

National Institute for Health and Care Excellence

BAD FEEDBACK ON DRAFT PUBLIC HEALTH GUIDELINES – SUNLIGHT EXPOSURE: BENEFITS AND RISKS

<p align="center">Section number</p> <p align="center">Indicate section number or 'general' if your comment relates to the whole document</p>	<p align="center">Page Number</p>	<p align="center">Comments</p> <p align="center">Please insert each new comment in a new row.</p>
<p>General</p>		<ul style="list-style-type: none"> • Our principal comment is that the remit of this guidance, and what it actually delivers, are inconsistent, limiting its usefulness for those tasked with delivery of the 'message' to the public. The guidance does not offer evidence-based guidance on the risks and benefits of sunlight exposure, but focuses almost entirely on communication delivery without any advice on the content of the messages. Communication delivery we understood would be only a part of the intended guidance. • The evidence-based messages need to be defined before the channels of communications are agreed, rather than the other way around. • The timing of this guidance when the SACN review has not been completed is questionable, as the SACN review findings may be pivotal to this guidance's messages. • The limited messaging around UVR and vitamin D (rather than around delivery of messaging) does not seem to be adequately evidence-based. This may not be the case but we would be keen to learn more about which evidence sources were used, and how the messages were then extrapolated from this evidence. • The evidence commissioned to form part of the guidance does not address the gaps in evidence around the role of UVR and vitamin D synthesis. • Rather than forming new guidance that seems to insinuate that the risks and benefits of sunlight are somehow equitable, would it perhaps be preferable to use existing sun safety guidance and caveat this with advice on vitamin D intake through diet and supplements? • The order of benefits and risks should be changed to risks and benefits throughout the document. The risks are well understood, the benefits less so. • The assumption seems to be that the only way to counter the risk of low vitamin D status is to increase exposure to sunlight. Except for a small number of people who cannot absorb oral vitamin D, this is just not true. The document should state clearly that when there is a risk of low vitamin D status, then oral supplementation is an effective way of improving vitamin D status for most people. • The document consistently discusses the need to protect the public from under- or overexposure to sunlight. This is the wrong way round.

0	1	"malignant non-melanoma" – Malignant non-melanoma is not a commonly used term and is confusing – please refer just to non-melanoma
0	1	The statement at the foot of page 1 that research suggests there may be other benefits, for example, protection against chronic diseases such as cancer, heart disease and diabetes is very misleading. Consensus does not support this statement and the brief background should reflect consensus and not add this as an afterthought.
0	2	This consensus statement 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. As such all authors should be referred to. Please note that this consensus statement also dates back to 2010 and is subject to review following the publication of new evidence (e.g. SACN, and 'Limited exposure to ambient ultraviolet radiation and 25-hydroxyvitamin D levels: a systematic review', British Journal of Dermatology).
0	2	The link to the consensus statement is to a press release rather than the statement, and the link within that page to the PDF is defunct. The statement is available at http://www.bad.org.uk/for-the-public/skin-cancer/vitamin-d?q=Vitamin%20D or please insert a working link to a PDF.
1: 3	6	'people who put themselves at risk of UV overexposure, for example by Sunbathing' – insert 'or using sunbeds'. This section should be expanded to include those who put themselves at risk of incidental exposure – such as gardeners, water sportsmen etc. Other occupational exposure should also be covered here as a high-risk group, not just outdoor workers – for example truck drivers (UVA penetrates glass).
1.5	8	"Ensure messages are simple, succinct and in line with recommendations 6-9." This is an oxymoron as recommendations 6-9 are not simple and succinct. We feel too much onus is being placed on the people delivering the messages at a local level, to decide what the messages should be and how best to deliver them. However, the guidance also shows that there is no available evidence to guide them on best practice. The statements "There is a lack of evidence on how health and social care practitioners and policy makers should convey messages about the benefits and risks of sun exposure, particularly in the UK" and "There is a lack of evidence on how messages about the benefits and risks of sun exposure can be effectively tailored for different groups" in the Gaps in Evidence section (p. 43-44) reveal the limited utility of this guidance. Despite the lack of evidence, could more advice be given to render this guidance useful 'on the ground', possibly including an algorithm that factors in population type / local demographics, target audience, mode of communication etc, to provide clear examples of campaign options. If not, perhaps the guidance should be postponed until such evidence is available?
1:5	8	Page 8 states that a skin cancer prevention campaign should also mention the risk of under-exposure. Our current knowledge suggests there is little risk of under-exposure for the majority of fair-skinned people targeted in skin cancer prevention campaigns. The prevention message will be confused by this approach which needs to be nuanced to those at risk of under-exposure due to cultural or religious reasons or dark skin colour.

