment. The recommendation has been updated to make clear it should provide the RNI.

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National Osteoporosis Society		6	It is not appropriate to use branded medication such as Healthy Start (unless picking up relevant issues with regards to manufacturing) and advice should use generic characteristics. Please supply the product characteristics and quality assurancefor healthy start.	Thank you for this comment. NICE considers it appropriate to mention Healthy Start vitamins in this recommendation.
National Osteoporosis Society		7	Recommendation 7: We agree that this recommendation is helpful and need to retain the clear distinction between public health advice rather than treatment.	Thank you for these comments.
National Osteoporosis Society		8-9	Recommendations 8 & 9: We welcome the appropriate emphasis around raising awareness among many groups and would welcome the opportunity to explore how we could support this work. Clear, consistent advice and information for both professionals and the public would be beneficial.	Thank you for this comment.
National Osteoporosis Society		9	Recommendation 10: We agree it is helpful to monitor and evaluate provision and would welcome clarity about how this can be achieved.	Thank you for this comment.
National Osteoporosis Society	Section 2: Who should take action	11	The idea of LA being more responsible for delivering the Public Health agenda is appealing. We feel that some of the domains within LA could access populations who may be most at risk of low vitamin D.	Thank you for this comment.
National Osteoporosis Society	Section 3: Context	13	The guidance states that low vitamin D status has been associated with some diseases and other long-term conditions such as osteoporosis, diabetes and some cancers, although the evidence is inconclusive. However, in the case of osteoporosis, this is more than an 'association'. The evidence base for causality with low bone mineral density/osteoporosis and low levels of vitamin D is supported mechanistically via secondary hyperparathyroidism.	Thank you for this comment. The association between long term conditions and vitamin D is under the remit of SACN. The guidance references statements from SACN 2007.
National Osteoporosis Society	Section 4: Consideratio	17	In 4.1 it states that whether older people should take vitamin D alone or combined with calcium is outside the remit of the guidance yet advice	Thank you for this comment. References to calcium have been amended in the text.

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	ns		on this is included in recommendation 1 on page 4 (although we would stress that we find recommendation 1 helpful).	
National Osteoporosis Society		18	There is a need for clarity on language used in existing vitamin D guidance as per the example used in paragraph 4.3. If housebound is defined by number of hours spent indoors, then many fit and able bodied adults may be considered 'housebound' as a result of lifestyle and work obligations rather than inability to get outside. This poses an challenge for communication of recommendations and implementation of advice.	Thank you for this comment. The wording of this para has been revised for clarity.
NCT	1	4	NCT supports the need for further clarification on vitamin D supplementation for children under 6 months of age (whether they are breast or formula fed). Great care must be taken to ensure that the guidance, or any communications resulting from greater awareness of the frequent vitamin D insufficiency seen in the UK, do not cause women to doubt the sufficiency of their breastmilk or the value of breastfeeding. Manufacturers of breastmilk substitutes are already using vitamin D insufficiency in toddlers to sell their follow-on and toddler milks. See bit.ly/**1m9SxWq**	Thank you for this comment. Updated recommendation 2 asks DH and PHE to consider whether there are any risks to infant from taking a supplement containing the RNI when they are consuming more than 500ml of infant formula per day. The recommendation notes that the complexity of existing advice may hinder uptake.
NCT		5	A campaign to raise awareness of the importance of vitamin D and emphasise the importance of a daily supplement for identified at-risk groups needs to be co-ordinated with the associated guideline on safe sunlight exposure yet this is not expected for another year. There is a real danger that campaigns are mre likely to reach well-educated people and thereby increase inequalities.	Thank you for this comment. The recommendation has been revised to include a reference to sun exposure. To note that other recommendations in the guidance highlight the importance of tailoring approach and awareness raising activities to meet the needs of different groups.

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NCT		6 and 7	Rec 5 and Rec 6. Given the high proportion of women of child bearing age who have low levels of vitamin D and the prevalence of vitamin D deficiency in children, and black children in particular, NCT supports the recommendation to consider offering free healthy Start supplements for all pregnant and breastfeeding women and children aged under 4 years in areas where there is either a high proportion of families with dark skin or little sunshine of the right wavelength to generate vitamin D in the skin. This is particularly relevant in view of the success of the Birmingham scheme (Moy RJ, et al. Successful public health action to reduce the incidence of symptomatic vitamin D deficiency Arch. Dis. Child. 2012;**97**:11 952-954) and the change in health and social care legislation which means Healthy Start supplements can no longer be sold to families who are not eligible.	Thank you for this comment and reference.
NCT	3 context	12 at end	mothers may become concerned about the adequacy of their breastmilk to supply everything that their baby needs if told that it is inadequate in this way. Several studies have found breastmilk vitamin D can be increased by maternal supplementation at levels higher than currently recommended. A systematic review found a strong positive correlation between maternal vitamin D intake during exclusive breastfeeding and infant serum 25-hydroxyvitamin D levels. The authors conclude that when maternal vitamin D intake is sufficient (by their definition), vitamin D transfer via breastmilk is adequate to meet infant needs. However, in the reviewed studies, doses up to 10 times the current recommended daily intake of vitamin D were needed to produce sufficient transfer from mother to breastfed infant. Thiele DK, Senti JL, Anderson C. Maternal Vitamin D Supplementation to Meet the Needs of the Breastfed Infant, A Systematic Review. J Hum	Thank you for this comment. The requirements for vitamin D during pregnancy and breastfeeding are outside the remit of this guidance.

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			Lact May 2013 vol. 29 no. 2 163-170.	
NCT	3	12/13	Suggest rewording this sentence: The breastmilk of women in the UK contains low levels of vitamin D and is not a significant source.	Thank you for this comment. We consider the wording appropriate as written.
NCT		14	3rd paragraph has some repetition on formula milk.	Thank you for highlighting this repetition – the paragraph has been amended.
NCT		18	NCT supports the need for further research as a priority, on outcomes of universal vitamin D supplementation for women during pregnancy and breastfeeding and for children under age 5, methods of communicating effectively with health professionals and parents, fe levels of sun exposure sand other areas as outlined under gaps in the evidence, with a focus on what works.	Thank you for this comment.
NCT		25	The section “Research should not” is helpful but would be better framed in a positive way – ie research should include wide consultation with local practitioners and the relevant local community.	Thank you for this comment, the wording has been revised.
NCT		29	**Low vitamin D status** Although it is appropriate to quote the DH definition, readers should be aware that SACN are considering this issue and other researchers consider a higher level an appropriate cut off. Eg Wei SQ, Qi HP, Luo ZC, Fraser WD.Maternal vitamin D status and adverse pregnancy outcomes: a systematic review and meta-analysis. J Matern Fetal Neonatal Med. 2013 Jun;26(9):889-99.	Thank you for this comment. The introduction to the guidance notes that is currently reviewing population dietary reference values for vitamin D and the recommendations should be read in conjunction with any advice published by SACN.
Digital Assessment Service – NHS Choices	General		Welcome this guidance and have no comments on its content.	Thank you h for this comment.

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NHS England	General		I wish to confirm that NHS England has no substantive comments to make regarding this consultation	Thank you for this comment.
NHS Health Scotland	General		The draft guidance is welcome and is a positive step forward to provide a 'safety net' for specific groups within the population who are known to be at greater risk of deficiency of Vitamin D.	Thank you for this comment.
NHS Health Scotland	1	Page 4 recommendation 1	The messages for women who are breastfeeding need to be much clearer. At present Vitamin D supplements may be required for Breastfed babies from 1 month of age if the mother did not take a vitamin D supplement throughout her pregnancy. It needs to be clear whether healthy start vitamins provide the correct dose for infants of this age and the identification of mothers who have not taken a supplement needs to be considered.	Thank you for this comment. Updated recommendation 2 asks DH and PHE to consider whether there are any risks to infant from taking a supplement containing the RNI when they are consuming more than 500ml of infant formula per day. The recommendation notes that the complexity of existing advice may hinder uptake.
NHS Health Scotland	1	Page 4 recommendation2	Wider distribution already happens in Scotland, so Scotland can share how this is done in practice.	Thank you for providing this information.
NHS Health Scotland	1	Page 6 Recommendation 5	A survey of uptake through Community Pharmacies from is currently underway in Scotland	Thank you for providing this information.
NHS Health Scotland	3	Page 13	More recent data available at : www.gov.uk/government/publications/national-diet-and-nutrition-survey-results-from-years-1-to-4-combined-of-the-rolling-programme-for-2008-and-2009-to-2011-and-2012	Thank you for providing this information. The draft has been updated to reference the 2008 to 2011 data.
NHS Health Scotland	3	Page 15/16	Note that the Feeding for Life Foundation is funded by a formula feeding company (Cow and Gate) and we would question why this report has been used as evidence to support this draft guidance as this poses a conflict of interest. We recommend using only the CMO report	Thank you for this comment. This reference has been replaced by McFadden et al 2013.

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NHS Stockport CCG	***Recommendation 2 Increase access to vitamin D supplements***	4	We feel there is a lack of clarity about access to supplements, when they should be prescribed on the NHS and when patients are expected to buy it. There seem to be mixed messages, talking about availability on prescription, implying they should be supplied by GPs on prescription, but later (recommendation 6) saying the healthy start vitamins should be made more available. We feel the latter is the better option. The Healthy start vitamins are now very restricted. Anyone used to be able to get them at the clinics for £1 for a month. Now you have to be on benefits to get them but the cost of dispensing alone is £1 per prescription plus the cost of the drug. Making the healthy start vitamins available to any child and older person seems far more sensible. The cost to treat older people on prescription would be significant (without the evidence of cost-effectiveness.)	Thank you for this comment. The guidance applies to both dietary supplements and products available on prescription. The aim of the guidance is to increase access through a variety of sources. The recommendations address both food supplements and licensed products. PHAC members were keen to ensure that options remained low cost both for the individual and NHS / local authorities. Updated recommendation 1 recommends that DH amend legislation to allow Healthy Start vitamins to be more widely distributed and sold.
		5	These access issues need resolving before developing a national campaign.	
	Recommendation 3: Develop a national campaign			
Norfolk & Norwich University Hospital	General		The document is meant to cover patients at risk from vitamin D deficiency; however, I feel that there is a group missing - those patients where malabsorption syndromes may occur. Patients with either short-bowel or cystic fibrosis are groups that spring to mind but there may be	Thank you for this comment. The introduction states: Clinical judgment will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase

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			other conditions which would manifest with this problem. I am concerned that the list for at-risk groups may be considered as the total at-risk population.	the risk of vitamin D deficiency.
PIP, NICE	General		We think this guideline could have a wider audience than usual, specifically members of the public, and it has been written in such a way that it will be really useful and accessible to them.	Thank you for this comment
PIP, NICE	What is the guideline about?	1	Can you put SACN in brackets as the abbreviation is used throughout the document?	Thank you, the guidance has been amended in line with your comment.
PIP, NICE	1 rec 3, 3rd bullet	5	Is it worth including whether the supplement can be obtained for free or at a low cost in this campaign as people may more likely to get them if they know this?	Thank you for this comment. Updated recommendation 3 states 'let people know where they can get vitamin D supplements free or as cheaply as possible.
PIP, NICE	1 rec 6 penultimate bullet	7	Should this say children aged under 5 years in line with the groups advised to take a vitamin D supplement on page 1?	Thank you for this comment. The guidance uses age 5 as the cut off for groups at risk and age 4 when referring to the age cut off for children eligible to Healthy Start vitamins.
PIP, NICE	1 rec 9, last bullet	9	We are really pleased to see this in the recommendation as it's really important to address any myths about vitamin D that might be useful to challenge when raising awareness.	Thank you for this comment.
PIP, NICE	1 rec 10, first bullet	10	Is there a standardised tool that can be given as an example or can more detail of what this tool might look like be included to help local authority commissioners collect this information?	Thank you for this comment. No standard tool is available. The wording of this recommendation has been revised.
PIP, NICE	1 rec 10, last bullet	10	Is 'on an ongoing basis' referring to people taking the supplements on an ongoing basis or ensuring the data is used on an ongoing basis? If	Thank you - the wording has been amended.

