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

A supplement to the Consensus Statement on Vitamin D and Sun Exposure in New Zealand

Health New Zealand Te Whatu Ora

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Vitamin D and Sun Exposure in Pregnancy and Infancy

Defining insufficiency/deficiency

In this companion statement:

- Vitamin D insufficiency is defined as a level of <50 nmol/L
- Vitamin D deficiency is defined as a level of <25 nmol/L.

Maternal health outcomes

There is some evidence to suggest the following health outcomes are linked to vitamin D insufficiency or deficiency:

- Gestational diabetes
- Pre-eclampsia

Infant health outcomes

There is sufficient evidence to suggest bone health is linked to adequate optimal vitamin D status.

There is some evidence indicating the following health outcomes linked to vitamin D insufficiency or deficiency:

- Low birth weight
- Dental caries
- · Acute respiratory infections

Advice
Discuss the following with whānau during pregnancy and infancy:

- Maternal and infant risk factors for vitamin D deficiency or insufficiency.
- Testing asymptomatic pregnant people and infants for vitamin D insufficiency is not routinely recommended.
- · Testing may be appropriate for:
 - · pregnant people with a known history of vitamin D deficiency/insufficiency
 - pregnant people with unexplained raised serum alkaline phosphatase, low calcium phosphate, atypical
 osteoporosis, unexplained bone pain, unusual fractures, or other evidence suggesting metabolic bone
 disease
 - infants presenting with seizures where hypocalcaemia is implicated, or unexplained raised serum alkaline phosphatase.

Recommendations for supplementation

Pregnancy

Offer vitamin D supplementation during pregnancy if they have any of the listed risk factors.

Prescribe 400-800 IU Colecalciferol 188 microgram/mL oral liquid per day (1-2 drops).

Individuals with all three risk factors during pregnancy may be at higher risk of vitamin D deficiency and testing may be considered. Where vitamin D insufficiency or deficiency is confirmed through testing, follow the advice from New Zealand Formulary.

Infancy

Offer to prescribe vitamin D supplements to all exclusively or partially breastfed babies. Supplementation should begin by 4 weeks and continue until 1 year of age.

Prescribe 400 IU Colecalciferol 188 microgram/mL oral liquid per day (1 drop).

Sun safety advice

Discuss the following messages with whanau where appropriate:

- · Follow the same sun safety messages as for the general population during pregnancy.
- Always avoid sunburn.
- There is no safe threshold of UV exposure from the sun that avoids skin damage and ensures sufficient vitamin D synthesis.
- Sunscreen should only be used on small areas of a baby's skin and should not be the only form of protection from the sun: use shade, protective clothing, broad-brimmed hats, and sunglasses.
- · Young children, once mobile, should follow the same sun safety advice as for the general population.

Risk factors in pregnancy

There is an increased risk of vitamin D deficiency during pregnancy if the pregnant person has any of the following:

- · naturally dark skin tone.
- live south of Nelson/Marlborough during winter or spring.
- spend limited time outdoors and/or have minimal sun exposure due to religious, cultural, personal or medical reasons.

Supporting breastfeeding

Breastmilk is the ideal food for infants and contains antibodies which protect infants against illness whilst providing all the energy and nutrients that the infant needs for the first months of life.

There is strong evidence on the benefits of breastfeeding for both mother and infant.

Everyone should be encouraged and supported to breastfeed

Further research

Further evidence is important to strengthen the understanding of vitamin D and sun exposure on health outcomes in pregnancy and on infants.

1 Purpose of this Companion Statement

This Companion Statement provides information about vitamin D and sun exposure in pregnancy and infancy (0–2 years). This Companion Statement is evidence-informed and based on expert consensus from the Steering Group. It should be read in conjunction with the <u>Consensus Statement on Vitamin D and Sun Exposure in New Zealand</u> (Ministry of Health and Cancer Society, 2012), the <u>Ngā Paerewa Health and Disability Services</u> <u>Standard 8134:2021</u> (Standards New Zealand, 2021) and the corresponding sector guidance. <u>Ngā Paerewa</u> provides a suite of information about best-practice health service provision.

2 Need for this Companion Statement

Vitamin D helps to maintain calcium and phosphate homeostasis in our body and optimises bone health and muscle function. Low levels of vitamin D are linked to hypocalcaemic seizures and bone conditions such as rickets in children, and osteoporosis and osteomalacia in adults.

The advice provided in this Companion Statement assumes that an adequate intake of calcium is maintained in pregnancy. During pregnancy, the foetus requires a large amount of calcium for skeletal development, especially in the third trimester (from 28+0 weeks' gestation until birth). To meet this demand, maternal production of 1,25-dihydroxyvitamin D (1,25(OH)D) increases, which improves the efficiency of intestinal calcium absorption, and also mobilises calcium from maternal bones if needed.

Serum 1,25(OH)D levels and maternal calcium absorption peak in the third trimester (Specker, 2004). This increase in 1,25(OH)D is dependent on available 25-dihydroxyvitamin D (25(OH)D), the biomarker of vitamin D status.

Neonatal vitamin D status is directly related to maternal vitamin D status through transplacental transfer of vitamin D (Hollis, 2007). Therefore, maternal vitamin D deficiency places the infant at a higher risk of vitamin D deficiency. As vitamin D stores are laid down predominantly in the third trimester, premature infants are also at a higher risk of vitamin D deficiency postnatally.

3 Intended users of this Companion Statement

This Companion Statement is written for health practitioners involved in antenatal and postpartum care and in the care of infants up to age two years in Aotearoa New Zealand. This includes midwives, nurses, obstetricians, neonatologists, paediatricians, lactation consultants and general practitioners.

Health practitioners can use this Companion Statement to support their clinical judgement, knowledge and expertise and provide for a timely, consistent and effective approach to inform antenatal and postpartum maternity care, paediatric care, primary care and early childhood care discussions about vitamin D and sun exposure with whānau.

Health practitioners are responsible for appropriately documenting discussions and decisions in individual health records.

Whānau can use this Companion Statement to understand their risk of vitamin D deficiency in pregnancy, the outcomes associated with insufficiency or deficiency in pregnancy and how to seek treatment for vitamin D deficiency.

4 Te Tiriti o Waitangi

Giving effect to the Pae Ora (Healthy Futures) Act 2022 can be demonstrated through the practical application of the principles of Te Tiriti o Waitangi as articulated by the courts and Waitangi Tribunal.²⁰ Applying the principles to maternity and primary care service delivery is vital to enabling Māori to express their mana motuhake²¹ and ensures Māori receive high-quality, culturally safe and equitable health outcomes. Using the principles to work effectively and respectfully with Māori requires maternity and primary care services and health practitioners to demonstrate the principles of Te Tiriti o Waitangi in their day-to-day practice.

4.1 Principles of Te Tiriti o Waitangi

The principles of Te Tiriti o Waitangi provide the framework for maternity, neonatal and paediatric care providers, general practitioners and health practitioners providing maternity and primary care services to Māori. How these principles apply to maternity services is supported by *Ngā Paerewa*, in particular, 1.1 Pae ora healthy futures.

The Waitangi Tribunal concluded that the persistent health inequities experienced by Māori are the consequence of failing to apply the principles of Te Tiriti o Waitangi at structural, organisational and health practitioner levels of the health and disability sector. Giving effect to Te Tiriti o Waitangi requires health practitioners to know and understand the principles of Te Tiriti o Waitangi and be able to capably apply them in partnership with Māori in their day-to-day maternity clinical practice.

For the health and disability sector, the five principles of Te Tiriti o Waitangi are as follows.

Tino rangatiratanga: Supporting the right of Māori to receive effective maternity, neonatal, paediatric and primary care. A person's decisions are a continuation of a much older, Māori collective endorsed practice of sovereignty over one's health and wellbeing and the health and wellbeing of whānau.

- Equity: Contributing to equitable maternity, neonatal and paediatric health outcomes for Māori by ensuring, at a minimum, their health outcomes match those of other New Zealanders. Equitable maternity and primary care outcomes will be achieved when the recommendations in this national consensus statement are implemented in ways that give effect to the principles of Te Tiriti o Waitangi, relevant professional competencies and *Ngā Paerewa*.
- Active protection: Sharing evidence-based information about maternity, neonatal, primary care and paediatric outcomes so Māori can make decisions and prepare themselves to uphold their tikanga or cultural practice (for example, karakia, rongoā and support people). Health practitioners actively support Māori to make decisions by providing quality evidence-based information, free from bias and judgement.
- **Options**: Ensuring Māori have maternity, neonatal and paediatric care that enables them to uphold their tikanga or cultural practice regardless of where antenatal and primary care takes place. Processes must complement a Māori person's mana or inherent authority and dignity, support their tikanga or cultural practice, and be culturally safe as defined by Māori.