1: 5	9	<p>'Develop resources that are downloadable from a central website and easy to adapt for local use by a range of agencies, to ensure a consistent message and to minimise duplication of effort.'</p> <p>What message do you refer to here? There is as of yet no uniform message – and with the lack of evidence (as mentioned above) this creates a conundrum for those trying to put a campaign into practice.</p>
1 : 6	9	<p>'advise people to go out in the sunlight for short periods (less than the time it takes for skin to redden or burn) between 11am and 3pm from the beginning of April to mid-October in the UK'</p> <p>This is the crux of the guidance and yet what evidence is this based on? A review of all available evidence, or isolated studies / statements?</p> <p>The latest review of available literature (January 2015*) that we are aware of states: "Interventional studies demonstrate that UVR can increase vitamin D levels in humans, but extrapolating from them to suggest that UVR is necessary for adequate vitamin D levels may be erroneous..."</p> <p>"This study demonstrates that many healthy adults in different populations across the world can maintain adequate serum vitamin D levels despite negligible UVR exposure for several months of the year. Public health campaigns promoting a high vitamin D diet or supplements to healthy adults could positively impact the burden to the individual and the health service of inadequate vitamin D levels and could avoid the negative sequelae of UVR exposure..."</p> <p>"While the findings of this review provide useful information for evidence based public health recommendations at the present time, more research is required in the form of prospective clinical trials that accurately record vitamin D intake, its UVR-related synthesis and its storage in the participants throughout the year, in particular in situations of negligible UVR exposure."</p> <p>*Limited exposure to ambient ultraviolet radiation and 25-hydroxyvitamin D levels: a systematic review, British Journal of Dermatology, DOI TBC.</p> <p>We are aware that the committee received the above mentioned study, yet its core findings are not reflected in the guidance's recommendations. Please could you inform us as to whether or not the study was used in the committee's review of evidence?</p> <p>All of the research commissioned by NICE appears to be around the economics and impact of public messaging, not around what the messages should actually contain, i.e. a systematic review of existing evidence around the role of UVR in vitamin D synthesis, or commissioning new research to breach gaps in this clinical evidence.</p> <p>For example, we cannot see reference to the recent modelling study mentioned in the systematic review that reported that 10–20 min of sun exposure (often advocated by public health statements) is inadequate to boost serum vitamin D levels significantly, and that sufficient sun exposure to achieve worthwhile benefit would compromise skin health.</p> <p>Please can more information be provided on how the messages contained within this guidance were formed, and more clearly detailing the evidence base for each message.</p>