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			it's the former then the wording can stay as it is, but on reading it we thought it might be referring to the data, in which case could that wording be moved earlier to make it clearer?	
PIP, NICE	3 background, 5th paragraph	13	Can short explanations be put in brackets or a definition added to the glossary for osteomalacia and hypcalaemia?	Thank you for this comment, these conditions have not been defined.
PIP, NICE	3 people at risk, 3rd paragraph	14	Should 'a day' be added after '500ml' referring to infant formula twice in this paragraph?	Thank you, the wording has been amended in line with your comment.
PIP, NICE	3 people at risk, 3rd paragraph	14	We think that the sentence about the Asian Feeding Survey is important and should remain but is there a connection between breastfeeding/formula intake and this last sentence? As it currently reads there doesn't seem to be a clear link between the two. We suggest either making a new paragraph or elaborating on the link if possible.	Thank you, the text has been amended in line with your comment.
PIP, NICE	3 people at risk, 3rd paragraph	14	Will readers understand this section to mean that breastfeeding should be stopped or formula should be given as well? Do the advantages of breastfeeding exclusively for 6 months outweigh the risks of the infant having a vitamin D deficiency? It might be useful to include more information here to avoid any misinterpretation. It is likely that members of the public (e.g. new mums etc) will read this guidance too and so important they don't misinterpret the advice.	Thank you, the text has been amended in line with your comment.
PIP, NICE	3 people at risk, 4th paragraph	14	Are the words 'pigmented' and 'less pigmented' necessary or is it clear enough to just say darker skin and paler skin?	Thank you, the text has been amended in line with your comment.
PIP, NICE	3 people at risk, 7th	14	Will SACN be giving guidance on how long one needs to stay in the sun, what hours of the day are better, whether sun cream has an impact	Thank you for this comment. NICE is developing parallel guidance on sun

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	paragraph		etc on a person's stock of vitamin D in their updated guidance? If not, can this guidance include such information as it would be good for the NICE guidance on safe sun exposure to complement each other?	exposure.
PIP, NICE	3 how to get vitamin D supplements , first paragraph	16	Is it possible to include here how much vitamin D should be in the supplement and why some products might not be suitable for particular at-risk groups? Although this information is in the document elsewhere some readers may not read the glossary definition for at-risk groups as they think they know what this means.	Thank you for this comment, an example has been added.
PIP, NICE	4 considerations	17	All the considerations seem highly relevant for those who need to take action but will they read this section? Is there a way that they can be flagged within Pathways or that this section can be highlighted to readers to ensure they are not missed?	Thank you for this comment. The guidance follows a standard template.
PIP, NICE	4.2	17	It may not be obvious to some that the recommendations are in order of priority for action as is suggested here. Can this be stated in the introduction or start of the recommendations section?	Thank you for this comment, this text has been amended
PIP, NICE	7 glossary	26	This glossary is very useful and comprehensive. As it includes a fair amount of technical information that is highly relevant to the recommendations we are hoping there is a way of it being obvious in the Pathway for this guideline.	Thank you for this comment. The guidance follows a standard template.
PIP, NICE	7 glossary, culturally appropriate	27	This is a really useful summary of what to take account of when developing culturally appropriate interventions. It could be missed – is there anywhere within the recommendations it can be added?	Thank you – there is a link from the recommendations.
PIP, NICE	7 glossary	28	Can a link be added to the website http://www.healthystart.nhs.uk/ for the Healthy Start entry to signpost readers? And is it worth elaborating what 'plain' means i.e. no added sugar, uncooked etc?	Thank you – a link to Healthy Start is given elsewhere.
PIP, NICE	7 glossary, vitamin D	29	Is it possible and would it be useful to include what the actual minimum target people need to achieve under this entry (vitamin D) in the glossary as the reference nutrient intake doesn't give this information?	Thank you, the wording has been checked for accuracy.

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Public Health England	1 – Draft recommendations	4	***Recommendation 1: Clarify existing guidance on, and which groups are at-risk of, vitamin D deficiency.*** The Scientific Committee on Nutrition (SACN) is currently reviewing the dietary recommendations for vitamin D. This will include careful consideration of vitamin D requirements for all population groups in the UK, including infants less than 6 months of age and children aged 4-5 years. The Committee will also consider which population groups might be at greater risk of vitamin D deficiency and these 'at-risk' groups will be carefully described. SACN's dietary recommendations for vitamin D for all populations groups will be based on the assumption that intakes of calcium are adequate.	Thank you for this comment.
Public Health England	1 – Draft recommendations	5	***Recommendation 3: Develop a national campaign.*** PHE's marketing programmes are developed around delivering behaviour change within key life-stages (Starting Well, Living Well and Ageing Well) rather than single issue awareness raising campaigns which are not necessarily cost-effective. However, the importance of vitamin D is recognised and messages are already included in the Start4Life campaign and the Information Service for Parents, which target pregnant women and families with young children. Once the at-risk groups have been confirmed the marketing team can review whether messages about vitamin D can be incorporated into other campaigns, included in the 'On Demand' digital health programme or conveyed through the PHE single customer view database. Messages about vitamin D, including advice on supplements and safe sun exposure, are also currently available on the NHS Choices website and local public health teams are encouraged to link to this content to	Thank you for this comment, the wording has been amended to ensure that action could be undertaken through a number of routes, including as part of existing programmes. The evidence considered by PHAC suggests that awareness raising activities to date have failed to increase population awareness of existing recommendations.

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			ensure consistent messages are disseminated to at-risk groups. Content across the site is regularly reviewed and PHE will work with NHS Choices to ensure that existing vitamin D messages are accurate and to identify where there may be opportunities to strengthen some of these messages for specific at-risk groups.	
Public Health England	1 – Draft recommendations	8	***Recommendation 8: Raise awareness among health, social care and other relevant professionals of the importance of vitamin D.*** PHE is happy to support Health Education England in ensuring health and social care professionals receive information about the importance of vitamin D, sources of vitamin D in the UK, groups at risk of low vitamin D status, and supplementation recommendations for different at-risk groups. PHE will work through its Centres to support local authorities, health and wellbeing boards and clinical commissioning groups in ensuring health and social care professionals in contact with at-risk groups are aware of local policies and procedures regarding vitamin D.	Thank you for this comment.
Public Health England	1 – Draft recommendations	9	***Recommendation 10: Monitor and evaluate the provision and uptake of vitamin D supplements.*** The UK National Diet and Nutrition Survey monitors the diet, nutrient intake and nutritional status of the UK population (adults and children) with a sample size of approximately 1000 people per year. Data are collected on vitamin D intake from supplements based on a four-day dietary record. Since 2012 NDNS has also collected information on use of vitamin D containing supplements over the previous year. This will provide on-going national level data about vitamin D supplement use** in the general population and the contribution of supplements to overall	Thank you for this comment.

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			vitamin D intake. However the current annual sample size is too small to provide reliable monitoring on an annual basis, particularly for specific age groups (such as 65 years +) and too small to report any reliable data on minority ethnic groups separately from general population average. Children under 18 months and pregnant women are not covered by the survey. It may be possible to cover these groups via questions in the Health Survey for England (and comparable health surveys in the devolved countries) and the UK quinquennial Infant Feeding Survey. The Infant Feeding Survey currently collects information about the use of vitamin supplements by pregnant women participating in the survey and whether their infants were given vitamin drops. **NDNS does not cover awareness of, provision of or access to supplements.	
Public Health England	5.1	24	We think that the term “ethnic minority” is probably not applicable in this context and should instead refer to people with darker skin, as “ethnic minority” can include white-skinned people such as eastern Europeans.	Thank you, the text has been amended in line with your comment.
Public Health England	7 – Glossary & 1 – Draft recommendations	26 & 6	At-risk groups – we think this should include ‘religious’ alongside ‘cultural’ (although there is some overlap, the two terms are different).	Thank you, the text reflects CMO letter 2012.
Royal College of Nursing	Recommendation 1	4	The ‘at risk groups’ should be clarified and the definition improved to ensure that readers have a clearer understanding.	Thank you for this comment.
Royal College of Nursing	Recommend	4	The over the counter vitamin supplements are already available with the	Thank you for this comment. Sources of

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	ation 2		appropriate recommended intake clearly shown. It would be useful if patients could be signposted to healthy start clinics where the supplements will be made available. Listing in the British National Formulary – a guideline on reference for nutrient intake would be beneficial to advise GP's about the appropriate Vitamin D supplementation for the 'at risk groups' or Vitamin D insufficient/deficient groups themselves.	supplements are included in updated recommendation 3 and 10.
Royal College of Nursing	Recommend ation 7	7	With regards to the National Osteoporosis Society (NOS) Vitamin D guidance, it should be noted that this doesn't actually include the management of Vitamin D deficiency in childhood, pregnancy or end stage Chronic Kidney Disease (stages 4-5). With regards to the statement that Vitamin D testing should be avoided for people who do not have symptoms: NOS actually recommends the 4 groups that should be routinely tested; • Patients with diseases that would benefit Vitamin D treatment (osteomalacia, osteoporosis) • Patients with symptoms that could be attributed to Vitamin D deficiency (suspected osteomalacia, chronic widespread pain) • Asymptomatic patients at high risk of Vitamin D deficiency • Asymptomatic healthy patients.	Thank you for this comment, the wording of this recommendation has been amended.
Royal College of Nursing	Recommend ation 9	9	There is a need to stress the importance of ensuring that Fracture Liaison Services are checking Vitamin D status on at risk patients. In addition, appropriate metabolic reviews should take place following DXA scan if it is indicated that the Vitamin D status may have an impact on a patient's diagnosis of osteoporosis.	Thank you for this comment. To note that the introduction to the guidance states: Clinical judgement will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase

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				the risk of vitamin D deficiency.
Royal College of Nursing	Context - background	12	Some background is already provided on page 1 – it may be an idea to incorporate page 12 onwards at the beginning of the guidance to help build 'the foundations of the guideline'. Again, information on the at-risk patients should be incorporated at the beginning of the guidance to form a picture of what this guideline aims to achieve.	Thank you for this comment. The guidance follows a standard template. Links to the context section re at risk groups are given in the introduction.
Royal College of Nursing	Who should do what at a glance	11	The table on page 11 should be revised to read as per below: • Clinical Commissioning Groups – 8,2,3,4,6 • Commissioner and senior managers in local authorities & the NHS – 4,5,6,7,8,10 • Council leaders and elected members – 4 • Department Of Health – 1,2,3,6,10 • Developers of standardised notes – 7 • Directors of public health – 4,10 • Health & social care professionals – 1,3,7,9 • Health & well being boards – 2, 8, 10 • Health Education England – 8,10 • Primary & community health commissioning groups – 3,7,8 • Public health teams – 4,9 • Manufacturers – 2 • Pharmacies – 2 • Public health England – 1,3,5,6,8,10 • Voluntary & community organisations – 4,6,8,9	Thank you for this comment. Who should take action has been updated in the final guidance. To note that this list focuses on those with lead responsibility rather than all those who may be involved.
Royal College of	Recommend	4	Agree with need to clarify existing Dept of Health recommendations as	Thank you for this comment. These issues

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Paediatrics and Child Health	ation 1 Page 4		current wording ambiguous. It would also be useful for more clarification of the term " people with darker skin".	are included in updated recommendation 3.
Royal College of Paediatrics and Child Health	General		In agreement with the recommendations from NICE. However there is a need to regard vitamin D supplementation of young children as of equal importance to immunisation if we are going to improve uptake of vitamin D supplements adequately to prevent rickets. This is of particular relevance if the awaited SACN report on vitamin D does not recommend more widespread food fortification. To ensure adequate uptake of Healthy Start vitamins an incentive system needs to be introduced e.g. Financial incentives to GP's to ensure a high proportion of their age 0 to 4 years patients are receiving Healthy Start or a mechanism whereby the provision of food vouchers or child benefit payments to a parent is linked to ensuring the child is receiving Healthy Start vitamins. Such a scheme operates successfully in some European countries and ensures a high uptake and low prevalence of rickets.	Thank you for this comment. GP payment is outside the remit of this guidance.
Royal College of Paediatrics and Child Health	General		It would be helpful if NICE could recommend further research into different methods of taking vitamin D supplements instead of daily e.g. a three monthly large dose.	Thank you for this comment.
Royal College of Paediatrics and Child Health	Section 9 – Summary of methods... Cost effectiveness	34	Cost effectiveness should consider costs of admissions and out-patient activity due to hypocalcaemic seizures, cardiomyopathy and rickets in children.	Thank you for this comment. In the economic model the number of patients with 'symptomatic vitamin D' (Moy, McGee and Debelle *et al*., 2012) and the cost of 'symptomatic vitamin D' (Zipitis *et al.*, 2006)

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				were applied. 'Symptomatic vitamin D' encompasses those costs outlined in the comment.
Royal College of Paediatrics and Child Health	General		The target should be eradication of rickets and osteomalacia, not vitamin D deficiency	Thank you for this comment. We agree that the ultimate target is the eradication of rickets and osteomalacia. However, this is achieved (as far as possible) in this guidance by the dietary supplementation of vitamin D. In that sense, supplementation becomes the intermediate target.
Royal College of Paediatrics and Child Health	General		Rickets in infancy is as unacceptable to public health as is measles or poliomyelitis. There is no valid justification for not implementing preventive procedures that have been shown to work and are low in cost.	Thank you for this comment.
Royal College of Paediatrics and Child Health	General		NICE and DOH should copy what works in other countries which is A) red book visits have to include check of vitamin D supplementation, B) Financial Family Support should be linked to documented attendance at red book visits, 3) Neonatal units should hand out vitamin D drops at discharge and inform parents about the necessity to prevent rickets, 4) Paediatric training needs to have the same focus on vitamin D supplementation as on vaccinations, 5) infants should ideally only be seen by paediatricians in community practise. In any case, the medical responsibility should be the same as for vaccinations.	Thank you for this comment. PHAC considered the best available evidence to address the questions outlined in the scope for this guidance. Updated recommendation 8 includes prompts in the red book. Provision of healthy start vitamins from a broad range of outlets is included in updated recommendation 6. Training of practitioners is included in updated recommendation 9.
Royal College of Paediatrics and Child	Draft recommenda	4	The document starts by only referring to England yet I thought NICE recommendations are for all 4 nations. Further in the document it goes	Thank you for this comment. NICE public health guidance applies to England only.

