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Recommendations for a National Policy on Vitamin D Supplementation for Infants in Ireland

Nutrition

Recommendations for a National Policy on Vitamin D Supplementation for Infants in Ireland

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FOREWORD

At a time when nutrition-related diseases, caused mainly by excess, are on the increase in Ireland, it would seem reasonable to assume that the problem of nutritional deficiency should no longer be a serious public health issue. Yet, the recent re-emergence of rickets (a severe form of vitamin D deficiency causing deformity of the bones) amongst infants in Ireland, which was thought to be eradicated at the end of the last World War, clearly demonstrates that this is not the case.

Vitamin D, which is involved in calcium metabolism and is necessary for good bone health, is primarily produced in the body via the action of sunlight on the skin. However, Ireland's northerly latitude means that vitamin D production from sunlight is severely compromised and as vitamin D is found in only a limited number of foods, dietary intakes have little impact on overall vitamin D status. Indeed, apart from the cases of rickets that have been reported, there is much evidence that sub-optimal levels of vitamin D in Ireland are widespread.

Other countries at latitudes similar to that of Ireland, e.g. Canada and the UK, have identified this problem and have long since adopted vitamin D supplementation and/or fortification policies to tackle vitamin D inadequacy. It is a matter of some urgency that Ireland joins these other countries and has in place a policy on vitamin D supplementation that is safe, unambiguous and easily implemented. Since the skeletal system is developing so rapidly in infancy, particularly in the first year of life, and rickets usually presents in early childhood, the recommendations for policy put forward by the Working Group on Vitamin D Supplementation for Infants in Ireland focus on infants aged 0-12 months.

Dr Mary Flynn
Chair, Working Group on Vitamin D Supplementation for Infants in Ireland
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EXECUTIVE SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Background

Vitamin D, a fat-soluble vitamin, is essential for good bone health. There is also accumulating evidence that it may play a role in the prevention of serious chronic diseases which affect the Irish population, including cardiovascular disease; diabetes mellitus; some inflammatory and autoimmune disorders; as well as some types of cancer.

The main source of vitamin D is synthesised in the body via the action of ultraviolet B (UVB) rays in sunlight on the skin. In addition, although to a lesser extent, some vitamin D is available from food and supplements.

Due to Ireland's northerly latitude, very little UVB light reaches the earth's surface resulting in reduced production of vitamin D, especially in winter. This fact, in conjunction with low dietary intakes, is compromising the vitamin D status of all groups of the population living in Ireland. Indeed, other countries with latitudes similar to that of Ireland, e.g. Canada, have already identified and addressed the problem of vitamin D deficiency by putting in place supplementation and/or food fortification programmes.

Although strategies to increase vitamin D intake in different age groups of the population in Ireland do need to be formulated, there is a matter of urgency amongst infants aged 0-12 months, due to the re-emergence of rickets.

Rickets, which was thought to be eradicated about 60 years ago, is a serious consequence of vitamin D deficiency which leads to major bone deformities. It would seem reasonable to assume that not all cases of rickets in this country are documented and therefore the problem may be underestimated. In addition, rickets represent the extreme end of the spectrum of vitamin D deficiency, indicating that sub-optimal levels of vitamin D are prevalent amongst infants.

This document presents evidence of poor vitamin D status amongst adults, adolescent girls and pregnant women living in Ireland. This has a direct impact on infants because the vitamin D stores infants are born with is dependent upon their mother's status. Since infants should never be exposed to sunlight, due to the risk of skin cancer, infants are entirely dependent on dietary intake for their vitamin D needs.

Dietary guidelines established in other countries such as North America (including Canada) suggest that whilst 200 International Units (IU) (5 micrograms (µg)) of vitamin D would currently be considered an adequate intake (AI) of vitamin D for infants aged 0-12 months, 400IU (10µg) per day might be preferable [1]. Whilst infant formula has some vitamin D added, exclusively breastfed infants have a very limited intake, due to the commonly low levels of vitamin D in breast milk. In addition, weaning diets of infants are usually low in vitamin D, as sources are limited to foods such as oily fish, offal, eggs, as well as some fortified margarines, milk and cereals. Therefore, regardless of whether babies are breastfed, partially breastfed or fed on infant formula during the first year of life, infants are at risk of having inadequate vitamin D intakes.

As it is necessary to adopt a clear, simple and safe recommendation, it is concluded that all infants aged 0-12 months living in Ireland would benefit from vitamin D supplementation. Although with this approach, breastfed babies would not be getting as much vitamin D as those who are fed on infant formula, breastfed babies would be getting sufficient vitamin D to prevent deficiency, whilst at the same time they would be gaining the enormous health benefits derived from breastfeeding. It is likely that vitamin D requirements of children aged 12 months to four years of age will be the next priority of the Working Group.