1.6	9	Current skin cancer prevention advice is to 'spend time in the shade between 11am and 3pm when the sun is at its strongest.' While this is not the same as telling people to stay in the shade (the whole time) as was advocated in previous decades, we need to ensure the wording is very carefully balanced. Fair skinned individuals can burn in less than 10 minutes in the summer between 11am and 3pm. The message regarding the perceived benefits of sunlight – to spend time in the sun – must never be given independently of the skin cancer message as this will be interpreted as two conflicting messages about whether or not to go outside between 11 and 3. Therefore a message that encompasses both issues must be used.
1 : 6	10	'Being aware that skin that has less previous sunlight exposure (for example, the back) is more likely to burn so extra care should be taken.' It may be sensible to caveat this with a warning that a base tan does not provide adequate sun protection (less than SPF 6) and therefore use of sunbeds or pre-holiday tanning as a way of preventing sun damage is not advised.
1:6	10	' Make people aware that tanned skin is an indicator of possible skin damage.' A sun tan is damaged skin so the word 'possible' is erroneous. It is the body's protective reaction to skin which has already been damaged by UVR. This message should be made clear.
1:6	10	The UV 400 label is not recognised in the BS EN 1836:2005 standard. Anyone can use the label and take it to mean whatever they wish. Secondly the concept of 100% UV protection is not recognised in the standard and is not achievable.
1 : 7	10 and 11	'Apply sunscreen (at least sun protection factor [SPF] 15)' In light of recent research (post the Feb 2012 review), the recommended SPF must be raised from 15 to 30. There is a volume of evidence to support this view. In fact, this very guidance from NICE states in section 5.12: "The Committee was aware of concerns that sunscreen prohibits vitamin D synthesis. Expert testimony clarified that this may be the case when sunscreen is tested in laboratory conditions. But it is unlikely to be the case in reality, <u>because people tend to apply much less sunscreen than the manufacturers recommend</u> and in a patchy fashion", acknowledging that people do not apply enough sunscreen to receive SPF15. The latest research** that "While either sunscreen [15 or 30], if delivering the nominal SPF over the entire exposed skin, would be sufficient to prevent any erythema, the simulation indicates that the combination of the average quantity applied with the variability in thickness over the skin surface will lead to erythema, especially in SPF15 sunscreen users. People who intend spending long periods outside in strong sunshine would be better advised to use SPF30 labelled sunscreens than SPF15 sunscreens". Further conclusions are: "Sunscreen products carry a sun protection factor (SPF) number (relating to UVB radiation) and (often) a star rating (relating to UVA radiation), both of which indicate the potential protection offered. However, the actual protection gained depends heavily on exactly how people use sunscreen, and typically sunscreens are applied too thinly. Using a product with a high SPF (30) is a practical way of addressing this issue" and "Failure to prevent sunburn is usually due to the way sunscreen products are applied rather than the technical inadequacy of the product. However, one can argue that if the majority of consumers do not use the product in accordance with the recommendation, then this is a technical inadequacy in itself. Low cosmetic acceptance and the high cost of sunscreen products may result in insufficient use." Furthermore, the article in the Journal Photochemistry & Photobiology (April 2011***) by De Villa et al

		<p>describes research into the effectiveness of reapplication (two coats) to achieve coverage closer to the recommended amount. Their research showed that even with two applications the amount of product on the skin was still lower than the recommended amount.</p> <p>It is the role of this guidance to reflect new and emerging scientific evidence, not to ensure consistency with what is currently being recommended by external stakeholders (i.e. the guidance should determine the advice delivered by external stakeholders, not the other way around). Therefore we feel it imperative that the higher SPF30 is recommended to address this issue.</p> <p>The wording 'if applied properly and regularly, SPF15 should be enough' cannot be conveyed to the public and is not sufficient (e.g. what is properly?). For this reason this statement should be deleted.</p> <p>Evidence references: **Pissavini M, Diffey B. The likelihood of sunburn in sunscreen users is disproportionate to the SPF. <i>Photodermatol Photoimmunol Photomed</i>. 2013 Jun;29(3):111-5. doi: 10.1111/phpp.12033. PubMed PMID: 23651270.</p> ***Lodén, M., Beitner, H., Gonzalez, H., Edström, D.W., Åkerström, U., Austad, J., Buraczewska-Norin, I., Matsson, M. and Wulf, H.C. (2011), Sunscreen use: controversies, challenges and regulatory aspects. <i>British Journal of Dermatology</i> , 165: 255–262. doi: 10.1111/j.1365-2133.2011.10298.x Iheanacho, I, Sunscreen SPFs: clear as daylight? <i>DTB Vol 49 DTB2011;49:61</i> , doi:10.1136/dtb.2011.02.0033 Iheanacho, I, Evidence review: Do sunscreens have a role in preventing skin cancer? <i>DTB June 2011 DTB2011;49:69-72</i> , doi:10.1136/dtb.2011.02.0036 De Villa D, Nagatomi AR, Paese K, Guterres S, Cestari TF. Reapplication improves the amount of sunscreen, not its regularity, under real life conditions. <i>Photochem Photobiol</i> . 2011 Mar-Apr;87(2):457-60. doi: 10.1111/j.1751-1097.2010.00856.x. Petersen B, Datta P, Philipsen PA, Wulf HC. Sunscreen use and failures--on site observations on a sun-holiday. <i>Photochem Photobiol Sci</i> . 2013 Jan;12(1):190-6. doi: 10.1039/c2pp25127b.
1 : 7	10	'...a hat is far better and more convenient' This should specify 'a wide-brimmed hat' as a cap or similar would not protect the neck and ears.
1 : 7 And 5.1	10 And 21	'sun screen...' Sunscreen is one word, not two
1 : 7	11	'4-star UVA protection'
		<p>Not all sunscreens use the star system as this was created for use within Boots, so please also refer to the UVA circle logo which is the European standard.</p> <p>An explanation might also be included of the UVA:UVB protection ratio algorithm that is used to determine satisfactory UVA protection offered by products.</p>
1:7	General	A point should be added regarding 'one-application-a-day' sunscreens, noting the potential dangers arising from improper application and accidental removal.
1:8	11	'Older people should: be encouraged to go out in sunlight for short periods (less