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Health	tion 1		on to say that there is agreement between the 4 CMO's of the four nations about supplementation. My only recommendation is that the document is clear about who this is for and states that this is for all 4 nations of the UK and not just England.	
Royal College of Paediatrics and Child Health	Section 7, Glossary where 'at risk groups' is defined	26	It would be helpful if disabled children and young people could be given as an example of those requiring vit D supplementation due to low or no exposure to sunlight (in addition to the current example of housebound people). Disabled children and young people have reduced exposure to sunlight through more limited access to outdoor activities, physical disabilities that restrict outdoor activity and a reduced family income that also restricts outdoor activities as well as opportunities for holidays in sunnier climates. Child and young people with disabilities are at increased risk of bone disease, especially osteoporosis, and given their more limited exposure to sunlight, it is important to highlight this group for receiving vit D supplementation to try to prevent bone disease.	Thank you for this comment. The introduction states: Clinical judgment will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency.
Royal College of Paediatrics and Child Health			Need to clarify the abbreviation SACN. Although the full wording is given on page 1 it is not linked to SACN on page 2 – could leave the reader wondering what SACN stands for.	Thank you, the text has been amended in line with your comment.
Royal College of Paediatrics and Child Health	Recommendation 8 & 9	8,9	Define safe sun exposure – even vaguely whilst awaiting NICE document to be published	Thank you for this comment. Examples of people who may have low sun exposure are given in the introduction (text taken from CMO letter 2012).
Royal College of Paediatrics and Child Health	Recommendation 9	9	Comprehensive recommendations for advertising Vit D at healthcare and educational centres are mentioned in the document. Most people eligible for treatment will be in contact with healthcare.	Thank you for this comment. PHAC considered the inclusion of places of workshop as appropriate in this instance.

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			Would have thought it inappropriate to advertise at places of worship as well and could super-saturate and irritate some people	
Royal College of Paediatrics and Child Health		19	Manufactures of MVT vitamin D preparation should note the changes to the RNI reference ranges and change preparations accordingly – e.g. most MVT for children only contain 5ug vit D. Liquid preps are higher although under the age of 1 year Abidec and Dalivit would need to be given at 0.6ml to provide 400iu (10ug) and 0.51ml for 8.5ug and 0.45ml for 7ug, which is not very practical.	Thank you for this comment. NICE hopes that manufacturers will implement the recommendations. NICE is aware that many supplements containing vitamin D do not contain the RNI.
Royal College of Paediatrics and Child Health	13	26	Need to include children with chronic diseases who are at risk for low vit D intakes or those who are excluding vit D rich sources from their diet. In some groups of children a calcium containing preparation should be given along with vitamin D and guidance should be given as to which groups e.g. allergy/ IBD.	Thank you for this comment. The introduction states: Clinical judgment will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency.
Royal College of Paediatrics and Child Health	Background	12	It may be useful for them to include "growing up milks" as well as infant formula as these have also been fortified with vitamin D and in at risk groups may offer a better alternative for years 1 – 3 than cow's milk as they usually contain 1 – 1.2ug of vitamin D per 100ml in addition to being fortified with iron and other micronutrients.	Thank you for this comment. The suitability of milks for infants is outside the remit of this guidance and covered by NICE guidance PH11 on maternal and child nutrition.
Royal College of Paediatrics and Child Health		13	Risk should also be included of infants excludinf cow's milk protein free as even if they drink more than 500ml of formula they usually don't meet the RNI for vit D.	Thank you for this comment. The introduction states: Clinical judgement will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency.
Royal College of Paediatrics and Child Health	General		There is a gap in the RNI which needs to be addressed for children age 3 - 18 years.	Thank you for this comment. SACN is currently considering dietary reference values. The introduction states that the

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				recommendations should be read in conjunction with any advice published by SACN.
Royal College of Paediatrics and Child Health	Recommendation 2		The DH need to work with the relevant agencies FSA, local authorities and manufacturers to ensure that there is appropriate quality assurance of the contents of vitamin D products.	Thank you for this comment. Updated recommendation 1 states that supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D.
Royal College of Paediatrics and Child Health	General		In the opening section where you describe 'at-risk groups', please consider specifically mentioning 'patients with a photo-sensitivity disorder which prohibits them from going out in sun.'	Thank you for this comment. The introduction states: Clinical judgement will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency.
Royal College of Paediatrics and Child Health	General		The guidance says that vit D levels should not be checked unless there are signs of vit D deficiency. Please consider some exceptions to this eg where supplements have not been previously taken and risk of deficiency is high eg severe eczema in darker children. The reason for this is that normal dose vit D may be inadequate replacement initially	Thank you for this comment. The introduction states: Clinical judgement will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency.
Royal College of Paediatrics and Child Health	General		Please clarify the daily doses required for replacement. The statement suggests doses in mg, but current prescriptions and OTC preps are in units, which is confusing.	Thank you, values by international units have been added to the glossary definition of RNI.
Royal College of	General		This guidance is peculiar in that it focuses on how to implement	Thank you for this comment and references.

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Physicians and Surgeons of Glasgow			others' guidance. It wisely states that in so doing it seeks to prevent vitamin D deficiency (and wisely by implication endorses the lack of evidence of any other health benefit – despite widespread hysteria around perceived benefits – other than to avoid deficiency (that can result in osteomalacia / rickets). It is important that this guideline is NOT seen as supporting the wide use of Vitamin D. We have concerns that this this guideline may lead to use of vitamin D **beyond** the current evidence base and may over emphasise the importance of vitamin D to health in some groups –robust trials are not available and there remains uncertainty about what low vitamin D levels actually reflect. Some critical points which need careful reflection: *1.* There is uncertainty whether low vitamin D levels blood necessarily cause disease or are a consequence of other adverse factors – for example, we know now that obesity is a causal factor leading to low vitamin D *Vimaleswaran KS, et al; Causal relationship between obesity and vitamin D status: bi-directional Mendelian randomization analysis of multiple cohorts. PLoS Med. 2013;10(2): e1001383.* 2. Smoking also leads to low vitamin D levels in blood. Further, factors such as sub-clinical illness and systemic inflammation lead to low vitamin D blood levels.	The introduction to the guidance emphasises that it is focused on the implementation of existing guidance for at risk groups. The guidance does not extend existing guidance, as issued by COMA, SACN and the CMOs. The context section of the guidance notes that existing guidance has been available for many years but has been poorly implemented.
Royal College of Physicians and Surgeons of Glasgow	General continued		Recent summaries of trials: please review this editorial *Welsh P, Sattar N. Vitamin D and chronic disease prevention.*	Thank you for this information. Population dietary requirements for vitamin D are currently being considered by SACN. The

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			BMJ. 2014 Apr 1;348:g2280. doi: 10.1136/bmj.g2280. PubMed PMID: 24690627. This editorial is on two major meta-analyses – below - of observational and trial data published only in April 2014: 1. *Chowdhury R, Kunutsor, S, Vitezova A, Oliver-Williams C, Kiefte-de Jong J, Khan H, et al. Vitamin D and risk of cause specific death: systematic review and metaanalysis of prospective observational and randomised intervention studies. BMJ2014;348:g1903* 2. *Theodoratou E, Tzoulaki I, Lina Z, Ioannidis JP. Vitamin D and multiple health outcomes: umbrella review of systematic reviews and meta-analyses of observational studies and randomised trials. BMJ2014;348:g2035.* These papers show clearly that current evidence that apparent vitamin D deficiency is a cause of multiple conditions is simply not proven. Rather, many links may be simply reverse causality or residual confounding. The two papers also show that trial evidence suggesting reduction in mortality are too weak / restricted to be used to form clinical guidance. The NICE committee may wish to review these major comprehensive meta-analyses and the editorial since their evidence / conclusions do **NOT** support either wide spread supplementation in elderly adults (outside of bone-related conditions) nor widespread measurements of vitamin D levels.	introduction to the guidance notes that it should be considered alongside SACN's recommendations. The context section of the guidance notes that the evidence for association between vitamin D and conditions such as diabetes and some cancers is inconclusive.

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Royal College of Physicians and Surgeons of Glasgow			The last two paragraphs from the *Welsh & Sattar* Editorial provide a balanced view of the evidence: *"We suggest three take home messages from these two new studies. Firstly, healthcare professionals should treat all observational data cautiously, as existing disease and associated risk factors may cause, rather than be a consequence of, low circulating 25-hydroxyvitamin D. Secondly, before widespread supplementation can be considered, new trial data are needed with a focus on potential risks as well as benefits; further reanalysis of existing data will not suffice. Fortunately, new trials are under way—for example, VITAL,21 which has recruited 26_000 men and women and randomised them to 2000 IU D3, omega-3 fatty acid, or placebo in a two by two factorial design. Its primary outcomes will be cancer, coronary heart disease, and stroke, and it is due to report around 2017. VITAL will also be able to assess whether any benefits of D3 vary by baseline 25-hydroxyvitamin D concentrations. This study alone will therefore substantially increase the available D3 trial evidence base, and, importantly, extend it to younger people.* *Finally, pending results of major trials, clinicians should avoid costly measurement of 25-hydroxyvitamin D in asymptomatic patients outside of bone disease related conditions.22 Some may argue that supplementing those who are apparently "deficient" is cheap, but patients may gain false reassurance from prescription of a "protective" tablet. To improve health and prevent chronic disease, we should stick to what is proven: encourage better*	Thank you for this comment. SACN are currently considering population recommendations. The introduction to the guidance notes that the recommendations should be ready alongside the forthcoming SACN report. Recommendation 7 states that health and social care practitioners should only test vitamin D status if someone has symptoms of deficiency or is at very high risk.

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			lifestyles in general and target established risk factors in people at elevated risk"	
Royal College of Physicians and Surgeons of Glasgow	General		The above new evidence suggest that the current NICE draft guidance is premature in several potential aspects – without robust trial evidence in some key areas such as the elderly, we cannot recommend supplementation. There may be unforeseen harms (including potentially false reassurance) and hence we must await the results ongoing trials such as VITAL to form proper guidance. As currently written, some aspects of the guidance are based on questionable evidence and it may lead to widening of vitamin D requests which would be costly and counterproductive – we need robust trials and not observations in this contentious area. All current data cannot answer these questions. We would advise await trial output before such guidance. In addition, There appears to be a lack of clarity within the document about both how vitamin D will be made available and what the aim of the supplementation programme is. As it stands the evidence at present is largely around prevention of osteoporosis and reduction in fracture risk. There is also some lower quality evidence suggesting that vitamin D supplementation might have a role in falls prevention programmes. Vitamin D is associated with some other conditions such as diabetes and multiple sclerosis however there is no evidence to support supplementation in these conditions. Even within the context of bone health there is a lack of clarity in	Thank you for this comment and references. The introduction to the guidance emphasises that it is focused on the implementation of existing guidance for at risk groups. The guidance does not extend existing guidance, as issued by COMA, SACN and the CMOs. The context section of the guidance notes that existing guidance has been available for many years but has been poorly implemented. The introduction to the guidance notes that it should be read alongside the forthcoming SACN report on population requirements for vitamin D.