• **Partnership:** Working in partnership with Māori, including whānau if requested. A partnered approach to the process and decision-making ensures Māori can enact their rangatiratanga or self-determine their futures while exercising mana motuhake or authority over their bodies.

Health service providers and health practitioners must consider their commitments to deliver equitable services and meet obligations under Te Tiriti o Waitangi. Further information on cultural safety is in Appendix A: Cultural safety.

4.2 Equity

In Aotearoa New Zealand, people have differences in health outcomes that are not only avoidable but are unfair and unjust. Health inequities are the result of avoidable structural determinants in our communities. People have little control over the structural determinants of health and wellbeing (for example, income, employment, education, housing, and multiple forms of discrimination) yet these determinants negatively impact health and wellbeing. When health practitioners understand the structures that create inequitable health outcomes, they can use different approaches and resources to achieve equitable maternity and paediatric outcomes. Health equity is best achieved with a preventive health approach. This includes identifying those at risk of vitamin D insufficiency or deficiency and offering supplementation to prevent rickets. By identifying risk factors, vitamin D deficiency of clinical concern can be detected early and treated effectively to mitigate the most severe adverse outcomes.

Achieving equitable outcomes for all population groups happens when service providers and health practitioners understand the structures that create disadvantage for Māori and others and are supported to follow the Companion Statement's advice in ways that give effect to the principles of Te Tiriti o Waitangi, meet professional competencies, and adhere to *Ngā Paerewa*.

5 Consensus statements

This section discusses:

- prevalence of vitamin D insufficiency and deficiency in New Zealand (section 5.1)
- recommended vitamin D intake (section 5.2)
- vitamin D status during pregnancy and infancy in New Zealand (section 5.3)
- vitamin D insufficiency and deficiency and maternal and infant health outcomes (section 5.4)
- the role of supplementation (section 5.5)
- time outdoors and incidental sun exposure (section 5.6).

5.1 Prevalence of vitamin D insufficiency and deficiency in Aotearoa New Zealand

This document defines maternal and infant vitamin D insufficiency as 25(OH)D less than 50 nanomoles per litre, and deficiency as 25 nanomoles per litre, which is broadly consistent with global consensus. The global consensus guideline on prevention and management of nutritional rickets defines vitamin D deficiency as 30 nanomoles per litre (Munns et al., 2016).

Individuals' vitamin D levels are influenced by a complex interaction between daily skin exposure to Ultraviolet-B (UVB), latitude and seasonality, skin tone and dietary sources. Our understanding of the clinical significance of vitamin D insufficiency and deficiency is developing. Throughout this document, where the evidence suggests insufficiency of vitamin D is associated with an outcome, this language is used. Similarly, where deficiency (and no evidence on insufficiency) is suggested to be associated with an outcome, this language is used. Where research suggests outcomes are associated with both insufficiency, insufficiency/deficiency language is used.

The 2008/2009 Ministry of Health National Nutrition Survey (screened-sample survey) measured vitamin D status in Aotearoa New Zealand adults. The mean adult serum 25(OH)D level was 63 nanomoles per litre. Most adults had a serum 25(OH)D level of 50 nanomoles per litre or greater (68.1 percent). Twenty-seven percent of adults had a serum 25(OH)D between 25 to 49 nanomoles per litre, 4.9 percent had serum 25(OH)D less than 25 nanomoles per litre and 0.2 percent had 25(OH)D less than 12.5 nanomoles per litre (Ministry of Health, 2012).

Two studies in the last 10 years have reported on the prevalence of vitamin D insufficiency in pregnancy in Aotearoa New Zealand. Compared to the national survey of the general adult population (Ministry of Health, 2012), both studies found a higher proportion of vitamin D insufficiency in pregnancy. Maternal vitamin D insufficiency in pregnancy (defined as serum 25(OH)D < 50 nanomoles per litre) was reported in 42 to 65 percent of study participants (Ekeroma et al., 2015; Wheeler et al., 2018a).

5.2 Recommended vitamin D intake

Vitamin D comes primarily from exposure to sunlight. Vitamin D is found naturally only in a few foods such as fatty fish, mushrooms, egg yolks and liver. A person needs to be exposed to low levels of radiation in the UVB range in order to synthesise vitamin D in their skin. UVA does not contribute to vitamin D production.

Nutrient reference values (NRVs) refer to a range of recommended dietary intakes for vitamins and minerals, including an upper level of intake defined as maximum daily intake unlikely to cause adverse health effects. The NRVs are a joint initiative of the Australian Commonwealth Department of Health and Ageing and the New Zealand Ministry of Health (NHMRC, 2006).

In Aotearoa New Zealand and Australia, the recommended adequate intake for vitamin D assumes no or minimal sunlight as sun exposure factors and environmental factors can vary widely between individuals.

The recommended daily intake is 200 International Units of vitamin D per day (5 micrograms per day) for infants and people aged until 50 years of age, with older adults aged 50 years and above having increased requirements (NHMRC, 2006). The upper level for infants (0-12

months) is 1,000 International Units per day (25 micrograms per day) and 3,200 International Units per day (80 micrograms per day) during pregnancy and breastfeeding.

Vitamin D supplementation is not universally recommended in the general adult population, but the NHMRC (2006) recommends a supplement of 400 International Units per day (10 micrograms per day) in pregnancy or when breastfeeding if there is little exposure to daily sunlight.

Table 1 shows the recommended intake across different countries and regulating organisations, including the upper level of intake of vitamin D set by the US Institute of Medicine.

	Australia and New Zealand (NHMRC 2006)	United States and Canada (Institute of Medicine 2011)	UK (SACN 2016)	Germany, Austria and Switzerland (Deutsche Gesellschaft für Ernährung 2012)	Tolerable upper intake level - adapted from IOM (2011)
Pregnancy	200 IU/day (5 µg) AI or 10 µg/day (400 IU) supplement	600 IU/day (15 μg)	400 IU/day (10 µg)	800 IU/day (20 μg)	4,000 IU/day (100 μg)
Infants	200 IU/day (5 μg)	400 IU/day (10 μg)	340– 400IU/day (8.5–10 μg)	400 IU/day (10 μg)	1,000 IU/day (25 µg)

Table 1: Recommended dietary intake of vitamin D

Abbreviations: μ g = micrograms, IU = International Units, AI = adequate intake

The NHMRC recommendation is lower than that identified by other countries and organisations (see Table 1) because those countries assume little or no exposure to sunlight when setting vitamin D levels.

Food fortification is a proven and cost-effective way to increase vitamin D intake in the general population, including during pregnancy.

Food fortification practices also vary between countries. Unlike in many northern hemisphere countries, only a few foods in Aotearoa New Zealand are fortified with vitamin D. Foods that are permitted to be fortified with vitamin D in Aotearoa New Zealand include:

- edible oil spreads at 40 International Units per 10 grams (1.0 micrograms)
- dairy products (including cheese, yoghurt, modified milks and skim milk)
- some analogues derived from legumes and cereals at 20 International Units per 200 millilitres (1.0 micrograms) (FSANZ, 2021).

Given that fortification is limited in Aotearoa New Zealand, it is hard to achieve an adequate intake of vitamin D from diet alone.

Table 2: Samp	le of foods	containing	vitamin D
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Food	Amount of vitamin D
Fatty fish (for example, canned tuna, canned pink salmon, canned mackerel, canned sardines)	68–680 IU per 100g (1.7–17 μg)
Salmon fillet (farmed)	960-1040 IU per 100g (24–26 μg)
Yoghurt	8–292 IU per 100g (0.2–7.3 μg)
Egg (equivalent to 2 large boiled eggs)	64 IU (1.6 μg)
Fortified foods (for example, margarine and some dairy products)	16–800 IU per 100g/mL (0.4–20 μg)

Abbreviations: μ g = micrograms, IU = International Units

Source: (The Concise New Zealand Food Composition Tables: 14th Edition 2021, 2022)

Breast milk

Exclusive breastfeeding is the recommended form of infant feeding in the first six months of life to achieve optimal growth, development and health (Ministry of Health, 2008). After six months, infants should start on solid food and it is recommended they continue breastfeeding until two years old and beyond. Historically, sun exposure was the main source of vitamin D for infants, along with being born vitamin D replete due to maternal vitamin D sufficiency during pregnancy. However, sun exposure is no longer recommended for infants. The evidence for protecting, promoting and supporting breastfeeding is strong although breastmilk alone is not a sufficient source of vitamin D for all infants. Approximately 20 to 30 percent of maternal circulating vitamin D (in the form of 25(OH)D₃) is transferred into breastmilk and oral vitamin D supplementation of the infant ensures they achieve optimal vitamin D status (Haggerty, 2011).