Before the policy of supplementing all infants with vitamin D can commence, a new supplement containing vitamin D only needs to be made available in Ireland. This is because the only currently available supplement for infants in Ireland also contains vitamin A, which when combined with infant formula, exceeds the safe upper limit of vitamin A. Once available, this new vitamin D supplement should be given to all infants aged 0-12 months.

The Working Group on Vitamin D Supplementation for Infants in Ireland provided the following conclusions and recommendations:

Conclusions

1. Ireland's northerly latitude compromises vitamin D status

As Ireland is located at latitude 51° to 55° North, little or no vitamin D can be produced from sunlight during the winter months, i.e. October to March. Although this affects all of the population of Ireland, (excluding infants who should never be exposed to sunlight) it is of particular importance to women of childbearing age and mothers: Factors which exacerbate the problem include:

- limited sun exposure due to the need to work indoors at times when UVB rays are at their peak
- the use of sunscreens which protect against skin cancer, and the lack of bare skin exposure because of clothing and cultural dress requirements
- the increasing number of dark skinned people living in Ireland who require greater amounts of ultraviolet light to produce vitamin D.

2. Low vitamin D status is widespread in Ireland

Due to the lack of sunlight vitamin D production, there is heavy reliance on dietary intakes of vitamin D to ensure adequate vitamin D intakes and status: However:

- there are only limited sources of dietary vitamin D in the form of D_3 (cholecalciferol) the most potent form of vitamin D. These include oily fish; liver; egg yolks and fortified foods such as fortified low-fat milks, cereals and margarines (it is recommended that the richest source, i.e. oily fish, be limited to no more than two portions per week for pregnant or lactating women due to heavy metal and dioxin contamination). Vitamin D_2 (ergocalciferol) is currently the predominant form of vitamin D found in supplements, although this is changing as manufacturers respond to expert advice to use cholecalciferol
- studies of Irish adults, adolescents and children show that dietary intakes of vitamin D generally fall short of the AI set by the US Food and Nutrition Board of the Institute of Medicine (1997), i.e. less than 200IU (5µg) per day [1]
- vitamin D status is inadequate in significant proportions of all the age groups from 11-75 years studied in Ireland to date
- preliminary data show that poor vitamin D status is a significant problem amongst pregnant women in Ireland [2].

3. Infants aged 0-12 months are at particularly high risk of vitamin D deficiency

Adequate vitamin D status during the rapid period of growth and development that occurs during the first 12 months of life is crucial for the healthy development of the skeletal system.

- Rickets, (a result of severe vitamin D deficiency), which was generally considered to be eradicated, has recently re-emerged as a public health problem in Ireland.
- All infants are at risk of vitamin D deficiency due to the fact that they obtain just 50-60% of their mother's vitamin D stores at birth. Infants are dependent on maternal vitamin D status which has been found to be low in Ireland.
- Breast milk is commonly low in vitamin D (25IU/litre).
- As infant formula has vitamin D added to take account of this high-risk group, exclusively breastfed babies who are not supplemented with vitamin D are at a greater risk of vitamin D insufficiency.
- Particular attention should be paid to dark skinned infants who are at an increased risk of vitamin D deficiency.
- From six months onwards, vitamin D status is also dependent upon the adequacy of weaning diets.

4. **A new vitamin D supplement that is suitable for all infants aged 0-12 months needs to be made available**

- There is a need to develop a clear policy of vitamin D supplementation for infants.
- A vitamin D supplement providing 200IU (5µg) of vitamin D per day should be provided to all infants from 0-12 months regardless of how they are fed.
- The only vitamin D supplement for infants currently available on the Irish market (Abidec) includes vitamin A, and, when combined with more than 500ml of infant formula, use of this supplement would exceed tolerable upper limits for vitamin A intake.
- Therefore, a supplement containing only vitamin D needs to be made available for use in Ireland, possibly in the form of D_3 (cholecalciferol) which may be more potent than D_2 (ergocalciferol).
- This new supplement will need to be in a suitable format for infants aged 0-12 months.
- The new supplement has to be accessible to all infants, and potential barriers to implementation of the recommendations such as cost and cultural issues need to be addressed.
- Whilst a new supplement of vitamin D is being made available, a safe interim measure is needed to prevent severe vitamin D deficiency (rickets) which recommends that breastfed babies are supplemented with Abidec.
- Partially breastfed babies can also be supplemented with Abidec safely providing they consume no more than 500ml infant formula daily.