		<p>than the time it takes for skin to redden or burn) between 11am and 3pm, from the beginning of April to mid-October in the UK'</p> <p>See previous comment. Actively encouraging people to go outside in the middle of the day in the height of summer will be misinterpreted. The two messages (skin cancer and vitamin D) must be combined and used in tandem. Focus should be given to dietary sources of vitamin D and supplementation – again, it is not sufficient for this to simply be addressed in a separate piece of NICE guidance.</p>
1.8	11	<p>'expose at least the forearms and hands (or similar amounts of skin)'</p> <p>What is this calculation based on?</p>
1:11	13	<p>'Encourage children and young people to spend time in the shade and to wear wide-brimmed hats, protective clothing and sunscreen to protect themselves when UV levels are high (above 3 on the UV index)'</p> <p>Given that many people are unaware of the UV index and its associated forecasts, might any health promotion work incorporate information on these and where they can be found?</p> <p>Also, the UV index needs to be used in conjunction with info on skin type – e.g. a UV rating of 4 has very different implications for fair versus dark skin.</p> <p>The BAD and Met Office produce a free-of-charge, non-commercial app (world UV app) which shows the UV index anywhere in the world, automatically geo-located to where you are, or you can select another location. It then provides sun safety information tailored to the UV index that day, and based on your own skin type. We would be happy for this to be used freely.</p> <p>Information about the UV index is also available on the Met Office and BBC websites, although this does not cross reference with advice based on skin type.</p>
1.11	13	<p>'Encourage parents of children at higher risk of skin cancer to provide their child with protective clothing as well as sunscreen'</p> <p>From the current wording it is unclear what you define as 'children at higher risk'. Also, all children's and adults' first line of defence is protective clothing, not just those who are at higher risk of skin cancer.</p>
3	16	<p>NICE correctly identifies the challenges in maintaining balance between sun safety and vitamin D promotion messages. As above, a useful tool to promote is the UV index, which can be added to weather bulletins.</p>
3	17	<p>An issue at the centre of the consistent messaging difficulty is that various organisations do not agree on some of the core pillars of sun safety advice, for example recommended SPF, vitamin D acquirement practices, time spent out of the sun etc, and as we have shown, this guidance does not clarify these issues.</p> <p>It is vital that this issue is addressed if we are to produce one clear, concise message to communicate to the public.</p> <p>In order to unite these conflicting views, and the lack of evidence-base for the messages contained within this guidance, NICE may wish to conduct an independent audit of the supporting evidence upon which these views are based and construct consistent messages through those means, before issuing this guidance.</p>
3	18	<p>The major issue with mass media campaigns for smaller organisations is funding. Whilst commercial funding opportunities do exist, they can be limited in number available and resource that is provided. Smaller organisations rely on health campaigns to increase their profile and fundraising capacity, so will continue to run individual campaigns in tandem to any national, mass media campaign.</p>