The content of vitamin D in breastmilk varies and is complex to measure. A systematic review and meta-analysis reported the mean vitamin D content of breastmilk as 58 International Units per litre (Rios-Leyvraz & Yao, 2023). This varies depending on supplementation of the mother, season of testing and latitude. This amount is lower than the recommended AI of 200 International Units per day (5 micrograms per day) for infants (NHMRC, 2006). Most breastfed infants do not develop clinical vitamin D deficiency rickets. This is likely to be because they obtain adequate vitamin D through incidental sun exposure or time spent outdoors (Weisberg et al., 2004).

Breastmilk is the ideal food for infants. It is safe and contains antibodies which protect infants against illness while providing all the energy and nutrients that the infant needs for the first six months of life.

Infants should be exclusively breastfed for the first six months of life, with continued breastfeeding to age two years and beyond alongside nutritionally adequate, safe and ageappropriate complementary feeding from six months of age (Ministry of Health, 2020, World Health Organisation & United Nations Children's Fund, 2003).

Exclusive breastfeeding is one of the most significant and cost-effective ways to improve equity and increase the health and wellbeing of a population (*National Breastfeeding Strategy for New Zealand Aotearoa* | *Rautaki Whakamana Whāngote*, 2014).

Health professionals should support and encourage whānau to exclusively breastfeed their infants for the first six months of life wherever possible, to improve the health and wellbeing of infants, young children, breastfeeding parents and whānau, and benefit society as a whole.

Infant formula and toddler milk

Infant formula and toddler milk became fortified with vitamin D in the middle of the 20th century after rickets was recognised as a significant health problem in young children (Greer, 2004).

Infant formula in Aotearoa New Zealand is fortified with vitamin D (FSANZ, 2021). The compositional and labelling requirements of infant formula is defined in subclause 1(2) of Australia New Zealand Food Standard 2.9.1 (FSANZ, 2021). The Standard applies to all infant formula whether in powder, liquid concentrate or ready-to-drink forms. The permitted minimum range established for vitamin D is 0.24 micrograms per 100 kilojoules. The permitted maximum range is up to 0.63 micrograms per 100 kilojoules for both infant formula and toddler milks.

An infant consuming over 500 millilitres of infant formula per day should receive the recommended adequate intake of vitamin D.

5.3 Vitamin D status during pregnancy and infancy in New Zealand

5.3.1 Risks for vitamin D deficiency include sun avoidance, living south of Nelson/Marlborough, winter and spring season, and darker skin tone

Sun exposure to low levels of radiation in the UVB range is the main activator of pre-vitamin D in the skin for most people. Primacy is given to Aotearoa New Zealand-based evidence when understanding infant and maternal risk factors for the Aotearoa New Zealand population because UVB exposure varies significantly by season, latitude/longitude, skin pigmentation, clothing choices, cultural views of sun exposure and sunscreen use.

Sun avoidance behaviours vary. Cultural practices, religious beliefs and specific clothing preferences can limit sun exposure and can reduce vitamin D photosynthesis. Health practitioners should recognise the impact of sun avoidance behaviours on vitamin D status.

5.3.2 South of Nelson/Marlborough and winter/spring months

There are strong seasonal differences in vitamin D levels in Aotearoa New Zealand. Adults are more likely to be vitamin D insufficient in late winter and early spring (August to October) because of the low UV levels in winter and spring and the reduced personal exposure to UV in the cold winter months, especially in the south.

In Aotearoa New Zealand, seasonal differences in UV are larger in the south than in the north. In the winter months, UV index levels are very low throughout NZ outside the midday period. Figure 1 shows peak the UV index in summer (left) and the peak UV index in winter (right).

The summer map shows that although the peak UV index is high in Aotearoa New Zealand compared with similar northern latitudes, it is not particularly high in the global context. In winter, the UV index in Aotearoa New Zealand remains low (less than 1 south of Taupō). The resulting large contrast between summer and winter is an additional risk factor for vitamin D production because skin that has tanned over the summer months is less efficient at transmitting UV necessary for vitamin D production.

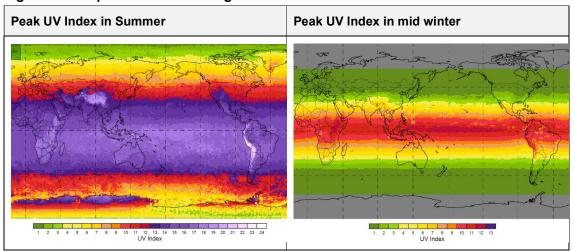


Figure 1: Comparison of UV strength over summer and winter

Source: Ben Liley, Richard McKenzie (NIWA)

Seasonal differences in UV are most marked in the South Island (excluding the Nelson Marlborough region). In the South Island between August and October, 18 percent of adults had serum 25(OH)D levels below 25 nanomoles per litre, and a further 46 percent had levels between 25 and 50 nanomoles per litre (Ministry of Health, 2012).

The 2002 Children's Nutrition Survey also demonstrated season as a strong determinant of risk of vitamin D insufficiency. In winter months (April to September), unadjusted prevalence of deficiency for New Zealand children was 5 percent and for insufficiency 43 percent. In the summer months (October to March), unadjusted prevalence of deficiency was 2 percent and for insufficiency 16 percent (Rockell et al., 2005).

The 1997 Adult Nutrition Survey found that women living in the South Island (latitude 40 to 47°S) had significantly lower mean serum 25(OH)D by 6 (3 to 9) nanomoles per litre compared with those living in the North Island (latitude 35 to 40°S) (Rockell et al., 2006).

Vitamin D insufficiency (25(OH)D < 50 nanomoles per litre) is common in pregnancy and in breastfed infants living south of Nelson/Marlborough. A 2018 longitudinal study of 126 women living at 45°S reported vitamin D insufficiency (25(OH)D < 50 nanomoles per litre) at one or more time-points in 65 percent of pregnant women and 76 percent of their infants. Three infants (2 percent) exhibited secondary hyperparathyroidism by postnatal week 20 (Wheeler et al., 2018a). A 2010 cohort study measuring the vitamin D levels of 929 infants living in Wellington or Christchurch reported that the median cord-blood level of 25(OH)D < 25 nanomoles per litre), and 57 percent were insufficient (25 (OH)D < 50 nanomoles per litre) in vitamin D (Camargo et al., 2010).

Variance in 25(OH)D levels was largely explained by season of blood collection. Data from a Dunedin study of 193 infants aged 12 to 22 months found a mean 25(OH)D concentration of 52 nanomoles per litre, which was consistent with the data from the 2002 National Children's Nutrition Survey (a mean of 50 nanomoles per litre for children aged 5 to 14 years) (Ministry of Health, 2003). In this cohort, almost 80 percent of the population of children had levels below 50 nanomoles per litre in winter compared with only 6 percent in summer (Houghton, et al., 2010).

Seasonality also affects people living in other parts of Aotearoa New Zealand. An Aucklandbased study reported 25(OH)D levels below 27.5 nanomoles per litre in 13 percent of infants and toddlers aged 6 to 23 months (46 out of 353 infants and toddlers). Results were strongly correlated to season of testing: 15 percent of those sampled in winter had low vitamin D, but only 1 percent of those sampled in summer had levels below 27.5 nanomoles per litre (Grant et al., 2009).

5.3.3 Darker skin tone

People with naturally dark skin tone have higher melanin pigmentation in the skin. Melanin acts as a filter for ultraviolet (UV) radiation. This reduces the production of vitamin D in the skin. Although people with naturally dark skin tone rarely burn and are better protected from skin cancer, they are at greater risk of vitamin D deficiency.