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			this document around the significance of the presence of vitamin D deficiency in different adult age groups. In younger adults the main issue is the potential association with osteomalacia (see comment below). Whilst osteomalacia can be also be an issue in older adults, in the majority of people the concern is increase in fracture risk.	
Royal College of Physicians and Surgeons of Glasgow			Further more, most healthcare professionals working in this area would agree with the NOS Guidance document that vitamin D blood level testing should not be routine but reserved for specific circumstances such as in association with malabsorption. The most important clinical syndrome associated with vitamin D deficiency in younger adults is osteomalacia. It should be noted within the document that measurement of calcium and alkaline phosphatase can be useful in this context, particularly in association with the presence of bone pain with vitamin D measurement reserved for where calcium is low and/ or alkaline phosphatase is raised. It should be acknowledged that the health benefits to the population of the approach that the guidance supports the implementation of remain unknown as do cost-benefits.	Thank you for this comment. SACN are currently considering population recommendations. The introduction to the guidance notes that the recommendations should be ready alongside the forthcoming SACN report. Recommendation 7 states that health practitioners should only test vitamin D status if someone has symptoms of deficiency or is at very high risk.
Royal College of Physicians and Surgeons of Glasgow	Recommendation 2		Supplements that are already available do allow for preparations that do not contain peanut oil, are halal and can be suitable for vegans. The problem here is that the dose in these preparations is higher than the recommended daily intake.	Thank you for this comment. NICE is aware that preparations are available but that they do not contain the RNI, hence this recommendation states that they should contain the RNI.
Royal College of Physicians and	Recommendations 5		Advising vitamin D supplements in high risk groups requires an overview as to who is getting these treatments. Although Recc 10 is a	Thank you for this comment.

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Surgeons of Glasgow	and 10		clearly desirable standard, the lack of direction around how to prescribe vitamin D supplement and the failure to incorporate this into routine General Practice care makes this recommendation largely impossible to meaningfully achieve. Vitamin D supplementation could be usefully incorporated into the Quality and Outcomes Framework (QOF) in primary care. Vitamin D could be *prescribed* to high risk groups by GPs and thus recorded on primary care systems. This would mean robust data would be then available to audit uptake and continuation of supplements as well as medium/longer-term effects on outcomes. Prescription for over 65's, for example, could be linked to other health care interventions such as annual influenza vaccination (or any other chronic disease reviews). In terms of "high risk groups", the guidance adopts a commendably pragmatic approach to defining high risk groups and how to widen access to supplements.Vitamin D is being advised for people with darker skin types. This would appear to be on a "whole population" basis rather than subgroups. However, there is little evidence that this would be practical to achieve and we are not aware of any evidence that this strategy would be overall beneficial. If bone health is the primary outcome benefit, this supplement is better targeted to where fracture risks are higher i.e. in older people – recognising that people from non-Caucasian racial groups tend to have lower fracture risks. The exception being around severe vitamin D deficiency and osteomalacia - however measurement of calcium and alkaline phosphatase in those patients presenting with bone pain will	QOF is outside the remit of this work. PHAC's priority has been to increase availability and access to supplements through a number of routes. Although this includes prescription, this is not their primary focus due to concerns about costs. The definition of at risk groups is based on existing guidance from COMA, SACN and the CMOs. The glossary definition of RNI has been amended to include international units.

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			identify many requiring intervention. This is an area where further research is required. Adults in high risk groups are advised to take a vitamin D supplement equivalent to 10ug/400IU per day however there is little/no information about how to do this. The dosing described should also state doses both in ug and IU to avoid confusion.	
Royal College of Physicians and Surgeons of Glasgow	Recommendation 6		It is clear that vitamin D sold as "food supplement" may contain variable amounts of vitamin D (which may be both significantly lower or higher than the labelled dose). Supplements should not be recommended where there is uncertainty around the available dose within the product. The existing recommendations are commendably conservative in their dose recommendations – given the absence of proven benefits other than avoidance of skeletal problems). It correctly highlights the challenge of accessing 400IU vitD (of pharmaceutical standard) supplements). However, If pharmaceutical grade vitamin D is to be used then consideration should be made of having a 10ug/400IU preparation available as "over-the-counter". Vitamin D can only be effectively supplemented *at the correct dose* by use of a pharmaceutical grade products. There are two products available on prescription i.e. Fultium D3 and Desunin. Both of these products contain 20ug/800IU vitamin D however. Since vitamin D is fat soluble and is stored in the liver, extended dosing regimens are possible and a 20ug/800IU capsule/tablet	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary. The updated recommendation also states that supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D.

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			could be taken every second day. Availability of a 2800IU preparation that could be taken weekly could also be a useful development (Fultium D3 is available as a 3200IU capsule that could potentially be used is this way). Since the guideline is aimed at manufacturers and providers of vitamin D supplement, production of a 10ug/400IU preparation (or 70ug/2800IU weekly preparation) should be encouraged. The recommendation for pharmacies and outlets selling food supplements to stock affordable vitamin D supplements and to promote the use of these can only be supported if there is confidence around the accuracy and consistency of the dose labelling of the preparation (see above). Otherwise the vitamin D content could be too highly variable to be supported for widespread use.	
Royal College of Physicians and Surgeons of Glasgow	Recommendations for research	23	There is a clear need for further research into the role of vitamin D supplement in non-Caucasian populations and whether this should be selectively used in different age-groups. Questions for research around how effective cost-effective an intervention programme might be can only be addressed if these is a database of individuals eligible for the intervention and of those who have taken up this intervention. This can then be linked to outcomes.	Thank you for this comment.
Royal College of Physicians (RCP)	General		The RCP is grateful for the opportunity to respond to the draft guideline. We would like to make the following comments.	Thank you.

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Royal College of Physicians (RCP)	General		We understand that this guidance relates to the *implementation* of existing guidance, and not directly to the guidance on Vitamin D (17/43)	Thank you for this comment.
Royal College of Physicians (RCP)	General		We also understand that one concern is that implementation has been poor because the initial guidance may be unclear and inconsistent; and the cost effectiveness is uncertain (15/43, 16/43)	Thank you for this comment.
Royal College of Physicians (RCP)	General		We recommend that the guideline should make it explicit that only licensed vitamin D products should be used, and not unlicensed products/food supplements, where vitamin D supplementation is indicated.	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary. The updated recommendation also states that supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D.
Royal College of Physicians (RCP)		2/43	'increase the risk of vitamin D deficiency. (This includes people who may be hypersensitive to vitamin D.) '	Thank you for this comment, the text has been amended.

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			Surely people hypersensitive to vitamin D are less at risk of deficiency (or more at risk of replacement therapy)?	
Royal College of Physicians (RCP)	1	4/43	'need a daily vitamin D supplement' 'require vitamin D-only supplements' As this is about potential benefit, words other than 'need' and 'require' are probably required.	Thank you for this comment, the text has been amended.
Royal College of Physicians (RCP)		4/43	Why halal and not kosher? Do the authors mean 'do not contain meat' or 'do not contain pork'? This requires clarification.	Thank you for this comment. The list provides examples and is not intended to be exhaustive. However, kosher has been added and definitions added to the glossary.
Royal College of Physicians (RCP)	3	14/43	'Older people are also at increased risk, particularly if they are frail, because they may spend more time indoors and have limited sun exposure' If this is the mechanism, then our experts believe that the advice should be to provide supplements to those who spend a high proportion of their time indoors (including frail people), not dependent on age. This is especially important given the number of people in institutions.	Thank you for this comment. This is based on existing guidance (CMO letter 2012). Existing guidance includes people that are housebound. Population requirements are currently being considered by SACN.
Royal College of Physicians (RCP)	4.2	17/43 & 18/43	We agree that there are a number of fundamental issues hindering uptake of the previous recommendations. However, we believe that clear evidence of efficacy and cost-effectiveness of treatment of 'low vitamin D status,' as distinct from osteomalacia and rickets, is needed before any sensible recommendations on uptake can be made.	Thank you for this comment. Section 4.15 of the Considerations section explains that this is not a guidance about whether vitamin D supplementation is cost effective, but which is the more cost effective way of supplementation: test-and-treat or treat-all. The comment would appear to wish to answer the alternative question (whether vitamin D supplementation is cost effective).

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Royal College of Physicians (RCP)	4.5	19/43	'Members agreed that there is unlikely to be a significant increase in the number of at-risk people taking a vitamin supplement unless a free or low cost vitamin D-only supplement is widely available. ' Our experts agree with this view.	Thank you for this comment.
Royal College of Physicians (RCP)	4.5	19/43	' The PHAC also noted that there is little point in awareness-raising activities to promote vitamin D supplements if affordable supplements are not widely available. ' Our experts agree with this view.	Thank you for this comment.
Royal College of Physicians (RCP)	4.17	22/43	'…it assumes everyone is given a prophylactic supplement without being tested. This means people who are severely deficient…' The severely deficient are those with symptoms or signs or both: which should be evident to the clinician. This is an underlying problem: osteomalacia and rickets are expected to be symptomatic - and the appropriate symptoms and signs should prompt proper biochemical investigation. The 'don't test, treat' paradigm is only valid in populations who have low vitamin D activity but are asymptomatic…	Thank you for this comment. If we have understood you correctly, we are of the view that what you are saying and what the draft guidance says amount to the same thing. You say that people who are severely deficient in vitamin D will be noticed by the clinician (through symptoms and signs) and treated separately. The remainder will be subject to a 'don't test, treat' course of therapy, which will include all those who have low vitamin D activity but are asymptomatic. (The guidance will also treat people with adequate vitamin D levels.) The PHAC were of the view that occasional cases of rickets or osteomalacia would not be looked for as assiduously if everyone were being supplemented. However the guidance has been amended in light of

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				your comments - "limitation" to "potential limitation" and "may be less likely to be given it" .
Royal College of Physicians (RCP)	4.19	23/43	See comments above.	See above
Royal College of Physicians (RCP)		23/43	'This section will be completed in the final document.' Stakeholders may wish to consider commenting on this section, once complete.	Thank you for this comment. The section is completed following PHAC consideration of stakeholder comments.
Royal College of Physicians (RCP)		29/43	'The action of sunlight (ultraviolet radiation of wavelength 290–310 nm) on skin converts 7-dehydrocholesterol to previtamin D3, which is then metabolised to vitamin D3.' Do (or could) sunlamps/tanning salons provide this wavelength?	Thank you for this comment. Sun exposure is being considered by a parallel piece of NICE public health guidance.
Royal College of Physicians (RCP)		29/43	'Low vitamin D status (sometimes called vitamin D deficiency) is defined by the Department of Health as a plasma concentration of 25 hydroxyvitamin D (the main circulating form of the vitamin) of below 25 nmol/litre (equal to 10 ng/ml).' Is there evidence for ethnic or genetic differences in the threshold of vitamin D concentration below which symptoms appear?	Thank you for this comment. The definition of low status is currently being considered by SACN.
Royal Pharmaceutical Society	General		The Royal Pharmaceutical Society welcomes the implementation of this guideline and the acknowledgement of the important role that community pharmacists have in preventing vitamin D deficiency. Community pharmacies are conveniently located and are readily accessible and there is no need for patients to make an appointment to have access to a registered health professional.	Thank you for this comment.
Royal Pharmaceutical Society	Recommend ation 2		We welcome the suggestion that the recommended reference nutrient intake for at risk groups are available on prescription and are listed in	Thank you for this comment.

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			the British National Formulary. We also welcome the suggestion that manufacturers are encouraged to supply supplements for the Healthy Start initiative direct to pharmacies.	
Royal Pharmaceutical Society	General		However we do not believe that this guidance addresses the major issue for both suppliers and prescribers of Vit D products. At present there is a huge range of unlicensed food supplement Vit D products on the market and relatively few products licensed by MHRA as medicines (GSL, P, or POM). Currently licensed products are available both for routine supplementation in at risk groups and for the treatment of insufficiency. The draft guidance makes no distinction between unlicensed (and largely unregulated) food supplements and licensed medicines. The RPS believes that this distinction should be made. There are greater risks to health professionals in terms of their legal responsibility in supplying food supplements rather than licensed medicines. There are specific risks for pharmacist as well as prescribers if prescriptions are filled using unlicensed products. Our guidance on specials which includes the hierarchy of risk makes this very clear.	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work. In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary. The updated recommendation also states that supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D.
Royal Pharmaceutical Society	General		Food supplements are far more variable in their composition, both in terms of active ingredient and potentially allergenic excipients, colours etc, that they contain. Formulations can legally be changed by the manufacturers pretty much at will leading to inconsistency and variability.	Thank you for this comment and references. The guidance is focused on the prevention of deficiency. Treatment of deficiency is outside the scope of the work.

