

Companion Statement on Vitamin D and Sun Exposure in Pregnancy and Infancy in Aotearoa New Zealand

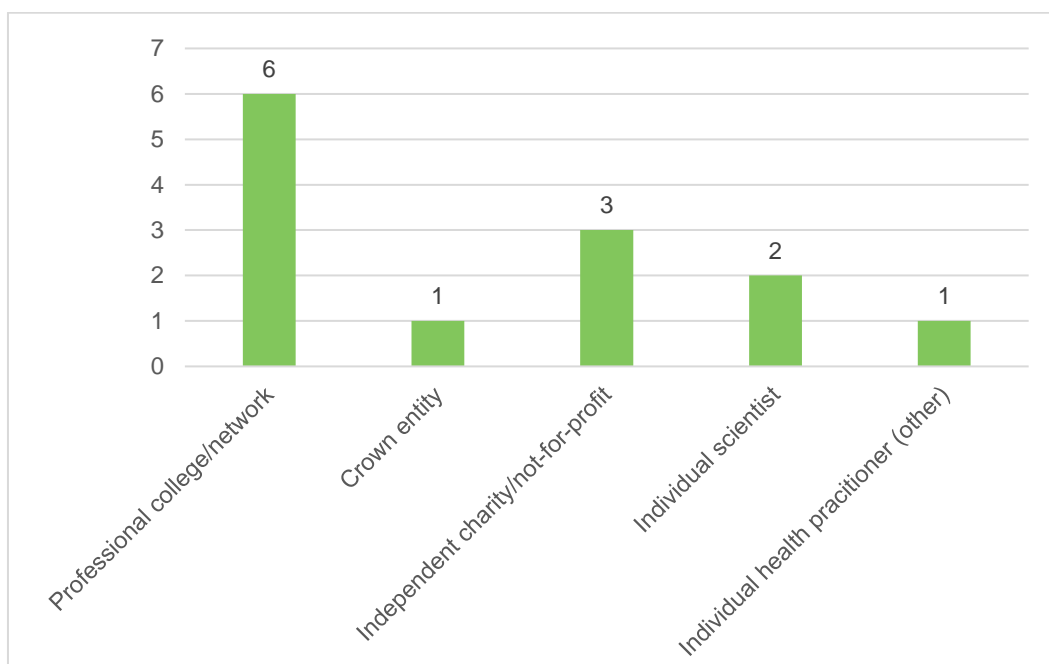
Tauākī Āpiti mō te Huranga Hihirā me te Huaora D i te Hapūtanga me te Nohinohitanga i Aotearoa

Allen + Clarke supported Te Whatu Ora to update the *Companion Statement on Vitamin D and Sun Exposure in Pregnancy and Infancy in Aotearoa New Zealand*. The Steering Group, chaired by Violet Clapham and Dr Karl Cole, consulted on a draft Companion Statement in October 2023. This paper summarises the feedback received and provides high-level advice on the Steering Groups responses to that feedback.

Submissions received

The Steering Group received 13 submissions: 10 from organisations, and 3 submissions from individuals. A breakdown by submitter type is included in *Figure 1*.

Figure 1: Breakdown of submitters by type



Organisational submitters were Cancer Society of New Zealand, MeINet, Newborn Clinical Network, New Zealand Breastfeeding Alliance, New Zealand College of Midwives, New

Zealand Dermatology Society, New Zealand Lactation Consultants Association, PHARMAC, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the Royal New Zealand College of General Practitioners. Individual submitters were two scientists and one health practitioner.

Summary of feedback and the Steering Groups response

Te Tiriti and equity

There was support for the Te Tiriti section at the front of the document. Suggestions to include the content in Appendix A into Section 4 were made to ensure key information is not missed by healthcare professionals.

Steering Group response

The split in between the te Tiriti section and the Appendices is consistent with Te Whatu Ora's approach in other clinical guidelines, the Steering Group agreed to keep this as is for consistency.

Prevalence of vitamin D insufficiency and deficiency in Aotearoa New Zealand

There was strong support that vitamin D deficiency is prevalent among pregnant women and that there is a strong correlation between maternal vitamin D concentrations in the third trimester and infant vitamin D levels. There was also agreement that the prevalence of vitamin D insufficiency in infants is high across Aotearoa New Zealand.