A 2015 Aotearoa New Zealand prospective surveillance study investigated incidence and characteristics of vitamin D deficiency in Aotearoa New Zealand among 58 children with confirmed vitamin D deficiency rickets (Wheeler et al., 2015). The median age was 1.4 years old from an observed range of 0.3 to 11 years. Key risk factors for developing vitamin D deficiency rickets were darker skin pigment, Indian and African ethnicity, age less than 3 years, exclusive breastfeeding and southern latitude, particularly when combined with season (winter/spring). Another study found the strongest determinants of low vitamin D status were winter month of birth and non-European ethnicity (Camargo et al., 2010). While skin pigmentation appears to be the most likely explanation for the ethnic differences in vitamin D levels, the potential influence of other genetic or environmental factors merits further research.

An Aotearoa New Zealand study involving 259 ethnically diverse pregnant women (grouped into European, Māori, Pacific, and other ethnic groups) reported that vitamin D insufficiency (serum 25(OH)D < 50 nanomoles per litre) was present in 42 percent of study participants. Vitamin D deficiency (serum 25(OH)D < 25 nanomoles per litre) was present in 11 percent of study participants. Enrolment season (p<.001) and ethnicity (Māori, Pacific, and other ethnic groups all at increased risk compared with those of European ethnicity) (p=.003) were independently associated with the likelihood of vitamin D insufficiency, but sunlight exposure or dietary vitamin D intake were not associated with deficiency. Of those enrolled in winter and spring, vitamin D deficiency was present in 80 percent of Pacific women, 67 percent of wāhine Māori, 59 percent of women of other ethnic groups, and 43 percent of European (Ekeroma et al., 2015).

Historical data shows that approximately 70 percent of children at risk of developing rickets are likely to belong to ethnicities including South Asian, African and Middle Eastern (Wheeler et al., 2015). Numerous factors influence this including skin tone and cultural views on sun exposure.

5.3.4 Testing for vitamin D insufficiency/deficiency

Testing asymptomatic pregnant people and infants for vitamin D insufficiency is not recommended (Bolland et al., 2012).

Vitamin D testing may be appropriate if symptoms of unexplained bone pain, atypical osteoporosis, or seizures where hypocalcaemia is implicated are present. This includes testing during pregnancy when there is evidence of:

- unexplained raised serum alkaline phosphatase, or low calcium or phosphate
- atypical osteoporosis

• unexplained bone pain, unusual fractures, or other evidence suggesting metabolic bone disease (consider specialist advice for people in this category) (Best Practice Advocacy Centre New Zealand, 2016).

It may be appropriate to test infants if they have seizures where hypocalcaemia is implicated or unexplained raised serum alkaline phosphatase. If testing is undertaken, a level of 50 nanomoles per litre or over is considered to be sufficient in pregnancy and for infants.

If there is clinical suspicion of severe symptomatic vitamin D deficiency, it is appropriate to investigate with serum calcium, phosphate, alkaline phosphatase, parathyroid hormone and vitamin D levels, plus other tests as indicated.

	Consensus Statement	Strength of statement
1.	 Discuss the following risk factors for vitamin D insufficiency/deficiency with whānau: sun avoidance seasonality (winter/spring) especially if living south of Nelson/Marlborough darker skin tone. 	Expert consensus opinion
2.	 Discuss the following risk factors below for vitamin D insufficiency/deficiency with whānau who have infants aged less than 6 months: exclusively breastfed or partially breastfed receiving less than 500 millilitres of infant formula per day breastfed over winter/spring months in Aotearoa New Zealand a sibling diagnosed with rickets or hypocalcaemic seizures maternal vitamin D deficiency or higher risk of maternal deficiency preterm infants and infants who weigh less than 2.5 kg at birth naturally dark skin. 	Expert consensus opinion
3.	 Consider vitamin D testing: in pregnancy if there is: unexplained raised serum alkaline phosphatase, or low calcium phosphate, or atypical osteoporosis, or unexplained bone pain, unusual fractures, or other evidence suggesting metabolic bone disease (consider specialist advice for people in this category), or known history of vitamin D deficiency for infants with: seizures where hypocalcaemia is implicated, or unexplained raised serum alkaline phosphatase. 	Good practice

5.4 Vitamin D deficiency may be associated with adverse maternal and infant health outcomes

Vitamin D levels are influenced by a complex interaction between daily skin exposure to UVB, latitude and seasonality, skin pigmentation and dietary sources. For infants aged less than 6 months, maternal vitamin D status after 28 weeks' gestation, gestational age at birth and family history of rickets are also important.

Further research is needed to expand our understanding of the relationship between vitamin D status and health outcomes. Much available evidence is from observational studies (not intervention studies) meaning that causal relationships between vitamin D status and health outcomes cannot be determined with certainty. Studies use variable cutoffs for vitamin D deficiency and insufficiency. Comparing vitamin D deficiency and the effects of interventions consistently is difficult.

5.4.1 Maternal health outcomes

There is currently insufficient evidence that vitamin D status is a causative factor for gestational diabetes mellitus (GDM) or pre-eclampsia; however, evidence that vitamin D deficiency/insufficiency during pregnancy may increase the risk of these adverse outcomes is increasing (Zhang et al., 2022). Many studies use differing definitions of insufficiency and deficiency of vitamin D and measure multiple outcomes. Establishing a causative link between maternal vitamin D status and GDM or pre-eclampsia is difficult to determine.

Gestational diabetes mellitus

The aetiology of GDM is a complex mix of genetic, health, and lifestyle factors. The cause of new-onset hyperglycaemia in pregnancy is not well-understood but dysfunction of pancreatic β -cells in response to the physiological changes to glucose levels necessary to support the healthy fetal growth has been suggested as causative (Shamsad et al., 2023).

There is insufficient evidence that vitamin D insufficiency/deficiency is a causative factor for GDM. Some studies suggest that maternal vitamin D deficiency or insufficiency increases the risk of GDM but the study definitions of vitamin D deficiency/insufficiency vary widely. A 2021 systematic review and meta-analysis reviewing 27 nested-case control trials and cohort studies reported those with vitamin D concentrations between 40 to 90 nanomoles per litre had a significantly reduced risk of GDM compared to those with vitamin D deficiency (less than 50 nanomoles per litre). Those with vitamin D less than 50 nanomoles per litre had a 26 percent greater risk of developing GDM (Milajerdi et al., 2021).

A 2020 systematic review and meta-analysis analysed 15 studies (40,788 participants) investigated GDM incidence and vitamin D supplementation (Sadeghian et al., 2020). Lower levels of serum 25(OH)D were associated with a higher risk of developing GDM however the level of vitamin D was not defined. The review also noted through linear analysis that for each 10 nanomole per litre increase in circulating 25(OH)D was associated with a 2 percent lower risk of developing GDM.

A trans-Tasman observational cohort study compared vitamin D status at 14 to 16 weeks' gestation in cohorts from Adelaide and Auckland to investigate the relationship between vitamin D status and pregnancy outcomes such as GDM, pre-eclampsia, gestational hypertension, preterm birth, and delivery of a small for gestational age (SGA) infant. Women in Adelaide had significantly lower levels of vitamin D than those in Auckland. This difference remained lower after adjusting for BMI and socioeconomic index (Adelaide: 58.4 +/- 50.3 vs.

Auckland: 70.2 +/- 54.5 nanomoles per litre, p<.001). There was a 53 percent decreased risk for GDM in those with high (more than 81 nanomoles per litre) vitamin D status when compared to those with moderate levels (63 to 81 nanomoles per litre) of serum 25(OH)D at 14 to 16 weeks' gestation (Wilson et al., 2018). This included both women who had vitamin D insufficiency and those who had adequate levels.

Pre-eclampsia

Pre-eclampsia occurs in 3 to 8 percent of pregnancies in Aotearoa New Zealand (Ministry of Health, 2021). There is insufficient evidence that vitamin D insufficiency is a causative factor for pre-eclampsia. This is because the definitions of vitamin D insufficiency and deficiency in these studies are inconsistent and include values that incorporate a large proportion of the pregnant population.

When looking at only those studies involving participants with 25(OH)D of more than 50 nanomoles per litre, a weak relationship between vitamin D status and pre-eclampsia appears to emerge. A 2022 systematic review and meta-analysis of 22 studies (case control, cohort and cross-sectional) with a total of 25,530 participants investigated the relationship between vitamin D status in pregnant women and the risk of pre-eclampsia. When comparing vitamin D deficient women (defined as 25(OH)D < 50 nanomoles per litre, with 4 studies using less than 37.5 nanomoles per litre) to replete levels (defined as 25(OH)D > 50 nanomoles per litre), those who were deficient had a higher pre-eclampsia rate (OR=1.35; 95% CI: 1.10, 1.66) (Hu et al., 2022). This finding had a moderate heterogeneity of 57 percent showing variation in individual study effect sizes among the included studies.