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			There is also a major concern that patients prescribed Vit D, and members of the public who have been advised to take supplements will not get the appropriate dose. The MHRA has assayed available vitamin D products and found variations between 14.3% and 149.6% of the stated content amongst the food supplements. This of course does not happen with licensed products.	In relation to products recommended by GPs and other health professionals, PHAC's priority is to increase access to supplements containing the RNI for prevention of deficiency. Updated recommendation 1 states that DH should Work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at-risk groups are available on prescription and are listed in the British National Formulary. The updated recommendation also states that supplements should undergo quality control checks to ensure they contain the correct dose of vitamin D.
Royal Pharmaceutical Society	General		Clearly when high dose Vit D is needed to correct deficiency, as defined by the National Osteoporosis Society, one cannot use a calcium-containing product due to the serious risk of hypercalcaemia. For those with Vit D deficiency, the right dose is key.	Thank you for this comment. Treatment is outside the scope of this work.
Scottish Green Party	What is this guideline about?	1	There is evidence that prevalence of low vitamin D status is more common than indicated in many parts of the UK. One study from Scotland suggests that 50% of those who are both obese and in a low socio-economic group will be under 25 nmol/l, many of them all year round and that currently even those taking supplements are not receiving enough to maintain adequate blood levels 33% of Scots were deficient according to this report Ref:http://www.foodbase.org.uk//admintools/reportdocuments/845-1-1545_FSA_Vit_D_2011_report_final.pdf	Thank you for this comment. The NDNS 2008-11 has indicated regional differences. However please note that this guidance only applied to England.
Scottish Green Party		1	The level set for deficiency status was to prevent rickets and	Thank you for this comment. The

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			osteomalacia, however, guidelines should be aimed at providing enough vitamin D for optimal health and not just for preventing deficiency Ref:http://www.vitamindwiki.com/Vitamin+D%3A+what+clinicians+need+to+know+-+Aug+2012	requirements are based on existing advice from COMA, SACN and the CMOs (letter 2012). The introduction notes that the recommendations should be read alongside the forthcoming SACN report on population requirements for vitamin D.
Scottish Green Party		13	A 2001 study is cited. More recent evidence suggests that levels of deficiency are increasing all over the UK but Northern latitudes and areas with high cloud cover are the worst. It is impossible to obtain sufficient UVB from sunlight for large parts of the year in these parts of the UK. People would need to be outside with skin exposed for large amounts of time and this is unlikely in the winter. Few indoor workers will obtain meaningful sun exposure during a working week, and children are outside less than previous generations Refs 1) Davis, S (2013) Annual report on children and young people's health from the Chief Medical Officer. 2) Webb, AR et al (2011) Photochem photobiol.May; 87(3) 741-5	Thank you for this comment. The reference to NDNS 2001 has been updated to reference NDNS 2008-11 published in 2014.
Scottish Green Party		4	Those with darker skin need up to six times more sun exposure, than those with fairer skin to synthesise the same amount of vitamin D and this is not obvious from the guidance. Ref http://www.vitamindcouncil.org/about-vitamin-d/how-do-i-get-the-vitamin-d-my-body-needs	Thank you for providing this reference. People with darker skins are identified as an at risk group in the guidance. Please note that NICE is developing a parallel piece of guidance on sun exposure.
Scottish Green Party		P13	Evidence from premier league footballers indicates that by December their vitamin D had dropped even though they were outside training every day and they had insufficient levels over the winter. This suggests	Thank you for this comment. The requirements are based on existing advice from COMA, SACN and the CMOS. The

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			that sufficient vitamin D cannot be stored to last the winter, and even those not in at-risk groups require seasonal supplementation Ref: 1. Morton et al. (2012) *Appl Physiol Nutr Metab.* **37:**798-802	introduction notes that the recommendations should be read alongside the forthcoming SACN report on population requirements for vitamin D.
Scottish Green Party		P13	Growing evidence of association between low vitamin D status and a range of illnesses such as MS, Chrohns, some cancers, autism etc. suggests that vitamin D levels are very important. You state that evidence is inconclusive but a precautionary principle should be applied given the concerning evidence stacking up. Adequate levels of vitamin D should be given to all citizens as is the case in France where all citizens are given injections twice each winter. Refs: http://www.healthresearchforum.org.uk/reports/scotland.pdf http://www.vitamindcouncil/health-conditions/autism/	Thank you for this comment. The at risk groups highlighted in the guidance are as those identified in existing guidance by COMA, SACN and the CMOs (letter 2012). The introduction notes that the recommendations should be read alongside the forthcoming SACN report on population requirements for vitamin D. To note that the introduction to the guidance also states that Clinical judgment will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency.
Scottish Green Party		P14	Older people are less able to synthesise vitamin D, so it has been argued that all over 50s should be given supplements all year round and not just those who are housebound. Ref: Burleigh and Potter (2008), *Vitamin D deficiency in outpatients:--a Scottish perspective* Scott Med J. **51**(2):27-31.	Thank you for this comment. The at risk groups highlighted in the guidance are as those identified in existing guidance by COMA, SACN and the CMOs (letter 2012). The introduction notes that the recommendations should be read alongside the forthcoming SACN report on population requirements for vitamin D.
Scottish Green Party		P12	*Breast feeding mothers should be warned that their milk may not*	Thank you for this comment. Population

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			contain sufficient vitamin D unless supplemented sufficiently but the literature suggests levels of around 4000iu are needed for pregnant and lactating mothers, which is higher than current and draft guidelines. *References:* *1. Wagner, (2011) FABM in Clinical Lactation **2**:27-31,* *2. Hollis and Wagner (2004) Am J Clin Nutr. **80**:1752S-8S.*	requirements are under the remit of SACN.
Scottish Green Party	General		There is evidence that it is much more cost effective to provide adequate supplementation on the basis of a precautionary principle than to treat the diseases associated with low levels. The cost of universal supplements could be as little as 1p per person per day according to the MS campaign 'Shine on Scotland'. The health deficits due to low vitamin D such as increased levels of osteomalacia, MS and cancer cost far more than this. References: 1.http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2004.045260 2. Garland et al.(2007) Nutrition Reviews ***65****(5):91-95*	Thank you for this comment.
Scottish Green Party		P13	In a study of 45 year olds, 92% of Scots had insufficient levels of vitamin D by winter's end - twice as many as the rest of the UK - so the argument for universal vitamin D supplementation here, is even stronger, particularly in winter. Ref: Hyppönen and Power (2007) *Hypovitaminosis D in British adults at age 45 y: nationwide cohort study of dietary and lifestyle predictors* **85**:860-8.	Thank you for this comment. The guidance applies to England only.
Scottish Green Party	General		Dame Sally Davis has argued for universal supplements for under 5s. However as one in three Scots has deficient and 90% insufficient levels of vitamin D there is a very strong argument for free universal	Thank you for this comment. NICE public health guidance applies to England only.

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			supplements for all age groups here in Scotland and a motion proposing this was passed at the Scottish Green Party conference, 2012 and subsequently NICE were asked whether Scotland was being specifically considered in guidance. Whilst the levels of vitamin D in other parts of the UK are marginally better, the benefits of supplementing still outweigh the costs if you extrapolate Garland's research. Garland et al.(2007) Nutrition Reviews ***65****(5):91-95*	
Seasonal Affective Disorder Association	General		The SADA committee have given further consideration as to whether vitamin D is an issue for SAD sufferers. Whilst we have seen evidence to support the fact that people taking anti-depressants may be deficient in vitamin D we feel it is prudent to obtain additional evidence before a proven link between vitamin D deficiency and SAD can be established. Therefore it has been concluded that on this occasion we must withdraw from the NICE Guidance process regarding this issue.	Thank you for this comment.
Solihull Metropolitan Borough Council	1 Recommendation 1	4	Solihull Metropolitan Borough Council (SMBC) support the recommendation to resolve inconsistencies in the wording of existing recommendations on vitamin D, particularly with regard to supplementation for children under 6 months of age (whether they are breast or formula fed). There is continual confusion over the need for supplementation from 4 weeks of age for babies of mothers who have not supplemented in pregnancy. This confusion causes mixed messages to mothers and a preventable lack of clarity and ongoing source of frustration for Health Visitors.	Thank you for this comment.
Solihull Metropolitan Borough Council	1. Recom	4	Clarity with regard to whether children aged 4 to 5 years require a vitamin D supplement would also be welcomed to ensure that the correct information is given to parents and carers.	Thank you for this comment.

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	mendation 1			
Solihull Metropolitan Borough Council	1. Recommendation 2	4	Vitamin D supplements should be as widely available as possible and should be halal, suitable for vegans and free from peanut oil.	Thank you for this comment.
Solihull Metropolitan Borough Council	2. Recommendation 2	4	Supplements should be available on prescription for at-risk groups to ensure greater availability and access for them as well as ensure that patients who are both entitled to free prescriptions and are in an at-risk group are enabled to obtain the supplements without charge. This would enable GPs to prescribe the supplement where they deem there is a clinical need, particularly for those in the at-risk groups.	Thank you for this comment.
Solihull Metropolitan Borough Council	1. Recommendation 2	4	Existing legislation should definitely be amended to enable Healthy Start vitamins to be more widely distributed and sold. An amendment to enable the products to be sold once more would greatly increase their uptake as the products can be retailed for a much cheaper price than the recommended alternatives. In Solihull, there is a system where the Health Visitors and Nursery Nurses give Healthy Start children's vitamin drops directly to those families who are eligible for the scheme at the 8-12 month development check, through the Healthy Child Programme. For families not eligible for free children's drops, the health professional recommends Abidec multi-vitamin drops that cost much more than the Healthy Start vitamins and are only available from shops and	Thank you for this comment.

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			pharmacies. If Healthy Start vitamins could be sold (as they were prior to April 2013), receptionists in clinics could sell them directly to parents and carers at the time of the recommendation, greatly increasing the likelihood of the supplementation occurring.	
Solihull Metropolitan Borough Council	1. Recommendation 2	4	In addition, if parents and carers were able to buy the vitamins in Children's Centres, clinics and pharmacies, it would be much more convenient and cheaper for them, compared with sourcing and buying an alternative. This would positively impact on the uptake of the vitamins. Many parents and carers relied on being able to purchase Healthy Start vitamins prior to April 2013, and trusted the NHS branding on the product. Enabling the vitamins to be sold would increase brand awareness of the product aligned with the reassuring endorsement of the NHS on the packaging, potentially enhancing the social acceptability of the vitamins (that they are not just for those low-income families on the scheme). As the stigma of accessing the Healthy Start vitamins was a finding of the evaluations, both locally and nationally for why the uptake has been so low, enabling the products to be used by all families, may help to tackle this.	Thank you for this comment.
Solihull Metropolitan Borough Council	1. Recommendation 2	5	Pharmacies and other outlets selling food supplements (such as supermarkets) should definitely stock affordable vitamin D supplements and promote them to at-risk groups.	Thank you for this comment.
Solihull Metropolitan Borough Council	1. Recommenda	5	Manufacturers of multivitamin supplements for children and adults should include vitamin D in their preparations.	Thank you for this comment.

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	tion 2			
Solihull Metropolitan Borough Council	1. Recommendation 3	5	A national campaign to raise awareness of the importance of vitamin D (particularly for at-risk groups) with information on how to access the supplements would be strongly welcomed. In order to increase the awareness of the importance of the vitamin and the effects of deficiency, a campaign is needed to generate dialogue and interest in communities, in a similar way to stopping smoking, safe sun exposure and other high-profile public health issues.	Thank you for this comment.
Solihull Metropolitan Borough Council	1. Recommendation 3	5	Campaign resources need to be easily adaptable for local use to minimise duplication of effort and ensure consistent, clear messages are communicated locally and nationally. The strengths of campaigns such as smokefree and the NHS Stop Smoking Services was due, in part, to a national campaign with high awareness that was very adaptable locally within branding guidance.	Thank you for this comment.
Solihull Metropolitan Borough Council	1. Recommendation 4		In Solihull, we have a multi-agency steering group for the Healthy Start scheme, which has its main focus on vitamin D supplementation. The group has been effective in ensuring that mechanisms are in place to increase the availability and uptake of supplements, including the universal supply of free Healthy Start vitamins to all pregnant and breastfeeding women (until the baby is 12 months old).	Thank you for providing this information
Solihull Metropolitan Borough Council	1. Recommendation 5	6	Solihull has a semi-universal scheme locally where all pregnant and breastfeeding women receive Healthy Start vitamins free of charge, regardless of income. Bottles of maternal vitamin supplements are given to women free at their booking appointment by their Midwife. This system has increased the uptake of vitamins locally and we would endorse this approach elsewhere to increase the availability of vitamins	Thank you for providing this information