4	18	<p>'People at risk of overexposure include outdoor workers and anyone else who generally spends a long time outdoors, for example, because of outdoor leisure pursuits such as sailing or gardening or because they like to sunbathe.'</p> <p>The guidance here is confusing cumulative sun exposure with intense, episodic sun exposure, which are different and carry different risks.</p> <p>Overexposure is certainly not limited to people who 'generally spend a long time outdoors', which in fact relates to chronic but not intermittent exposure. It is intermittent exposure that is linked to sunburn and melanoma (chronic sun exposure is linked more to squamous cell carcinoma) and this does not usually mean people who spend a lot of time outdoors, indeed it is usually people who spend little time outdoors and then sunburn during occasional holidays or weekend leisure time. This is different to people who are in the sun for long periods on a daily basis and who have cumulative sun damage.</p> <p>It is vital that we do not imply that it is people who spend much of their time outside who are at the greatest risk, as this is not the case.</p> <p>See National Cancer Institute http://www.cancer.gov/cancertopics/pdq/genetics/skin/HealthProfessional/page2):</p> <p>While there is no standard measure, sun exposure can be generally classified as intermittent or chronic, and the effects may be considered acute or cumulative. Intermittent sun exposure is obtained sporadically, usually during recreational activities, and particularly by indoor workers who have only weekends or vacations to be outdoors and whose skin has not adapted to the sun. Chronic sun exposure is incurred by consistent, repetitive sun exposure, during outdoor work or recreation. Acute sun exposure is obtained over a short time period on skin that has not adapted to the sun. Depending on the time of day and a person's skin type, acute sun exposure may result in sunburn. Intense intermittent recreational sun exposure has been associated with melanoma and BCC, while chronic occupational sun exposure has been associated with SCC.</p>
4	20	<p>'In 2011, 13,348 cases of melanoma and 102,628 cases of non-melanoma skin cancer were diagnosed in the UK.'</p> <p>The NMSC figure used here is based on incomplete data. The actual figure is that 200,000 patients have 247,000 BCCs removed in the UK in 2010* (though this only counts those who had BCC surgically removed, not those treated with topical preparations). And this does not include SCC. So the commonly cited figure is more than 250,000 cases of NMSC per year.</p> <p>*Clin Exp Dermatol. 2013 Jun;38(4):367-9. doi: 10.1111/ced.12016. Epub 2013 Mar 18. Basal cell carcinoma epidemiology in the UK: the elephant in the room. Levell NJ1, Igali L, Wright KA, Greenberg DC.</p>
5.1	21	<p>"The contribution sunlight makes to vitamin D status ...was beyond the remit of this guideline."</p> <p>We appreciate that this guidance will feature the findings of the SACN review, possibly as an update, and is designed to be read in conjunction with the NICE guidance on increasing vitamin D supplement use. However, how can sunlight's contribution to vitamin D be beyond the remit of this guidance, if this guidance gives the key messages about the sunlight and vitamin D balance?</p>
5.2 AND 5.15	21 AND 24	<p>"The Committee acknowledged that the people at risk of overexposure to sunlight and those at risk of not having enough vitamin D are usually in different groups, so messages can be adapted accordingly."</p> <p>AND</p>