Similarly, a systematic review and meta-analysis of 23 studies (Morales-Suarez-Varela et al., 2022) reported 25(OH)D of more than 50 nanomoles per litre during pregnancy may be associated with the development of pre-eclampsia. The study reported vitamin D supplementation during pregnancy may act as a protective factor against the development of pre-eclampsia and preterm birth (before 37 weeks' gestation). Moderate heterogeneity of 53 percent was reported.

A 2019 Cochrane review suggests that taking vitamin D during pregnancy may lower the risk of pre-eclampsia, low birthweight, and preterm birth compared to not taking anything or using a placebo. It also found vitamin D supplementation in pregnancy may reduce the risk of severe postpartum haemorrhage (PPH), and likely makes little or no difference to the risk of preterm birth (Palacios et al., 2019).

	Consensus Statement	Strength of statement
4.	Advise whānau that there may be a possible role of vitamin D insufficiency/deficiency in developing GDM and pre-eclampsia. However, further studies are required to confirm this relationship and explore the potential effects of vitamin D supplementation on preventing GDM and pre-eclampsia risk.	Good practice

5.4.2 Infant health outcomes

There is convincing evidence that vitamin D deficiency (25(OH)D < 25 or < 30 nanomoles per litre) is associated with vitamin D deficiency rickets. Observational evidence suggests maternal vitamin D deficiency in pregnancy is associated with an increased risk of low birth weight. There is insufficient evidence that vitamin D insufficiency/deficiency is associated with dental caries or acute respiratory illness.

Rickets

Rickets is a preventable bone disorder caused by a lack of vitamin D, calcium or phosphate. It is associated with biochemical abnormalities, bone deformities, impaired growth, developmental delays and, late in the course of the disease, seizures. Rickets is characterised by bone changes including bowing of the legs, rachitic rosary of the rib cage, frontal bossing, and epiphyseal enlargement of the wrists and ankles (Weisberg et al., 2004). Hypocalcaemic seizures in infants and young children are also linked to vitamin D deficiency and rickets. A New Zealand study found 15.5 percent of rickets cases presented with symptomatic hypocalcaemia (seizure and tetany) (Wheeler et al., 2015).

Rickets is a health issue in Aotearoa New Zealand. A 2015 New Zealand prospective surveillance study investigated incidence and characteristics of vitamin D deficiency in Aotearoa New Zealand. Wheeler et al. (2015) identified 58 children with confirmed vitamin D deficiency rickets. The median age was 1.4 years old (range 3 months to 11 years). Overall annual incidence of rickets in children aged under 15 years was 2.2 per 100,000 children (95% CI: 1.4, 3.5); with incidence in those aged under 3 years being 10.5 per 100,000 children (95% CI: 6.7, 16.6). The highest rates were among children living at the highest latitude in the South Island of New Zealand (Otago/Southland). When considering country of birth of the mother, most were born in Africa (24.0 percent) or India (22.4 percent).

Bone health

The IOM reviewed evidence to update dietary reference intakes (DRIs) for calcium and vitamin D in 2011, incorporating systematic evidence reviews (Institute of Medicine, 2011). The report stated that the risk of rickets increases below a serum 25(OH)D level of 30 nanomoles per litre and is minimal when serum 25(OH)D levels are between 30 and 50 nanomoles per litre (when calcium intakes are also adequate). For infants aged to 12 months, the IOM found that maintaining serum 25(OH)D levels above 30 and closer to 50 nanomoles per litre appears sufficient for most infants to maintain normal bone accretion. They found evidence to support the following vitamin D intakes for bone health, shown in Table 3 below.

Life stage/age	Adequate Intake	Estimated Adequate Intake	Recommende d Dietary Allowance	Tolerable Upper Intake level
Infants 0-12 months	400 IU	-	-	1,000 IU
Children 1-3 years	-	400 IU	600 IU	2,500 IU
Pregnancy and breastfeeding	-	400 IU	600 IU	4,000 IU

Table 3: Vitamin D dietary reference intake for infants, children aged 1-3 years,
pregnancy and breastfeeding (IU per day) – adapted from IOM, 2011

Abbreviations: IU = International Units

Low birth weight (under 2,500 grams)

Observational evidence suggests maternal vitamin D insufficiency/deficiency may be associated with an increased risk of low birth weight in infants. A 2021 systematic review and meta-analysis investigated the relationship between maternal vitamin D deficiency during pregnancy defined as 50 nanomoles per litre (20 nanograms per millilitre) and low birth weight (below 2,500 grams). Maternal vitamin D deficiency was consistently correlated with an increased risk of low birth weight. When compared with normal serum levels of vitamin D (more than 50 nanomoles per litre), maternal vitamin D deficiency had an increased risk of low birth weight (OR=2.39; 95%CI: 1.25, 4.57; p=.008). Similar results were found in the comparison of the mean: the total mean birth weight decreased by 0.08 kg (95%CI: -0.10, -0.06; p<.001) (Fang et al., 2021). This finding had high heterogeneity of 81 percent showing variation in individual study effect sizes among the included studies.

A 2021 Western Australian cohort study assessed the effect of maternal vitamin D levels during the second trimester on the risk for GDM, pregnancy and infant outcomes including type of birth, gestational age at birth, and birth weight. A total of 890 pregnant women had vitamin D status measured at 18 weeks gestation and were grouped into serum vitamin D quartiles (25(OH)D < 30, 30 to 49, 50 to 79 and > 78 nanomoles per litre). Maternal vitamin D status may be positively associated with infant birth weight, (r = 0.10; p=.003), body length (r = 0.10; p=.005), and head circumference (r = 0.10; p=.007) of the infant (Mosavat et al., 2021). Despite reporting an association with birthweight, using binary logistic regression, no association was found between maternal vitamin D and the risk for low birth weight (under 2,500 grams).

Dental caries

Dental enamel is the most mineralised tissue in the human body, with calcium and phosphate identified as important for enamel mineralisation during early tooth development. As with bone, vitamin D deficiency can induce defective tooth mineralisation, resulting in dentin and enamel defects which may increase the risk of the onset and progression of dental caries (Beckett et al., 2022).

A 2022 Aotearoa New Zealand cohort study examined the dental consequences of vitamin D insufficiency/deficiency during pregnancy and infancy in a cohort of 81 New Zealand children (Beckett et al., 2022). Maternal vitamin D insufficiency (25(OH)D < 50 nanomoles per litre) during the third trimester of pregnancy was associated with more dental caries experienced in primary dentition. Study participants were largely from a homogenous European ethnicity.

Acute respiratory infections

The burden of acute respiratory infection (ARI) hospitalisation in young children in Aotearoa New Zealand is high, with the highest incidence among children aged under three months (Prasad et al., 2019). There is limited evidence to suggest vitamin D insufficiency/deficiency may be associated with ARI.

A 2021 nested case control study in Aotearoa New Zealand assessed if vitamin D deficiency at birth is associated with ARI hospitalisation during infancy. Study participants were 384 infants aged between 0 to 12 months with more than one ARI hospitalisation, measured against 1,536 controls. Median 25(OH)D levels were lower among ARI cases (46 nanomoles per litre) than controls (61 nanomoles per litre). After adjustment for season of birth and covariates describing demographic, antenatal, perinatal, and infant characteristics, vitamin D insufficiency at birth (25(OH)D < 50 nanomoles per litre) was associated with increased odds of ARI hospitalisation during infancy (OR = 2.20, 95% CI: 1.48, 2.91) (Saraf et al., 2021). The study noted that in comparison to children included in the analysis, the mothers of the excluded children were living in more socioeconomically deprived areas during pregnancy,

which may underestimate the strength of association of low vitamin D status at birth with the odds of ARI hospital admission during infancy.

	Consensus Statement	Strength of statement
5.	Discuss the importance of maternal vitamin D levels during pregnancy.	Expert consensus opinion
	Key points:	
	 it is important the infant is born with sufficient levels of vitamin D 	
	 infants are likely to be born with insufficient vitamin D levels if their mothers had insufficient levels of vitamin D during pregnancy, especially during the 3rd trimester 	
	 maternal vitamin D deficiency increases the risk of developing of vitamin D deficiency rickets in infant 	
	• vitamin D insufficiency/deficiency may play a role in the development of low birth weight, dental caries and acute respiratory infection the infant. However, further studies are required to confirm this relationship and explore the potential effects of vitamin D supplementation on preventing these adverse health outcomes.	