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			and promote a culture of supplementation. Currently, members of the group are considering the universal free supply of vitamins to all babies in Solihull from 4 weeks to 2 years old. Current activity will be supported by promotional resources and an awareness raising campaign locally but awareness will be more greatly enhanced with a national campaign.	
Solihull Metropolitan Borough Council	1. Recommendation 6	6	In Solihull, all pregnant and breastfeeding women and all eligible families with children aged 6 months to 4 can collect their free Healthy Start vitamins at a range of outlets, such as, high street and supermarket pharmacies, children's centres and clinics, to ensure their ease of access. SMBC have a contract with NHS Property Services to manage the vitamin stock and deliver a regular batch of vitamins quarterly to distribution points. This system is the result of the multi-agency group and SMBC Public Health considering how accessibility, availability and uptake could be improved.	Thank you for providing this information
Solihull Metropolitan Borough Council	1. Recommendation 7	7	In Solihull, the multi-agency Healthy Start group has champions from Maternity Services (a Community Midwife Team Leader) and Health Visiting (a Team Leader). Their role, in addition to attending group meetings and contributing to the planning and development of the scheme, is to disseminate information to their team and to other team leaders and, thus, front-line health professionals to ensure that they recommend a daily vitamin D supplement to people from at-risk groups at every available opportunity.	Thank you for providing this information
Solihull Metropolitan Borough Council	1. Recomme	7	SMBC would welcome computerised prompts on vitamin D to be integrated into health and social care systems to recommend and record vitamin D supplement use among at-risk groups.	Thank you for this comment

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	nda tion 7			
Solihull Metropolitan Borough Council	1. Rec om me nda tion 7	7	SMBC would strongly agree with the booking section of the standardised handheld maternity notes and the personal child health records (the 'red book') having specific questions about vitamin D supplement use.	Thank you for this comment
Solihull Metropolitan Borough Council	1. Rec om me nda tion 8	8	In Solihull, a short training session has been delivered to a range of health professional teams. The training includes local policies and procedures in relation to vitamin D as well as local distribution points for Healthy Start supplements and a recommended alternative children's product for non-eligible families (Abidec multi-vitamin drops). This could be extended to social care professionals and voluntary and community groups in contact with those at-risk of vitamin D deficiency.	Thank you for this information.
Synergy Biologics	General		**Vegetarian** Products marked as 'suitable for vegetarian' should not contain meat, poultry, game, fish, shellfish or crustacea, or bi-products of slaughter. In addition to this, there are additional requirements for people who are vegetarians on religious grounds (for example Hindus, Buddhists, and Sikhs). In particular, processing and packaging machinery must all be **dedicated** to the vegetarian line and not be used to produce any other non-vegetarian products.	Thank you for this comment.
Synergy Biologics	General		**Halal**	Thank you for this comment.

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			There are internationally recognised guidelines that clearly lay out standards for Halal compliance http://apps.who.int/medicinedocs/documents/s18036en/s18036en.pdf Nutritional supplements should comply with these standards to achieve Halal status. In particular machines, utensils, supply lines and cleanrooms including mixing, dosage and blister packing must all be **dedicated** to the Halal line and not be used to produce any other products. It has been reported by the editor of 'Chemist and Druggist' that a study conducted at Keele University in 2004, an estimated 58% of Muslim consumers would refuse medication if they consider the medicine as culturally inappropriate. http://www.chemistanddruggist.co.uk/feature-content/-/article_display_list/13459829/which-medicines-are-halal	
Synergy Biologics	General		**Allergens** Vitamin D supplements should avoid the inclusion known allergens particularly peanuts, soya, gluten and lactose. Inclusion of known allergens is a barrier to establishing safe supplementation and should be a major consideration. According to Food Standards Agency, the rules for food supplements establish a list of 14 food allergens, which have to be indicated by reference to the source allergen whenever they, or ingredients made	Thank you for this information

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			from them, are used at any level in food supplements. The list consists of cereals containing gluten, crustaceans, molluscs, eggs, fish, peanuts, nuts, soybeans, milk, celery, mustard, sesame, lupin and sulphur dioxide at levels above 10mg/kg, or 10 mg/litre, expressed as SO2. http://www.food.gov.uk/science/allergy-intolerance/label/#.U6g7gyqF8jo The inclusion of this information on food supplement packaging contributes hugely to consumer safety, beyond self-selection of medicines.	
The British Dietetic Association	General		Thank you for giving The British Dietetic Association the opportunity to comment on the draft guidance.	Thank you.
The British Dietetic Association	**Draft Recommendation 2** **Section 3** How to get vitamin D supplements	4 16	We hope that the guideline development group will provide clear guidance for health professionals on the supply of and access to vitamin D supplements	Thank you for this comment.
The British Dietetic Association	Draft Recommendation 6 **Section 3**	6 16	We hope that the guideline development group will provide clear guidance for health professionals on the supply of and access to vitamin D supplements …… in particular the Healthy Start supplements and that addresses barriers in relation to knowledge and attitudes	Thank you for this comment.

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	How to get vitamin D supplements **Section 4** 4.14 Training	22		
The British Dietetic Association	Draft Recommendation 7	7	Recognising the importance of Children's Centres and other early years settings for families with young children, we would suggest that 'health and social care professionals' is expanded to include other early years practitioners	Thank you for this comment. Early years staff are covered included in updated recommendation 9 and 10. To note that the who should take action list focuses on those with lead responsibility rather than all those involved.
The British Dietetic Association	Draft Recommendations 8 & 9 **Section 4 Considerations** 4.2 Background 4.3 Communications	8-9 17 18 18 20-21	We hope that the guideline development group will provide clear guidance for health professionals on the supply of and access to vitamin D supplements …… in particular the Healthy Start supplements and that addresses barriers in relation to knowledge and attitudes	Thank you for this comment.

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	4.4 Availability Healthy Start 4.9, 4.11			
The British Dietetic Association	4.2 Background 4.4 Availability **Healthy Start** 4.9 - 4.13	17 18 20-21	The guidance development process should look at some of the practical barriers / obstacles to uptake of the scheme by both health professionals, other key practitioners supporting pregnant women and families 0-5 years and the public, such as: • Reformulating the children's vitamins so they have a longer shelf life • Supply chain issues • Accessibility to the Vitamin supplements – consideration is needed to be given to where families can access them for example venues families health centres, early years settings and at a range of times over the day if they cannot be made available through retail outlets	Thank you for this comment. These issues are currently dealt with in recommendations 4, 5 and 6.
The British Dietetic Association	Recommendation 2 Recommendation 3 (bullet point 3) 4.4 Availability	4-5 18	The guideline should also consider what advice health professionals should give to those who are not eligible for Healthy Start supplements, for example what Vitamin D supplements to advise those patients take and where to advise patients to buy from.	Thank you for this comment, This is addressed in updated recommendations 3,6, 9 and 10
The food partnership Ltd	General	P1-43	The Vitamin D Mission welcomes draft guidance on Vitamin D:	Thank you for this comment

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			implementaion of existing guidelines to prevent defiency published by NICE on 13 May 2014.	
The food partnership Ltd	General	P1-43	The Vitamin D Mission is a public health awareness initiative, which aims to eradicate vitamin D deficiency in infants and children aged 0-5 years in the UK. It is supported by a number of founding partners including the Royal National Orthopaedic Hospital NHS Trust, Cow & Gate Growing Up Milk, the supplements company BetterYou, and Kellogg's. www.vitamindmission.co.uk	Thank you for this comment
The food partnership Ltd	General	P1-43	The Vitamin D Mission urges all parents to *make every day a Vitamin D day*, incorporating naturally-rich or fortified foods and drinks into toddler's diets, with appropriate supplementation and safe sun exposure. The Vitamin D Mission 'calculator' is a tool designed to help parents to take the test to find out how much vitamin D their child is getting through their diet. The tool provides practical solutions about incorporating naturally-rich or fortified foods and drinks into toddler's diets as well as appropriate supplementation and safe sun exposure.	Thank you for this comment.
The food partnership Ltd	General	P1-43	The Vitamin D Mission believes the draft guidance is a positive step towards recognising that aall infants and children in the UK aged 0-5 years are at risk of not getting the vitamin D they need to support their healthy growth and development, and finding solutions that address this problem holistically is a priority.	Thank you for this comment. To note that the at risk groups are as identified in existing recommendations from COMA, SACN and the CMOs (letter 2012).

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The food partnership Ltd	General	P1-43	The NICE draft guidance backs up the key findings of the Generation D-report, recently published on behalf of the Vitamin D Mission. This report found that despite government recommendations, only one in seven parents provides their child with a daily vitamin D supplement, with three in five admitting they never give their child vitamin supplements at all, and over a third of parents unaware that their child needs a daily dietary source of vitamin D. The average British toddler is only getting 27% of the daily dietary vitamin D they need.	Thank you for this information.
The food partnership Ltd	General	P1-43	The Vitamin D Mission is pleased to make the following comments as these relate to the target group included within the scope of the Mission's activities, namely infants and children aged 0-5 years.	Thank you for this comment.
The food partnership Ltd	Recommendation 1	P 4	***Recommendation 1: Clarify existing guidance on, and which groups are at-risk of, vitamin D deficiency*** The Vitamin D Mission supports the recommendation to clarify guidance on vitamin D supplementation for children under 6 months (whether they are breast fed or formula fed) and make it clear whether children aged 4-5 years require a vitamin D supplement. Once final guidance is published, the Vitamin D Mission will incorporate guidance about appropriate supplementation for childern in our materials and communication tools.	Thank you for this comment.
The food partnership Ltd	Recommendation 2	P 4-5	***Recommendation 2: Increase access to vitamin D supplements*** The Vitamin D Mission agrees that vitamin D supplements should	Thank you for this comment.

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			provide the RNI as recommended by SACN and these should be widely available for children and adults. The Vitamin D Mission advocates use of daily supplements for children aged 6 months – 5 years, in accordance with the advice issued by the four UK Chief Medical Officers in February 2012. This advice is included in the Mission's materials and campaign tools aimed at parents and carers and health care professionals.	
The food partnership Ltd	Recommendation 3	P 5	***Recommendation 3: Develop a national campaign*** The Vitamin D Mission welcomes the recommendation for a national campaign to raise awareness of the importance of vitamin D. The Mission supports the campaign goals outlined as follows: • emphasise the importance of vitamin D for good health • emphasise the importance of a daily supplement for identified at-risk groups • let people know where they can get vitamin D supplements. The Vitamin D Mission's own campaign launched in March 2014 www.vitamindmission.co.uk aimed at the at-risk group, infants and children aged 0-5 years, is fully aligned to the goals recommended by NICE. The Vitamin D Mission campaign promotes a holistic approach to encouraging appropriate levels of vitamin D intake from all sources and recommends incorporating naturally-rich or fortified foods and drinks	Thank you for this comment.

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			into toddler's diets as well as appropriate supplementation and safe sun exposure. The Mission will be pleased to engage with Public Health England to find ways of collaborating, to avoid duplication and promote consistency of message.	
The food partnership Ltd	Recommendation 4	P 5-6	***Recommendation 4: Co-ordinate local action to increase use of vitamin D supplements in line with existing guidance*** The Vitamin D Mission supports a multiagency approach advocated by NICE, to improve awareness of the importance of vitamin D and increase the availability and uptake of supplements.	Thank you for this comment.
The food partnership Ltd	Recommendation 5	P 6	***Recommendation 5: Increase local availability of vitamin D supplements for at-risk groups*** This recommendation is specifically targeted to local authorities and the Mission has no specific comment to make.	Thank you for this comment.
The food partnership Ltd	Recommendation 6	P 6-7	***Recommendation 6: Improve access to Healthy Start supplements*** This recommendation is specifically targeted to local authorities and the Mission has no specific comment to make.	Thank you for this comment.
The food partnership Ltd	Recommendation 7	P 7-8	***Recommendation 7: Ensure health and social care professionals recommend vitamin D supplements*** The Vitamin D Mission agrees that health and social care professionals	Thank you for this comment.

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			should recommend a daily supplement to people from at-risk groups at every available opportunity. An important part of the Mission's campaign activities fosters engagement and information sharing with relevant health care professionals. The Mission's campaign messages aimed at HCPs includes the advice issued by the four UK Chief Medical Officers in February 2012 advocating the use of daily supplements for children aged 6 months – 5 years. In addition, as the Mission's campaign promotes a holistic approach to encouraging appropriate levels of vitamin D intake from all sources, the Mission also recommends incorporating naturally-rich or fortified foods and drinks into toddler's diets as well as appropriate supplementation and safe sun exposure.	
The food partnership Ltd	Recommendation 8	P 8	***Recommendation 8: Raise awareness among health, social care and other relevant professionals of the importance of vitamin D*** The Vitamin D Mission agrees with the recommendation to ensure health and social care professionals receive information on the following as part of their registration and post-registration training or continuing professional development: • the importance of vitamin D for good health • sources of vitamin D in the UK (from safe sun exposure, supplements and limited dietary sources) • groups at risk of low vitamin D status	Thank you for this comment.