Risk factors

There was support for the proposed risk factors. Minor editorial comments were made to clarify risk factors based on ethnicity and religious skin or face coverings.

Steering Group response

The Steering Group proposed skin tone and ethnicity should be captured as two separate risk factors. The statement around ethnicity needs to explicitly state the ethnicities that are at higher risk, this will be presented in a box under section 5.3.3.

Risk factors include sun avoidance however it does not explain what this is. Clarity around the meaning of sun avoidance will be added to the Companion Statement in section 5.3.

The wording of risk factors around geographical region will be changed to south of Nelson/Marlborough to reflect the evidence.

Definition of deficiency and insufficiency

One comment was received on changing the definition of vitamin D deficiency to < 50 nanomoles per litre, with insufficiency defined as < 75 nanomoles per litre.

Steering Groups response

The document will be amended to acknowledge the global consensus guideline cut of 30 nmol/L for the development of rickets in children. However, the document will continue with definitions of 25 nmol/L for deficiency and 50 nmol/L for insufficiency to align with cut offs used in labs and the evidence associated with the cut off of 25 nmol/L and 50 nmol/L. There is currently limited evidence of a clinical risk associated with vitamin D levels of 75 nmol/L.

Maternal health outcomes

There were mixed views on Statement 4 relating to pre-eclampsia and gestational diabetes mellitus. Submitters supported the evidence of these health outcomes is limited, but supplementation probably reduces the risk for gestational diabetes and pre-eclampsia.

Steering Group response

The Steering Group agreed the Palacios et al (2019) Cochrane review should be included in the maternal outcomes section. There was agreement to use the same wording as the Cochrane review to allow for consistency and agreement that this information should be offered to pregnant women/people to advise them of the potential risk.

Statement 4 will be reworded to remove the word 'uncertain' and replace with wording that there 'may be' a link between these maternal health outcomes (gestational diabetes and pre-eclampsia) and vitamin D deficiency. In the body of the text, language will reflect the level of certainty to be consistent with the Palacios et al (2019) Cochrane review.

Infant health outcomes

Submitters supported the strength of the evidence demonstrating that vitamin D insufficiency poses a threat to the health of children, and severe vitamin D deficiency increases risks of hypocalcaemic seizures and rickets.

Steering Group response

No change required.

Supplementation

There were mixed views received on supplementation of both pregnant women/people and infants. Views depended on perspectives about the strength of evidence underpinning clinical benefit for whānau.

Steering Group response

The Steering Group recommend a risk-based approach to supplementation during pregnancy. A statement will be made that those without the risk factors may also benefit from supplementation. The Steering Group recommend future research including monitoring and evaluation of this risk-based targeted approach.

The Steering Group recommended universal supplementation for all exclusively or partially breastfed infants, initiating at 4 weeks and continuing until 1 year of age.

The recommendations will be reworded to reflect this, and caveats will be made that infants receiving 500mL of infant formula per day, or those who are fully formula fed will not require supplementation as they will receive sufficient vitamin D through formula.

The statement on calcium intake will be moved to the end of the section on supplementation.

Care is needed in the wording of the recommendation to not promote infant formula

There was support for supplementation of infants, however there was mixed views around the recommendation restricting to infants receiving less than 500 mL of formula per day. Some submitters discussed the importance of careful messaging to ensure breastfeeding is not undermined.

Steering Group response

The Steering Group agreed quantifying amounts of formula milk per day is difficult, however recommendations must ensure infants are not receiving more than the upper tolerable level of vitamin D. Therefore, infants receiving 500mL of infant formula will be receiving approximately 1000 IU of vitamin D. Due to this, infants who are receiving 500mL or more of infant formula per day, or are fully formula fed should not be offered a supplement of vitamin D.

Vitamin D testing

There was no support for introducing testing for vitamin D during pregnancy.

Steering Group response

The Steering Groups suggested there is a need to testing high risk pregnant women/people (those who have all three risk factors) to allow for individualised dosages of vitamin D, as the recommended supplementation dose will be for maintenance, not for severe deficiency.