		<p>“The Committee recognised the importance of persuading children of the benefits and risks of sunlight. This is partly because of the higher risks they face from both low vitamin D status (for example, the development of rickets) and skin cancer (often associated with sunburn in childhood).”</p> <p>These two statements are contradictory. One says those at risk of vitamin D deficiency are not the same as those at risk of overexposure to the sun, while the second statement says that children are at risk of both.</p> <p>Also these statements do not take into account varying risk levels within groups of children.</p>
5.3	21	<p>“The only consistent message is that the risks can be reduced if people never expose their skin long enough for it to redden or burn.”</p> <p>This message is echoed within the recommendations, and provides advice which is retrospective. Different skin types burn faster and more slowly in different conditions, with the only way of knowing how long an individual took to burn in a certain condition being for the individual to be exposed to that situation and to burn.</p> <p>Advice should focus more on making protective precautions a habit as opposed to experimentation on how long skin takes to burn before protective measures are taken.</p>
5.3	21	<p>“One reason why it is difficult to provide a simple message is that the amount of UV someone gets from sunlight depends on a range of biological, environmental and behavioural factors”.</p> <p>For this reason, would it not be more sensible to use the dietary / supplementation messages instead, rather than encouraging people to spend time in the sun which may either place detrimental, increasing skin cancer risk, or ineffective (according to aforementioned modelling study)?</p>
5.6	22	<p>‘The Committee noted that once the body has synthesised vitamin D, more time in the sun is harmful and can also break surplus vitamin D down.’</p> <p>This is a bit misleading – in terms of skin damage, the sun is harmful even before the level that causes skin to redden or burn, but this implies that skin damage only occurs after this point, rather than this being the point when the worst damage occurs. Also, it is not just the ‘surplus’ vitamin D that is broken down after the point of reddening. So perhaps change to:</p> <p>‘The Committee noted that once the body has synthesised vitamin D, more time in the sun will actually reduce vitamin D levels, while also increasing skin damage’.</p>
5.8	22/23	<p>“The Committee questioned the usefulness of referring to ‘skin types’ (I–VI) to help people assess how to benefit more from, and reduce their level of risk from, sunlight exposure. It noted that both practitioners and the public find it difficult to judge skin types. They opted instead to refer to lighter and darker skin types.”</p> <p>While we are aware of studies examining public understanding of the Fitzpatrick scale, in our experience, the referencing of Skin Types I-VI, has both been an engaging and useful tool in communication to the public the risks of sun exposure, when supported with appropriate, public-friendly information. Whilst lighter and dark skin permit for an instant understanding, using these terms runs the risk of over-generalisation and lack of detailed reference and meaning.</p>
General		<p>We would prefer to see discussion of the "Risks and Benefits" of sunlight exposure rather than the repeated mention of "Benefits and Risks", to reflect</p>

		<p>where the weight of evidence lies. Skin cancer in the UK is by far the most common cancer and is a rising epidemic, under the pressure of which dermatology services are struggling to cope. The impact of vitamin D deficiency is arguably not of this magnitude, and much of the evidence is emerging, unlike the proven impact of UV damage. While we support guidance that incorporates both the risks and benefits, emphasis on vitamin D benefits must not be at the expense of reducing potentially deadly cancers, and the wording must carefully reflect this. Greater emphasis should be put on the role of dietary vitamin D intake and supplementation, which cannot reasonably be excluded from this guidance as they are the 'safe' alternatives to UVR exposure. UVR and diet / supplements as sources of vitamin D cannot be considered in isolation of one another.</p>
5.11	23	<p>"Members were also aware that some people use sunscreen because they want a tan and believe that its use means they can stay in the sun for longer without burning."</p> <p>Is there evidence available to support the first part of this statement, i.e. that people use sunscreen because they want a tan? Sunscreen, when used correctly, prevents tanning so we would be keen to see the evidence behind this as it may help guide our campaign work, and could form an important message about sunscreen application.</p>
5.12	23	<p>"The Committee was aware of concerns that sunscreen prohibits vitamin D synthesis. Expert testimony clarified that this may be the case when sunscreen is tested in laboratory conditions. But it is unlikely to be the case in reality, because people tend to apply much less sunscreen than the manufacturers recommend and in a patchy fashion."</p> <p>The notion of relying on poor sunscreen application as a source of Vitamin D in contrast to attempting to advocate proper sunscreen application is unhelpful.</p>
5.2.9	28	<p>"This section will be completed in the final document."</p> <p>What will this include and will this be circulated, to form part of the stakeholder consultation?</p>
6	28	<p>The section 'Recommendations for Research' should include research around the health risk / benefit ratio, rather than just research around delivery of messages. The development of more instructive and definitive advice should be a priority, as this guidance fails to add any real clarity to a confusing topic, due to lack of available evidence.</p>
10	General	<p>Within the key questions, which outline the scope of this guidance, no mention is made as to what the current messages regarding sunlight exposure risks and benefits are, where they come from, or how can these messages be reviewed and amalgamated into one set of concise messages.</p>
12	43-44	<p>The gaps in the evidence section is striking, and raises the question of the utility and purpose of this guidance.</p>