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			• supplement recommendations for different groups An important part of the Mission's campaign activities is engagement and information sharing with relevant health care professionals and our messages are fully aligned to NICE recommendations outlined above.	
The food partnership Ltd	Recommendation 9	P 8-9	***Recommendation 9: Raise awareness of the importance of vitamin D supplements among the local population*** The Vitamin D Mission supports the call to increase people's awareness of: • the importance of vitamin D for good health • sources of vitamin D in the UK (from safe sun exposure, supplements and limited dietary sources) • groups at risk of vitamin D deficiency and the importance of a daily vitamin D supplement for these groups • local sources of vitamin D supplements • local sources of Healthy Start supplements • sources of further information. These messages are fully aligned to the Vitamin D Mission goals and communications.	Thank you for this comment.
The food partnership Ltd	Recommendation 10	P 9-10		Thank you for this comment.

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			Recommendation 10: Monitor and evalulate the provision and uptake of vitamin D supplements This recommendation is specifically targeted to The Department of Health, Public Health England and local authority commissioners and the Mission has no specific comment to make.	
The food partnership Ltd	General	P 23-24	NICE guidance has also identified a number of gaps in the evidence concerning vitamin D supplement uptake, awareness raising activities, and health professional training. The Vitamin D Mission recognises that it is pivotal that a campaign such as ours invests in research to further our knowledge in this area and specifically in relation to the health outcomes/health benefits for young children. As such The Vitamin D Mission has committed to working together with key collaborators and stakeholders in child health and nutrition, to increase parental awareness and understanding, enlist the support of healthcare professionals, conduct research into vitamin D and establish future strategies for combatting low levels of vitamin D in children aged 0-5 years. The Vitamin D Mission is establishing an Independent Research Group to develop a robust research programme to continue to deliver research with and on behalf of the Vitamin D Mission in line with the research	Thank you for this comment.

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			objectives outlined below. • Establishing and monitoring of the rate of rickets in the UK • The potential role that fortification of vitamin D in foods & drinks can have • The economic impact of vitamin D deficiency • Perceptions and awareness	
The food partnership Ltd	General	P1-43	In summary, The Vitamin D Mission supports the draft guidance issued by NICE and looks forward to working with key collaborators and stakeholders in child health and nutrition, to help UK parents ensure their children receive appropriate vitamin D intake.	Thank you for this comment.
The Proprietary Association of Great Britain	What is this guideline about?	1	The Chief Medical Officer acknowledges that individuals with darker skins require additional vitamin D, however the Department of Health does not specify this cohort in its guidance on dosing for at risk groups, nor does it include them in the wording of the document Recommended wording and conditions of use for labelling messages concerning Government advice on vitamin D supplementation. This should be amended and clear advice should be given for dosing in this group.	Thank you for this comment. The guidance is concerned with the implementation of existing guidance The requirements of particularly groups and labelling issues are outside the scope of this work.
The Proprietary Association of Great Britain	What is this guideline about?	2	SACN had said that their preliminary report would be published in 2014 however judging from the minutes of the SACN meetings it is unlikely that such a document will be issued this year.	Thank you for this comment. NICE are working closely with the SACN secretariat to ensure joined up working where possible. The introduction to the guidance notes that the recommendations should be read alongside the forthcoming SACN report.
The Proprietary	What is this	2	Hypersensitivity to vitamin D is rare and is generally the result of a pre-	Thank you for this comment. This text has

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Association of Great Britain	guideline about?		existing medical condition. To apply a precautionary principle to protect a limited cohort who will no doubt already be aware of risks associated with consuming vitamin D will disadvantage the wider population who are in need to additional vitamin D from food supplements.	been amended.
The Proprietary Association of Great Britain	Draft Recommendation 2	4	Healthcare professionals (HCPs) need to be made aware of the availability of self-care options to purchase cost effective vitamin D from pharmacies, health food shops and supermarkets.	Thank you for this comment. Awareness raising amongst health and social care practitioners is addressed in updated recommendation 9.
The Proprietary Association of Great Britain	Draft Recommendation 2	4	The BNF currently states (section 9.6.4 Vitamin D: Ergocalciferol): *There is no plain vitamin D tablet available for treating simple deficiency[ ]. Alternatives include vitamins capsules (section 9.6.7), preparations of vitamins A and D (section 9.6.1) and calcium and ergocalciferol tablets (although the calcium and other vitamins in supplements are unnecessary).* This needs to be amended as it currently implies that no such products exist, either as licensed or unlicensed food supplements products. However this is not the case, there are a number of licensed products which the BNF do not list and there is a wide range of food supplement products available on the open market which consumers can self-select.	Thank you for providing this information. Updated recommendation 1 states that DH should work with manufacturers to ensure licensed products containing the recommended reference nutrient intake for at risk groups are available on prescription and are listed in the BNF. The introduction to the guidance notes that supplements refers both to food supplements and licensed products.
The Proprietary Association of Great Britain	Draft Recommendation 2	5	Vitamin D food supplements are widely available in pharmacies and health food stores. Supermarkets are more likely to carry multi-vitamin products, however many of these are specifically targeted at the at-risk groups and contain the RNI for these cohorts.	Thank you for this information.
The Proprietary Association of Great	Recommendation 3	5	Any national campaign should include safe sun exposure advice along with the information that vitamin D can only be synthesised in the UK	Thank you for this comment. The guidance has been amended to include a reference to

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Britain			from May-September	sun exposure.
The Proprietary Association of Great Britain	Recommendation 4	5	Too many healthcare professionals still seem unaware of the Vitamin D issue and there is no co-ordinated effort to ensure a consistent message to the various at-risk groups.	Thank you for this comment.
The Proprietary Association of Great Britain	Recommendation 6	6-7	Distribution and healthcare professional awareness of healthy start vitamins are both extremely poor. PAGB have previously offered to discuss and provide advice to the Department of Health on both issues, however these advances were firmly rebuffed.	Thank you for this comment.
The Proprietary Association of Great Britain	Recommendation 7	7	Midwives should be included in the list of healthcare professionals who should be aware of and disseminating the advice regarding vitamin D.	Thank you for this comment. Antenatal appointments are included in updated recommendation 8 and midwives are identified as a group who should take action in updated recommendation 10 and would be covered by recommendation 9.
The Proprietary Association of Great Britain	Recommendation 9	8-9	Make use of grassroots organisations such as the Women's Institute, Mumsnet and Netmums	Thank you for this comment. The recommendations as they stand do not preclude involvement of these organisations.
The Proprietary Association of Great Britain	Background	13	This draft guidance has only recently been issued; it is unclear why data from the National Diet and Nutrition Survey from 2001 has been used when there is a great deal of more up-to-date data, including blood analyte reports from 2008/09 and 2009/10 which show significantly higher proportions of the population are at the least sub-clinically deficient, if not suffering from overt deficiency. Under People at Risk; page 13 the background notes that the NDNS data suggests almost a	Thank you for this comment. The reference has been updated to include data from the 2008-11 NDNS, published in 2014.

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			fifth of UK adults have low vitamin D status, more recent NDNS data suggests up to 75%.	
The Proprietary Association of Great Britain	Background	13	Sun exposure in the UK is inadequate as a source of vitamin D as too many individuals spend too much time indoors or, if outside, tend to cover up or use sun protection creams which prevent vitamin D synthesis from taking place. In addition it is worth noting that there have been a number of instances of children developing rickets as a result of sun protection cream use.	Thank you for this comment.
The Proprietary Association of Great Britain	People at risk	13	There is a great deal of debate as to optimal levels of 25-hydroxy vitamin D and what would constitute inadequate levels. Consensus appears to be moving towards levels below 50nmol/l being inadequate and 75nmpl/l being optimal.	Thank you for this comment. This issue is under the remit of SACN.
The Proprietary Association of Great Britain	People at risk	14	PAGB has concerns that the statistics used in evaluating the needs of Asian population groups in the UK are very out of date; there are more recent statistics which show much higher levels of deficiency in the entire population.	Thank you for this comment. This section has been updated to include references to NDNS 2008-11.
The Proprietary Association of Great Britain	UK recommendations on vitamin D supplements	16	There is evidence to suggest that the level of testing being requested is having a significant financial impact on pathology labs across the UK. It may be advisable, where healthcare professionals suspect low vitamin D status to simply recommend a high dose food supplement for three months prior to testing to see if symptoms improve or resolve without the need for expensive testing.	Thank you for this comment. Treatment is outside the remit of this guidance.
The Proprietary Association of Great Britain	UK recommendations on vitamin D supplements	16	Treatment of low vitamin D status could, in many instances, be addressed through the principles of self-care, where healthcare practitioners advise patients to purchase high dose vitamin D food supplements. These are widely available and reasonably priced; this strategy would represent a significant cost saving to the NHS and allow	Thank you for this comment. Treatment is outside the remit of this guidance.

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			individuals the opportunity to take responsibility for their own health and wellbeing.	
The Proprietary Association of Great Britain	How to get vitamin D supplements	16	As noted above, the Healthy Start vitamins have had a number of issues around awareness, distribution and availability. They have a relatively short shelf life, which has made many pharmacies reluctant to stock them, particularly as awareness to the products is low and they are therefore slow moving. PAGB understands that a great deal of stock is returned unused once it has passed the end of shelf life. There is no consistent policy in distribution and availability between the four UK countries, or even within these countries, and healthcare professionals and the public are often not aware of the existence of these products.	Thank you for this comment.
The Proprietary Association of Great Britain	Availability of vitamin D supplements 4.5	19	It is not true that commercially available vitamin D supplements containing 100% of the RNI are not widely available. Boots the chemist, for example, has a wide range appropriate for all at risk groups as do other chains of pharmacies. The health food store chain Holland & Barrett likewise has a wide range of products, as do all independent health food shops. Admittedly, single ingredient products are not widely available in supermarkets; however there are a number of specifically targeted multivitamin products which are widely sold in supermarkets and which contain the RNI for the various at risk groups.	Thank you for this comment, the wording of this section has been amended.
The Proprietary Association of Great Britain	Availability of vitamin D supplements 4.5	19	It is not true that commercially available vitamin D supplements are "prohibitively expensive". Some examples of single ingredient product which are widely available at extremely reasonable prices are: Holland & Barrett 250 tablets at 10µg £7.99 = 0.03p per tablet Boots 90 tablets at 10µg £2.19 = 0.02p per tablet Healthspan 240 tablets at 10µg £7.95 = 0.03p per tablet	Thank you for this comment, the wording of this section has been amended.

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			There are many more products on the market which are not necessarily single ingredient products but which contain the RNI for the various at-risk groups which are also reasonably priced.	
The Proprietary Association of Great Britain	Evidence 4.6	19	As none of the measures discussed (training of healthcare professionals, making vitamin D or Healthy Start supplements more widely available or activities to increase awareness among at-risk groups) have been effectively implemented it is impossible to quantify any impact, relative or otherwise.	Thank you for this comment. This paragraph highlights the dearth of evidence available.
The Proprietary Association of Great Britain	Healthy Start 4.9	20	There is extremely low uptake of Healthy Start supplements largely because awareness of low among healthcare professionals and even lower among the cohorts the products are intended for. In addition, distribution is ineffective and therefore even if awareness were there, the products are simply unavailable.	Thank you for this comment.
The Proprietary Association of Great Britain	Cost effectiveness 4.17	23	The risk of deficiency is significantly greater than the risk of excess. The Expert Group on Vitamins and Minerals established a safe upper intake level for the majority of the population of 25µg/d and more recent modelling has found intakes of 35µg/d to be well tolerated with little or no risk of adverse events. There are some medical conditions which may make individuals less tolerant of high intakes of vitamin D, however these are well known and appropriate risk management would reduce any adverse events in these cohorts.	Thank you for this information The consideration section of the updated guidance states that 'The PHAC agreed that there is a negligible risk associated with taking the prophylactic dose.
The Proprietary Association of Great Britain	Cost effectiveness 4.19	23	If awareness of the vitamin D concerns were raised among both healthcare professionals and the general population)not simply the at risk groups), and government advice was for all individuals, at risk or otherwise, to take a vitamin D supplement, the cost of averting deficiency would fall significantly as the population would increase their general vitamin D status and only those with overt deficiency would	Thank you for this comment. The statement re cost is not the question that NICE was asked to look at. If everyone took a vitamin D supplement, this would be at a cost which would have to be offset against the

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			require treatment and or testing.	benefit of reduced vitamin D deficiency. This guidance did not examine that question.
The Proprietary Association of Great Britain	Recommendations for research 5.1	24	Evidence from the Feeding for Life Mind the Gap study in Birmingham shows clear cost effective benefits for pregnant women and small children. One could expect that similar results would be found if awareness was raised in other at risk groups. It is worth noting that the study provided free Healthy Start vitamins to all women and children, irrespective of whether they were claiming benefits or not (i.e. were "eligible" to receive free supplementation).	Thank you for this comment. To note that NICE is undertaking an additional piece of work considering the cost effectiveness of moving healthy start from targeted to universal provision.
The Proprietary Association of Great Britain	Recommendations for research 5.4	25	Whilst PAGB accepts that research should not focus on interventions in only one setting or target group, study design would be crucial as covering multiple target groups would make it increasingly complex	Thank you for this comment.
The Proprietary Association of Great Britain	Glossary Reference Nutrient Intake	29	The assumption that the action of sunlight on skin will provide adequate vitamin D (except for specific at-risk groups) is potentially dangerous. Much of the population now spends the majority of their time in doors and, if exposed to sunlight, will frequently either cover up, or use sun protection creams which prevent the synthesis of vitamin D from sunlight. This assumption should be re-examined in the light of current data (blood anylates from the NDNS survey 2009-10) which shows sub-optimal levels in a large proportion of the population.	Thank you for this comment. The glossary definition of vitamin D states that vitamin D is a fat soluble pro hormone. It is obtained either through the action of sunlight on skin or from dietary source.
The Proprietary Association of Great Britain	Gaps in the evidence 1	37	The Feeding for Life foundation did an excellent study in Birmingham (see comments on Recommendations for research P24 above) and have published a number of peer review articles based on the study. None of this material appears in the reference lists PAGB has checked in the various consultation documents.	Thank you for this comment. An extensive search for papers was undertaken (see section 9, summary of the methods used to develop this guideline and the supporting evidence). If the study wasn't included it must not have met the inclusion criteria.