5.5 Supplementation may help to improve maternal and infant vitamin D levels and is unlikely to cause harm

Supplementation during pregnancy

Available evidence focuses on different populations with varying baseline levels of vitamin D. Variable dosages of vitamin D supplementation were used in the studies. This highlights the both the complexities and uncertainty of causation of outcomes, as well as showing the importance of further evidence to strengthen the statements related to the effect of vitamin D supplementation on health outcomes in infants and during pregnancy.

The main aim of vitamin D supplementation in pregnancy is to ensure that the foetus has sufficient vitamin D and that the infant is not born vitamin D deficient. Sufficient vitamin D inutero may allow for bone health and prevention of rickets in infants. Vitamin D supplementation during pregnancy is likely to increase maternal and infant vitamin D status (serum and cord blood 25(OH)D).

As transplacental passage of maternal 25(OH)D is the only source of vitamin D for the foetus in-utero, infants born to those deficient in vitamin D are at risk of vitamin D deficiency. Ensuring sufficient levels of vitamin D in pregnancy reduces the likelihood of the infant being at risk of vitamin D deficiency.

A 2019 Cochrane review found, based on a small number of trials, that vitamin D supplementation during pregnancy probably reduces the risk of pre-eclampsia, low birthweight and preterm birth compared to no treatment or placebo. The Cochrane review found that supplementation with vitamin D in combination with calcium supplementation may increase the risk of preterm birth, as shown in three studies. The level of calcium provided

alongside vitamin D in these studies ranged from 300 to 1,200 micrograms per day (Palacios et al., 2019).

This review included studies involving vitamin D supplementation during pregnancy irrespective of the regimen (dose, frequency, duration, or time of commencement of supplementation during pregnancy). Additionally, the duration of supplementation in included trials varied with many not specifying how long supplementation lasted.

Another systematic review with meta-analysis conducted since 2019 that considered the dose of supplementation has shown a reduced risk of GDM at vitamin D doses more than 2,000 International Units per day (seven randomised controlled trials; risk ratio = 0.70, 95% CI: 0.51–0.95, $l^2 = 0$) and pre-eclampsia at doses of $\leq 2,000$ International Units per day during pregnancy (three randomised controlled trials; risk ratio = 0.29, 95% CI: 0.09–0.95, $l^2 = 0$). No effect on birth weight of either a lower ($\leq 2,000$ International Units per day) or higher dose (more than 2,000 International Units per day) vitamin D supplement was found (Irwinda et al., 2022).

Increasing vitamin D levels

A 2020 Cochrane review found that vitamin D supplementation (daily doses of 500 to 6400 International Units per day, or monthly doses of 50,000 International Units per dose to 120,000 International Units per dose) provided to breastfeeding women who were vitamin D deficient (25(OH)D < 30 nanomoles per litre) and insufficient (25(OH)D < 50 nanomoles per litre) may increase vitamin D levels and prevent maternal deficiency (Tan et al., 2020).

In a 2022 systematic review with meta-analysis, doses of vitamin D supplementation provided to pregnant women higher than 4,000 to 6,000 International Units per day were associated with an increase in vitamin D concentration in newborns of supplemented mothers compared to placebo (Colonetti et al., 2022).

A 2018 systematic review found that maternal vitamin D supplementation during pregnancy was associated with reduced risk of neonatal mortality and small for gestational age (Bi & Wei, 2018). It is still unclear what the optimal maternal vitamin D supplementation dose or ideal time to begin supplementation, as studies use variable dosages and timings.

Maternal vitamin D supplementation has also been assessed in an Aotearoa New Zealand context with a high-quality randomised controlled trial (RCT) (Wheeler et al., 2016). Women planning to exclusively breastfeed were provided with either a dose of 50,000 International Units per month,100,000 International Units per month or a placebo monthly from weeks 4 to 20 postpartum. Changes in maternal serum 25(OH)D at 20 weeks were higher in the 50,000 International Units per month and 100,000 International Units per month group compared to placebo. Unadjusted changes in infant serum 25(OH)D were no different between supplementation arms and placebo group. However, when adjusted for potential confounders including season of birth, formula intake and infant skin colour, the mean change effect size for the breastfed infant 25(OH)D for mothers supplemented with 100,000 International Units per month group was significantly higher than the placebo group.

Infancy

A Cochrane review and meta-analysis including 19 randomised controlled trials determined the effect of vitamin D supplementation on infant vitamin D status (deficiency and insufficiency), nutritional rickets and adverse effects such as hypercalcaemia (Tan et al., 2020). Healthy term infants and breastfeeding mothers were included (n = 2,837 infant-mother pairs) and the effect of vitamin D supplementation to each group were considered. The review found that for breastfed infants up to six months of age, compared to placebo vitamin D supplementation at 400 International Units per day may:

- increase 25(OH)D levels: mean difference: 22.63 nanomoles per litre; 95% CI: 17.05, 28.21; participants = 334; studies = 6; low-certainty (upper and lower levels not reported)
- reduce vitamin D insufficiency: RR=0.57; 95% CI: 0.41, 0.8.

Infant supplementation at 400 International Units per day may increase vitamin D levels to a point that reduces the incidence of insufficiency (25(OH)D < 50 nanomoles per litre).

High-dose maternal supplementation of \geq 4,000 International Units per day provided similar infant vitamin D levels to infant supplementation of 400 International Units per day, suggesting both maternal and infant supplementation are effective at increasing levels of vitamin D at these dosages.

A systematic review and meta-analysis considered the effects of vitamin D supplementation during pregnancy on bone health and growth (Luo et al., 2022). It found maternal supplementation during pregnancy (at a range of doses from 400 to 4,400 International Units per day, plus fortnightly, and monthly doses) was associated with increased humeral length in the uterus and body length at birth, as well as higher cord blood 25(OH)D concentration.

An Aotearoa New Zealand randomised control trial provided daily vitamin D supplement to pregnant women from 27 weeks' gestation and their infants from birth until 6 months of age compared to placebo. It found positive effects on both reduction in primary care visits due to ARIs, the proportion of infants with serum $25(OH)D \ge 50$ nanomoles per millilitre (Grant et al., 2014), and the proportion of children sensitised to dust mites at age 18 months (Grant et al., 2016).

Establishing breastfeeding can be difficult and often an infant will spill its feed or is unwell. Unless an infant is suffering from hypocalcaemic seizures or are very deficient, missing a dose of supplements due to spillage from a feed will cause no harm.

A national audit of infant vitamin D supplementation across four infant groups (breastfed, born in winter months, southern latitude, and low birth weight) in Aotearoa New Zealand found that currently there is under-dispensing of supplements for breastfed infants at a southern latitude, born in winter months, and with darker skin tone (ethnicity as a proxy) with only 8 to 10 percent of infants in these groups being prescribed the recommended vitamin D supplement. The audit observed dispensing rates for low birthweight infants (under 2,500 grams) was higher at 70 percent. (Jelleyman, Personal communication, 4 August 2023)

Dosage of vitamin D supplementation

There is no universal consensus on the optimal dose or timing of vitamin D supplementation during pregnancy or when breastfeeding; however, adequate intakes and upper limits to avoid poor bone health outcomes have been set out by IOM (Institute of Medicine, 2011) and other international bodies (see Table 1).

Data from a 2019 Cochrane review considered dosing regimens in pregnancy comparing the effect of doses of 601 International Units per day or more to 600 International Units per day or less, and 4,000 International Units per day or more to 3,999 International Units per day or less on pregnancy and neonatal outcomes (Palacios et al., 2019). It found little evidence that doses of 601 International Units per day or more of vitamin D supplementation in pregnancy had a different effect on the risk of pre-eclampsia, preterm birth or low birthweight compared to dose of 600 International Units per day or less, but that higher doses may further reduce the risk of GDM compared to the lower dose. Doses of 4,000 International Units per day or more vitamin D during pregnancy made no difference to the risk of any of the outcomes compared with a supplement of 3,999 International Units per day or less.

Contraindications and precautions for vitamin D supplements

Supplementation is not recommended when hypercalcaemia, hypervitaminosis D or renal osteodystrophy with hyperphosphataemia are present. Care should be taken when considering supplementation in the presence of atherosclerosis or cardiac function impairment, hypersensitivity to vitamin D, renal function impairment, or sarcoidosis (Medsafe, 2018).