5. **Communication of the recommendations to both the general public and health professionals should be targeted and clear**

- Involvement of key target groups, such as health professionals, ethnic minority representatives, and the general public would be beneficial in helping to ensure that the recommendations are clear and well understood.
- This would also be important to help identify issues that need to be addressed to ensure implementation and compliance with recommendations on vitamin D supplementation of infants.

6. **Further working groups need to be established to address vitamin D status in other groups in Ireland**

- As vitamin D status is low in many groups of the population in Ireland, future working groups need to be established to develop policy relevant to others at risk of vitamin D deficiency.
- The groups that should be prioritised include children aged 12 months to four years of age, pregnant women and older schoolchildren.

Recommendations

1. As an interim measure until a new vitamin D_3 supplement is made available: all exclusively breastfed infants (particularly those who are dark-skinned), should be supplemented with 0.3ml of Abidec per day (providing 200IU (5μg) of vitamin D). This should start at birth and continue to 12 months of age. Partially breastfed infants should also be supplemented with 0.3ml of Abidec per day, from birth to 12 months of age, providing they do not receive in excess of 500ml of infant formula per day.

2. A supplement providing exclusively vitamin D_3 (cholecalciferol) needs to be made available for use in Ireland. This new product has to be in a suitable format for infants and also needs to be accessible to all infants; i.e. potential barriers to implementation, including the cost of the supplement and cultural issues need to be addressed.

3. Irrespective of how they are fed, all infants in Ireland should be given this new supplement so that they receive a minimum of 200IU (5μg) of vitamin D every day from birth to 12 months of age.

4. Further working groups should be established to develop recommendations to improve vitamin D status in other population subgroups, with priority given to toddlers and pre-school children, pregnant women and older schoolchildren.

5. Health professionals and parents need to be made aware that vitamin D deficiency is prevalent in Ireland, particularly among dark-skinned infants and young children.

1. INTRODUCTION

1.1 Background

European recommended daily allowances of vitamin D need to be updated, including the current recommendation for dietary vitamin D intakes in adults and children in Ireland (0-400 International Units (IU) or 0-10 micrograms (μg)/day) [3]. A substantial amount of data on vitamin D status are already available from studies conducted in Ireland showing that vitamin D deficiency is a problem. Ongoing research will provide further data to better inform the process of updating recommendations [4].

Ireland's latitude is similar to that of Canada, and in 1997, under a joint United States-Canadian initiative, the Food and Nutrition Board of the Institute of Medicine in the United States, updated their recommendations on vitamin D [1]. Their reference intakes, collectively known as Dietary Reference Intakes (DRI's) set an Adequate Intake (AI) recommendation for infants aged 0-12 months of 200 IU/day (5μg/day). For the purposes of this report, data presented on dietary intakes will be compared to 200IU (5μg) per day.

Whilst the revision of recommended intakes of vitamin D is awaited, there is some urgency in addressing the issue of vitamin D status amongst infants in Ireland:

- **Ireland's latitude and its' impact on vitamin D status**
  The most important source of vitamin D, produced from the action of sunlight on the skin, is severely compromised by Ireland's geographic location and the ineffectiveness of the sun's rays in synthesising sufficient vitamin D to maintain adequate status. To compound the problem, there is much evidence that people in Ireland of all ages, lack sufficient dietary vitamin D to compensate, and sub-optimal vitamin D status is widespread. Infancy is a vulnerable period, when growth is occurring at an increased rate. Sub-optimal vitamin D status in infancy has long-term implications for bone health throughout the life-cycle [5,6,7].

- **The re-emergence of rickets In Ireland**
  Rickets, a condition affecting the skeletal system, is the result of severe and prolonged vitamin D deficiency in infancy. The process which leads to mineralisation of the bone is impaired and rigidity is adversely affected. Children with rickets may have bowed arms and legs, they may have delayed closure of the fontanels (soft spots) in the skull and the rib-cage may become deformed due to the pulling action of the diaphragm.

Rickets was, to a great extent, eradicated in Europe just after the Second World War, although sporadic cases occur from time to time. Alarmingly, there are now documented reports of an increase in the number of nutritional rickets among children in Ireland. Over the last four to five years, there have been reports of up to 20 cases of rickets, among infants and toddlers attending two paediatric hospitals in Dublin [8]. It is likely that these numbers underestimate the true prevalence of rickets.

Nutritional rickets represents the extreme end of the spectrum of vitamin D deficiency, indicating a likely higher incidence of undiagnosed vitamin D deficiency in the wider paediatric population in Ireland.