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The Proprietary Association of Great Britain	Gaps in the evidence 2	37	Awareness raising activities, health professional training and supplement provision (Healthy Start) has been largely ad-hoc and ineffectual thus far; therefore it is impossible to evaluate the impact on uptake of vitamin D supplements.	Thank you for this comment.
The Proprietary Association of Great Britain	Gaps in the evidence 3	37	See data from the Feeding for Life foundation. Current estimates suggest that whilst 80% of eligible individuals are registered for the Healthy Start scheme, less than 2% of children actually receive the supplements to which they are entitled. The study carried out in the Heart of Birmingham saw increased public awareness of vitamin D from 61% to 89% and uptake of vitamins increase from 4% to 21%	Thank you for this comment. Section 4.12 of the considerations states: 'The PHAC discussed the fact that universal free provision of Healthy Start vitamins can improve uptake, but that without wider action the impact may be limited. One study suggests uptake may almost treble with universal free provision, but only to around 4% for children's drops and 7.7% for women's tablets.) Another study showed a year-on-year increase in uptake to 23% for women's tablets and 20% for children's drops when universal supplementation was supported by action to increase awareness (McGee and Shaw 2013).'
The Royal College of Midwives (RCM)			RCM supports the useful recommendations made in this guideline	Thank you for this comment.
The Royal College of Midwives (RCM)		4	We are very pleased to see the recommendation to clarify guidance on which groups are at risk of Vitamin D deficiency. Current advice accessed by pregnant and a breastfeeding woman is often unclear, particularly on the issue of supplementation pre six months. Many parents are unaware of their child's requirement of a daily vitamin D	Thank you for this comment.

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			supplement	
The Royal College of Midwives (RCM)		5	We agree with the need to develop a national campaign to raise the importance of Vitamin D	Thank you for this comment.
The Royal College of Midwives (RCM)		7	We agree with the recommendation to consider ' offering free Healthy Start supplements to all pregnant and breastfeeding women and children aged under 4 years' This is an issue of concern when the current uptake on the healthy start scheme that provides vitamin D vouchers to some mothers has been very low.	Thank you for this comment.
The Royal College of Midwives (RCM)		7	The campaign should include raising awareness among health, social care and other relevant professionals of the importance of vitamin D and information on where to the access supplements. The suggested computerised prompts will be useful in this context.	Thank you for this comment. Awareness raising among practitioners is addressed in updated recommendation 9
The Royal College of Psychiatrists	General		NICE should consider whether people suffering their first psychosis or established psychosis should be one of the "at risk" groups. The paper by Crews et al (2013) [published late 2013] Schizophrenia Research 150 533 covers the evidence: *Vitamin D deficiency in first episode psychosis: a case-control study.*	Thank you for this comment. The definition of at risk groups is outside the remit of this work and based on existing guidance from COMA, SACN and the CMOs. The introduction to the guidance notes that 'Clinical judgement will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency'.
The Vitamin D Association	3 Context *Background*	12	We would like to bring to the attention of the committee the unconditional statement in the final paragraph on p12 'Breast milk	Thank you for this comment. Population requirements for D are outside the scope of

Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			contains very little vitamin D and is not a significant source', which we believe to be accurate and supported by evidence. We would also like to draw to the attention of the committee that this unconditional statement is at odds with the current guidance outlined in the Chief Medical Officers' Letter to Health Professionals on 'Advice on Supplements for at risk groups', of the 2nd February 2012, which states that 'Breastfed infants may need to receive drops containing vitamin D from one month of age if their mother has not taken vitamin D supplements throughout pregnancy' i.e. if the mother is taking a supplement throughout her pregnancy vitamin D drops are not needed by the infant in the first six months of life. We have raised the point with the Department of Health (DH) and Chief Medical Officers of England and Scotland that the evidence shows unequivocally that a mother taking a supplement at the level recommended by the DH (400IU) has breast milk which still contains very little vitamin D and is totally insufficient to meet her infant's needs. The British practice of not recommending vitamin D drops from birth is out of line with almost every other developed country. In 2008 The American Academy of Pediatricians (AAP) changed their vitamin D recommendations for newborns from 200IU starting at 2 months of age to 'The new recommended daily intake of vitamin D is 400 IU/day for all infants, children, and adolescents beginning in the first few days of life.' (AAP 2008) Unfortunately, the net result of low levels of vitamin D in breastmilk is that in Europe the majority of cases of rickets occur in breastfed infants.	this work. The guidance focuses on the implementation of existing advice from the CMOs (letter 2012), SACN and COMA. SACN are currently considering the dietary reference values for all population groups and the introduction to the guidance notes that the recommendations should be considered alongside the SACN report once published.
The Vitamin D	7 Glossary	26	In NICE's draft document and indeed the current DH guidance there is	Thank you for this comment. Clarity of advice

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Association	*At risk groups*		a need to clarify the term 'at-risk' group and the definition of those who are at risk of low vitamin D status. Our discussions with GPs shows that lack of clarity and rigour in the current guidelines contributes to the lack of execution. Specifically the definition of at risk groups is severely lacking in rigour – in the context of vitamin D, clinically meaningful decisions have to be made at to what constitutes membership of an at risk group – what percentage of a group have to have a low vitamin D status to be at risk – 10%, 25%, 50%,or 75% - does the status have to be low at all times, or is the qualifying criterion the status at the end of winter? The current list of groups includes "people who have low or no exposure to the sun". If the criterion is 10% at the end of winter, then possibly everyone living in the UK who wears clothes and works indoors is in an 'at-risk' group. The UV index in Glasgow is ¼ of what it is in London, and on that basis everyone north of a certain line in the UK should be categorised as an at risk group.	is addressed throughout the guidance. However, the definition of an at-risk group is outside the scope of this work. These issues are likely to be addressed by SACN who are currently considering population requirements for vitamin D. The introduction to the guidance notes that it should be read alongside the SACN report once published.
Unite the union	general		We would like to congratulate the advisory committee for a professional and comprehensive piece of work; we have nothing further to add.	Thank you for this comment.
University of Leeds	General		The incidence of melanoma continues to increase dramatically and therefore health promotion experts recommend sun avoidance on holiday. This is appropriate for pale skinned peoples who are especially at risk of this cancer [1]. However several studies have reported that the very pale skinned anyway run at lower levels of vitamin D (presumably because of sun protection) [2, 3]. Skin cancer patients advised to reduce their sun exposure and indeed their families who are also advised to reduce their sun exposure, if compliant at least are likely to have sub-optimal vitamin D levels. Although the NICE Public Health Guidance currently mentions those people who don't get much sun exposure as a target group, it does not specifically mention skin cancer	Thank you for this comment. NICE is developing parallel public health guidance on sun exposure. The introduction to the guidance notes that 'Clinical judgement will be needed to determine whether NICE's recommendations in this guideline are suitable for people with conditions that increase the risk of vitamin D deficiency'.

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			patients using protective measures. The Guidance refers to poor uptake of supplementation so that I think the document should take the opportunity to highlight this at risk group specifically and to identify skin cancer multidisciplinary teams as target groups for education.	
University of Leeds	General		Although the Guidance refers to the possible risks associated with not measuring vitamin D levels, I wonder if the Committee considered the papers suggesting a "j" or "u" shaped effect of vitamin D levels? That is that an association was suggested between high vitamin D levels and increased mortality [4]. Although this study was an association study only, there is an element of concern. References Gandini, S., et al., *Meta-analysis of risk factors for cutaneous melanoma: III. Family history, actinic damage and phenotypic factors.* Eur J Cancer, 2005. **41**(14): p. 2040-59. Glass, D., et al., *Pigmentation and vitamin D metabolism in Caucasians: low vitamin D serum levels in fair skin types in the UK.* PLoS One, 2009. **4**(8): p. e6477. Davies, J.R., et al., *The determinants of serum vitamin D levels in participants in a melanoma case-control study living in a temperate climate.* Cancer causes & control : CCC, 2011. Durup, D., et al., *A Reverse J-Shaped Association of All-Cause Mortality with Serum 25-Hydroxyvitamin D in General Practice: The CopD Study.* J Clin Endocrinol Metab, 2012. **97**(8): p. 2644-52.	Thank you for this comment. This issue is outside the remit of the current guidance and is currently being considered by SACN.

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Association for Improvements in the Maternity Services.doc	Association for Improvements in the Maternity Services	1	
Association for Nutrition.doc	Association for Nutrition	5	
Birmingham Vitamin D steering Group.doc	Birmingham Vitamin D steering Group	5	
Breastfeeding Network.doc	Breastfeeding Network	5	
Bristol University.doc	Bristol University	9	
British Association of Dermatologists.docx	British Association of Dermatologists	3	
British Medical Association.doc	British Medical Association	4	
Consilient Health Ltd.doc	Consilient Health Ltd	2	
Consumers for Health Choice.doc	Consumers for Health Choice (CHC)	5	
Department of Health.doc	Department of Health	24	
Dudley Metropolitan Borough Council.docx	Office of Public Health, Dudley Metropolitan Borough Council	18	
First Steps Nutrition Trust.doc	First Steps Nutrition Trust	4	
Foodtalk CIC.docx	Foodtalk CIC	18	
Health and Social Care Board, Northern Ireland.doc	Health and Social Care Board, Northern Ireland	5	
Health Food Manufacturers' Association.doc	Health Food Manufacturers' Association	7	

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Internis Pharmaceuticals Limited.doc	Internis Pharmaceuticals Limited	28	
Leeds City Council.doc	Leeds City Council	15	
Leicester City Council.doc	Public Health, Leicester City Council	19	
Mersey Care NHS Trust.doc	Mersey Care NHS Trust/Brain Injury Rehabilitation Centre	4	
National Osteoporosis Society.doc	National Osteoporosis Society	17	
NCT.docx	NCT	9	
NHS Choices.doc	Digital Assessment Service – NHS Choices	1	
NHS England.doc	NHS England	1	
NHS Health Scotland.doc	NHS Health Scotland	6	
NHS Stockport CCG.doc	NHS Stockport CCG	1	
Norfolk & Norwich University Hospital.doc	Norfolk & Norwich University Hospital	1	
PIP, NICE.doc	PIP, NICE	20	
Public Health England.doc	Public Health England	6	
Royal College of Nursing.doc	Royal College of Nursing	6	
Royal College of Paediatrics and Child Health.doc	Royal College of Paediatrics and Child Health	21	
Royal College of Physicians and Surgeons of Glasgow.doc	Royal College of Physicians and Surgeons of Glasgow	9	
Royal College of Physicians.docx	Royal College of Physicians (RCP)	16	

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Royal Pharmaceutical Society.docx	Royal Pharmaceutical Society	5	
Scottish Green Party.doc	Scottish Green Party	11	
Seasonal Affective Disorder Association.doc	Seasonal Affective Disorder Association	1	
Solihull Metropolitan Borough Council.doc	Solihull Metropolitan Borough Council	17	
Synergy Biologics.doc	Synergy Biologics	3	
The British Dietetic Association.doc	The British Dietetic Association	7	
The food partnership Ltd.doc	The food partnership Ltd	18	
The Proprietary Association of Great Britain.doc	The Proprietary Association of Great Britain	30	
The Royal College of Midwives.doc	The Royal College of Midwives (RCM)	5	
The Royal College of Psychiatrists.docx	The Royal College of Psychiatrists	1	
The Vitamin D Association.doc	The Vitamin D Association	2	
Unite the union..doc	Unite the union	1	
University of Leeds.doc	University of Leeds	4	