There are no documented problems with intake of colecalciferol (vitamin D3) to the level of normal daily requirements in pregnancy; however, maternal hypercalcaemia during pregnancy may be associated with increased sensitivity to the effects of vitamin D, suppression of parathyroid function, or a syndrome of elfin faces, mental retardation and congenital aortic stenosis in infants.

Animal reproduction studies have shown an adverse fetal effect when given in doses 4 and 15 times the dose recommended for human use. There are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. Colecalciferol is Food and Drug Administration (FDA) Pregnancy Category C (Medsafe, 2018).

Toxicity

Vitamin D is a fat-soluble vitamin. While the therapeutic index (the range of doses at which a medication is effective without unacceptable adverse events) is wide, vitamin D toxicity (hypervitaminosis D) can occur through excessive oral intake of vitamin D (through supplementation or fortification). Hypervitaminosis D usually presents as signs of hypercalcaemia including poor appetite, nausea and vomiting. Weakness, frequent urination and kidney problems may also occur. Hypervitaminosis D does not occur by prolonged exposure of the skin to UV light.

The Institute of Medicine states the tolerable upper levels of vitamin D intake as 1,000 International Units per day for infants, 2,500 International Units per day for children aged 1 to 3 years, and 4,000 International Units per day in pregnancy and when breastfeeding (Institute of Medicine, 2011). These reference values assume minimal sun exposure. For children and adolescents aged 1 to 18 years, estimate average requirements and recommended daily allowances are based on a serum 25(OH)D concentration of 40 and 50 nanomoles per litre. These intakes are higher than the indicated adequate intake of 400 International Units per day, suggesting vitamin D supplementation is safe and significant intake of vitamin D supplements or fortified foods would be required to elicit a toxic dose.

Recommendations about supplementation assume an adequate intake of calcium. Health practitioners could offer supplementation with calcium during pregnancy for those who have a major risk factor for pre-eclampsia, particularly those with low dietary intake of calcium, from booking to birth (1.5 to 2.0 grams oral elemental calcium is recommended).

Appropriate advice on vitamin D supplementation must balance the benefits of breastfeeding, and the risks and benefits of vitamin D supplementation.

	Consensus Statement	Strength of statement			
Sup	Supplementation during pregnancy				
6.	Discuss vitamin D supplementation during pregnancy, noting that vitamin D:	Good practice			

		1
	• stores are predominantly laid down in infants during the third trimester of pregnancy	
	 supplementation in pregnancy aims to ensure that the infant is born with sufficient stores of vitamin D in order to support infant bone health and prevention of rickets 	
	 supplementation during pregnancy may reduce the risk of adverse pregnancy outcomes (such as pre-eclampsia and gestational diabetes) 	
	levels are influenced by presence of risk factors	
7.	Advise people at lower risk of vitamin D deficiency during pregnancy that they may benefit (and are unlikely to suffer harm) from vitamin D supplementation of between 400 IU per day (10 micrograms/day) and 800 IU per day (20 micrograms/day) throughout their pregnancy, particularly in the third trimester.	Expert consensus opinion
8.	Advise pregnant people who are at risk of vitamin D deficiency (according to the risk factors stated in <u>section 5.3</u>) that they are likely to benefit from supplementation and offer to prescribe vitamin D.	Expert consensus opinion
	Offer vitamin D supplementation during pregnancy if they have any of the following risk factors:	
	 naturally darker skin pigmentation and/or are of South Asian, African or Middle Eastern heritage. 	
	• live south of Nelson/Marlborough during winter or spring.	
	 are sun avoidant and/or spend limited time outdoors for religious, personal or medical reasons. 	
	Prescribe 400 to 800 IU (1 to 2 drops) colecalciferol oral liquid (7,500 IU per millilitre/188 micrograms per millilitre) vitamin D drops per day for prevention. Discuss the availability of subsidised Clinicians® 188 microgram/mL oral liquid vitamin D drops. See <u>New Zealand Formulary: colecalciferol.</u>	
	Individuals with all three risk factors in pregnancy may be at higher risk of vitamin D deficiency and blood testing may be considered. Where vitamin D insufficiency or deficiency is confirmed through testing, follow the advice from New Zealand Formulary (<u>New Zealand Formulary: colecalciferol</u> .)	
	Explain:	
	• Each drop provides approximately 400 IU (10 micrograms)	
	 Explain that supplementation at this low dose cannot cause toxicity and people are unlikely to suffer harm from supplementation during pregnancy. 	
	 For severe deficiency, an individualised treatment programme will be required initially. 	

	Always check what, if any, other supplements are being taken, especially if they contain vitamin D, and adjust advice/dose accordingly.	
9.	Healthcare practitioners should be attentive to cultural nuances, employing a culturally sensitive approach to education and preventive measures that consider the historical and traditional factors influencing sun exposure behaviours in these communities.	Good practice

	Consensus Statement	Strength of statement			
Sup	Supplementation for breastfed infants				
10.	Advise whānau that all exclusively or partially breastfed infants may benefit from vitamin D supplementation to reduce the risk of rickets and support bone health.	Expert consensus opinion			
	• Explain that breastmilk is the ideal food for infants and encourage breastfeeding by discussing the benefits of breastfeeding for both infants and mothers, including protection against common illness and decreasing the chances of adverse health outcomes later in life in infants, as well as reducing the risk of mothers developing ovarian cancer and breast cancer.				
	 Explain that vitamin D supplementation is appropriate until the infant is mobile, or up to 12 months of age. 				
	• Discuss that the need for vitamin D supplementation has come from a change in human behaviour and lifestyles which has led to a decrease in sunlight exposure to our skin, and subsequently increased risk of vitamin D deficiency.				
11.	Following this discussion, offer to prescribe vitamin D supplements to all exclusively or partially breastfed infants as soon as practical, but by 4 weeks until 12 months of age.	Expert consensus opinion			
	Prescribe colecalciferol oral liquid (188 micrograms per millilitre/7,500 international units per millilitre), vitamin D drops, one drop per day. See <u>New Zealand Formulary for Children:</u> <u>colecalciferol.</u>				
	Explain:				
	• Each drop provides approximately 400 IU (10 micrograms)				
	 Infants are unlikely to suffer harm from supplementation. 				
	 Explain that infant formula is fortified with vitamin D so fully formula fed babies should receive adequate vitamin D and do not require supplementation. 				

•	Additionally, infants receiving 500mL of formula per day should receive sufficient vitamin D and do not require	
	supplementation.	

5.6 Time outdoors and incidental sun exposure

Refer to the **Consensus Statement** for advice on sun exposure for the general population.

UV radiation from the sun has both beneficial and harmful health effects. High UV radiation in summer contributes to skin cancer, while low radiation in winter contributes to vitamin D deficiency. Exposure to UV radiation (both UVA and UVB) is the likely cause of over 90 percent of all skin cancer cases in countries with high levels of UV exposure in summer (Armstrong, 2004; IARC, 2012). Aotearoa New Zealand has among the highest rates of melanoma in the world (Arnold et al., 2022). UV radiation is also the major contributor to photoaging of the skin. A balance is required to avoid excessive sun exposure which increases the risk of skin cancer and spending enough time outdoors to maintain adequate vitamin D levels.

The intensity of UVA rays remains relatively consistent during all daylight hours throughout the year. UVA can penetrate clouds and glass. UVB intensity varies throughout the year and time of day (refer to Figure 1). The peak UVB period (that is, the time of greatest risk from sun exposure) is between 10 am and 4 pm from September to April. This is largely when the UVB levels are 3 or above on the Ultraviolet Index, which measures UV radiation. UVB rays can burn and damage the skin year-round, especially at high altitudes and on reflective surfaces such as snow or ice, which can reflect up to 80 percent of the rays. UVB rays do not significantly penetrate glass.

An infant's skin barrier remains immature throughout at least the first two years of life. Accumulation of UV radiation-induced changes in the skin may begin as early as the first summer of life (Paller et al., 2011). There is international agreement that infants should not be exposed to direct sunlight for at least the first six months of life. In Aotearoa New Zealand, infants should not be left in direct sunlight. This approach balances the risks (skin cancer later in life), benefits (predominantly vitamin D and outdoor physical activity) and practicality as, once independently mobile, it is difficult to keep an active toddler out of direct sun.

Caution is also required when infants and young children are travelling in vehicles for long periods as side and rear windows are usually made from non-laminated glass which allows significant UVA (but not UVB) exposure.