Time outdoors and incidental sun exposure

There was support for the change of language to 'time outdoors' and the suggestions about management of time outdoors.

Steering Group response

As this is a companion statement, changing the title from 'sun exposure' to 'time outdoors' would be inconsistent with the Consensus Statement, and makes the title less clear.

The change in language to include 'time outdoors' within the document is supported by the Steering Group. We understand the nuance of UV exposure and understand vitamin D can be synthesised when in non-direct sunlight, however this becomes complex as you then need to consider shade density, the UV index, and the time of day. Noting the type of sun exposure in this document may lead to overcomplication and complexity for practitioners. This document is also not about skin cancer. We propose to check the language for consistency with this feedback, but to make no substantial changes.

Emphasis needs to be put on a change in lifestyles leading to reduced sun exposure, rather than the breastmilk being a poor source of vitamin D

There were some comments that recommendations should emphasise that the change in human behaviour and lifestyles, including the decrease in sunlight exposure to our skin, has led to vitamin D deficiency and subsequently the need to recommend vitamin D supplementation.

Steering Group response

It is important to balance the importance of breastfeeding with notifying people of the risk of vitamin D deficiency in exclusively breastfed babies. Adding emphasis to the change in human behaviour leading to the need to recommend vitamin D supplementation will be added to the talking points in statement 11.

Importance needs to be placed on the need to protect from the sun at all times

Some submitters discussed the importance of providing clarity that people should be protected from the sun at all times. There was some comment to change the recommendation of SPF30+ to SPF50+.

Steering Group response

The Steering Group support the recommendation to protect yourself from the sun with high-SPF sunscreen. All mention of SPF30+ in the document can be changed to SPF50+.

A note that sunscreen should always be used when exposing the skin to the sun as vitamin D synthesis is correlated with DNA Damage will be added under statement 16 advising whānau to use shade, protective clothing and sunscreen.

Audit and research priorities

There was support for continued research to support population health improvements, especially with regard to increasing equitable health outcomes for Māori, Pacific and other priority populations which are disproportionately affected by vitamin D insufficiency.

Steering Group response

The additional research topics can be added. Where possible, we will add further epidemiological data to the draft *Companion Statement*.

The Steering Group recommend future research including monitoring and evaluation of this risk-based targeted approach to supplementation in pregnant women/people.

Audit criteria

No submitters commented on the audit criteria.

Summary table/infographic

There was support for a summary table, however comments were received to strengthen the breastfeeding language, as well as the table needing to enable easy interpretation of assessments and recommendations, and the current draft required further clarity for practitioners.

Steering Group response

The summary graphic will be re-worked to include discussion points (advice) for whānau based on the recommendations throughout the *Companion Statement*. This will allow the summary graphic to provide a simple way for users to access the recommendations.

Additional comments

Submitters provided a number of suggestions on other aspects that are related to vitamin D, but which are not specific to the draft *Companion Statement*.

The draft guideline is important

There was support for the development of a nationally consistent *Companion Statement* that reflects current evidence and good practice. These submitters stated this *Companion Statement* is a useful tool to promote a consistent approach to vitamin D supplementation across health professions throughout Aotearoa New Zealand.

Format of the document

There was one suggestion that the final version needs to contain consolidated recommendations in one section placed in the front of the document so that they are easy to find, with the evidence review in main part of the document.

Steering Group response

In a short *Companion Statement* document with evidence statements, a balance needs to be struck between providing sufficient information, repetition and ease of finding information. The intention of the flowchart/graphic summary is to provide a simple way for users to access the recommendations (rather than repeating these at the front of the document). Recommendations (including those about supplementation) will be strengthened in the graphic.

Consumer advice and information will be needed

Additional comments were received including the importance of implementation and consumer advice, this including developing new and revised patient education materials, the content of these materials, and consulting with stakeholders when developing these materials.

Supply chain and funding of vitamin D supplements needs to be considered

Additional comments were received relating to the PHARMAC contract for vitamin D supplements, the need to restrict infant formula companies from marketing vitamins, the cost of supplementation, and the impact of increased prescribing on the PHARMAC budget.

Steering Group response

Though an implementation and communications plan are not within the scope of this update, this can be included as a recommendation for consideration. This is the same for education materials.