The first-line choices for sun protection are shade, protective clothing, broad-brimmed hats, sunglasses, and for adults and adolescents, sunscreen. When additional sun protection is required for infants, a 50+ broad spectrum sunscreen is considered safe for use. For infants and children with sensitive skin, a chemically inert sunscreen (micronised titanium dioxide and/or zinc oxide) is recommended. The Cancer Society recommends testing a patch of skin before applying a previously untried sunscreen to all exposed skin (*SunSmart*, 2021). It does not recommend use of sunscreen on infants under six months because they should be kept in the shade as much as possible.

UV information

Sources of advice to the public on the Ultraviolet Index include:

 Sun Protection Alert (<u>www.sunsmart.org.nz</u>), which outlines the times of day when the Ultraviolet Index is over 3.

- The Ultraviolet Index regional forecast service for Aotearoa New Zealand <u>www.niwa.co.nz/our-services/online-services/uv-and-ozone/forecasts).</u>
- UVI smartphone apps (<u>https://niwa.co.nz/our-services/online-services/uv-ozone/uvi-smartphone-apps</u>).

	Consensus Statement	Strength of statement
12.	Discuss sun safety messages with all adults including during pregnancy (see the <i>Consensus Statement</i>):	Good practice
	always avoid sunburn	
	 there is no safe threshold level of UV exposure from the sun that both avoids skin damage and ensures sufficient vitamin D synthesis 	
	 when people are exposing themselves to the sun for vitamin D, this should always be done with sunscreen as we know that sun exposure correlates with DNA damage without sunscreen. 	
13.	Discuss the following infant sun safety messages with whānau:	Expert consensus opinion
	 infants should not be exposed to direct sunlight, particularly between 10 am and 4 pm from September to April 	
	 first use shade, protective clothing, broad-brimmed hats, broad-spectrum sunscreen for young children over 6 months, and sunglasses when infants and young children are outdoors 	
	 sunscreen should only be used on small areas of an infant's skin and should not be the only form of protection from the sun. 	
	 advise whānau that young children, once mobile, should follow the same sun prevention advice as for the general population 	
15.	Discuss time spent outdoors (in the shade as opposed to direct sunlight) with whānau as this may allow sufficient vitamin D synthesis for infants without risk factors (see <u>section</u> <u>5.3</u>)	Expert consensus opinion
	 Note the denser the shade the better the sun protection and less vitamin D produced. 	
	• Sitting in the peripheral edge of shade or in dappled shade will offer considerably less protection from the sun than sitting in the centre of a large area of intense shade.	

6 Audit and research

Advice on vitamin D and sun exposure in pregnancy and infancy has been available since 2013 together with targeted supplementation recommendations for pregnancy and infancy (Ministry of Health, 2013). There is little data on how existing guidance on vitamin D and sun exposure has been implemented and no evidence for interventions aimed at increasing uptake of vitamin D supplements (for example, training for health professionals, increasing awareness of the importance of optimal vitamin D status during pregnancy and breastfeeding). Moreover, the limited evidence available points to low dispensing rates of vitamin D supplements for infants.

Ongoing monitoring and evaluation of awareness, availability and uptake of vitamin D supplements among high-risk pregnant people and breastfeeding infants, is important at a national level. Monitoring and evaluation data will support effective implementation.

Taking into account the above factors and issues, the following recommendations for research to support practice improvements should be addressed in conjunction with regular review of ongoing international science and policy developments.

The aim of the recommendations is to provide high-quality evidence to inform clinical practice and public health efforts to ensure appropriate advice on vitamin D and sun exposure in pregnancy and infancy, and ultimately improve the health and well-being of mothers and babies.

All the recommendations should aim to apply the principles of Te Tiriti o Waitangi in partnership with Māori, identify the structures that create inequitable health outcomes, and examine different approaches and resources to achieve equitable maternity and paediatric outcomes.

Recommendations for research to support practice improvements are:

- Review the effectiveness of interventions to increase vitamin D awareness, access, uptake and adherence (including vitamin D status) among high-risk pregnant people and infants.
- Continue to monitor and evaluate the uptake of vitamin D supplements among the target population groups, at a national and local level.
- Data reporting the current annual incidence of health determinants arising from vitamin D deficiency in Aotearoa New Zealand.
- Monitor the implementation of this national Companion Statement, including a review of how a multi-agency approach can improve awareness, availability and uptake of vitamin D and sun exposure in pregnancy and infancy best be established, improved and sustained.
- Further review of interventional studies that show how supplementation impacts clinical outcomes, including studies that explore the efficacy of post-partum supplementation during breastfeeding to boost vitamin D levels in exclusively breastfeed infants.
- National nutrition survey to establish population levels of vitamin D especially amongst people of childbearing age.
- The estimated relative risk reduction in an outcome by the intervention compared to placebo, along with the confidence intervals and p-value.

This national Companion Statement should be reviewed in 2027.

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Te Whatu Ora Health New Zealand contracted *Allen* + *Clarke* to review and update the advice on vitamin D and sun exposure in pregnancy and infancy in Aotearoa New Zealand.

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Members of the Companion Statement Steering Group were:

- Dr Karl Cole (co-chair, Royal New Zealand College of General Practitioners)
- Violet Clapham (co-chair, New Zealand College of Midwives)
- Professor Ben Wheeler (Paediatric Society of New Zealand)
- Chloe Taylor (Ngā Maia Māori Midwives)
- Isis McKay (Women's Health Action)
- Jeshua Manu (Women's Health Action)
- Jo Purea-Anand (Pasifika Midwives Aotearoa)
- Professor Lisa Houghton (Nutrition Society of New Zealand)
- Karen Magrath (Whānau Awhina Plunket)
- Dr Meera Sood (Royal Australian and New Zealand College of Obstetricians and Gynaecologists)
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Appendix A: Cultural safety

Practising in a culturally safe way is important and a requirement of Te Tiriti o Waitangi, particularly the principles of active protection, options and partnership. It is important health practitioners know tikanga or correct protocols and practices are often specific to whānau, hapū, rūnanga and iwi and that tikanga is not 'one size fits all'. Similarly, mātauranga Māori or Māori knowledge is not a single entity; rather there are both traditional and contemporary. Mātauranga Māori that is specific to hapū and iwi environments includes land, seas, waterways, weather systems, the stars, flora and fauna, and things seen and unseen. Well-known forms of mātauranga Māori have been somewhat protected from colonisation by virtue of having been composed or narrated in te reo Māori.

Rangatiratanga or self-determining rights over tikanga and mātauranga Māori is crucial to Māori safety and survival. For this reason, health practitioners should be careful not to impose their understanding of tikanga or mātauranga Māori onto Māori through maternity and primary care; nor should they assume all Māori are familiar with terms such as tikanga, mātauranga and Te Tiriti o Waitangi. Unfamiliarity with such terms can be experienced by Māori as a diminishment of their mana as expressed by Te Tiriti o Waitangi; an outcome that is antithetical to Te Tiriti o Waitangi, this Companion Statement and *Ngā Paerewa*.

Health practitioners may find advice from their professional association to be helpful in terms of giving effect to the principles of Te Tiriti o Waitangi. Sources of advice may include:

- Medical Council of New Zealand: He Ara Hauora Māori: A Pathway to Māori Health Equity (Medical Council of New Zealand, 2019)
- Midwifery Council of New Zealand: Statement on Cultural Competence for Midwives (Midwifery Council of New Zealand, ND)
- Ngā Maia Turanga Kaupapa: principles that give life and meaning to the midwifery profession's recognition of Māori as tangata whenua and the profession's obligations under Te Tiriti (developed by Ngā Maia, and formally adopted by *Midwifery Council of New Zealand); see Midwives' Handbook for Practice* (New Zealand College of Midwives, ND)
- Royal Australasian College of Physicians: *Guideline commentary on consulting with Māori and their whānau* (Royal Australasian College of Physicians, ND)
- Nursing Council of New Zealand: Te Tiriti o Waitangi Policy Statement (Nursing Council of New Zealand, 2020)

Health practitioners may also find value in familiarising themselves with:

- Māuri Ora Associates: Best health outcomes for Māori: Practice implications (Medical Council of New Zealand, 2008)
- New Zealand Medical Association: Improving Māori health through clinical assessment: Waikare o te Waka o Meihana (Pitama et al., 2014)
- University of Otago MIHI 501 Health Professionals Course: Application of Hui Process and Meihana Model to Clinical Practice (The University of Otago, 2022).

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