It is against this background that the Working Group on Vitamin D Supplementation for Infants in Ireland was convened. The Working Group was tasked with providing specific recommendations on vitamin D in infancy. At a later date, it is expected that the vitamin D needs of other "at-risk" groups such as pregnant women and children aged 12 months to four years will be addressed.

2. VITAMIN D – METABOLISM AND FUNCTIONS

Key Conclusions

- The main source of vitamin D is produced from the action of sunlight on the skin.
- Vitamin D is found to a lesser extent from a limited number of foods in the diet and from supplements.
- A serious consequence of vitamin D deficiency is rickets, which has re-emerged as a problem in Ireland recently.
- Accumulating evidence also suggests that vitamin D may play a role in the prevention of other serious public health problems such as cardiovascular disease, diabetes mellitus and some types of cancer.

2.1 Metabolism of Vitamin D

Vitamin D is a fat-soluble micronutrient which plays a vital role in bone health, via its regulation of calcium metabolism.

It is produced by the body primarily when the skin is exposed to ultraviolet B (UVB) light although it can also be obtained from a limited number of foods and dietary supplements.

Briefly, on exposure to Ultraviolet B light (290-320nm), vitamin D is synthesised in the cell membranes of skin from cholesterol. Vitamin D from dietary sources such as oily fish, e.g. pilchards, sardines and tuna, liver, egg yolks, fortified foods (margarine, breakfast cereals, and milk), and vitamin D in synthetic form, found in supplements, enter the circulation after absorption from the gut.

Once either produced in the skin or absorbed from the gut, vitamin D is transported first to the liver, and then to the kidney, where it is metabolised into the biologically active form of vitamin D. One of the main functions of this form of vitamin D is to maintain an adequate concentration of calcium in the blood (see Appendix 1 for further detail on the metabolism of vitamin D).

The form of vitamin D produced by the skin and found in foods is known as vitamin D_3 (cholecalciferol), and the form usually found in supplements is known as vitamin D_2 (ergocalciferol). There is some evidence from human studies that cholecalciferol may be more potent compared to ergocalciferol [9,10,11].

2.2 Consequences of Vitamin D Deficiency

If the supply of vitamin D is restricted, bone becomes the main target organ for calcium release, which leads to increased bone turnover and risk of bone loss in the long term. It is well established that prolonged and severe vitamin D deficiency leads to rickets in children and osteomalacia in adults.

Less severe vitamin D deficiency, sometimes referred to as mild or marginal or vitamin D insufficiency, may increase bone turnover and contribute to osteoporosis [12,13].

There is also growing concern that low vitamin D status may contribute to a range of chronic diseases, e.g. hypertension, cardiovascular diseases, diabetes mellitus, some inflammatory and autoimmune diseases and some forms of cancer, which pose serious public health problems in Ireland as well as in other Western countries [12,14,15,16].

3. FACTORS AFFECTING SUNLIGHT PRODUCTION OF VITAMIN D

Key Conclusions

- Ireland's northerly latitude means that the synthesis of vitamin D from sunlight is compromised.
- Other factors which further hinder the synthesis of vitamin D include: lack of exposure to sunlight due to time spent indoors and clothes which cover the skin; sunscreen use and dark skin which takes longer to manufacture vitamin D.

3.1 Introduction

The skin is physiologically designed to manufacture vitamin D, and given the optimal conditions, the action of sunlight on the skin would provide most of the vitamin D needed by the body. However, the amount of vitamin D synthesised in skin over a given period of sun exposure, e.g. ten minutes, is determined by:

- latitude
- skin pigmentation
- sunscreen use
- exposure of bare skin

as well as other factors such as age, time of day and altitude. Some of these factors, act as barriers to the dermal synthesis of vitamin D, thereby diminishing vitamin D status.

3.2 Latitude

During the winter months from October to March, at latitudes of greater than 42° North, little or no vitamin D can be produced from sunlight [17]. This is due to the inadequate quality and quantity of sunlight that reaches the earth's surface [15,18] and it means that the populations of a large portion of North America, Canada, Europe, Asia, the southern tip of South America and New Zealand rely on body stores and dietary vitamin D for one third to one half of the year to maintain normal vitamin D status.

Ireland, at latitude 51 to 55° North (see Figure 1.), is one of the countries which is heavily reliant on body stores and diet to maintain vitamin D status for six months of the year. Unfortunately, evidence shows that most population sub-groups in Ireland have failed to achieve the US DRI of 200IU (5µg) per day.

3.3 Skin Pigmentation

Dark skin requires much longer exposure (10-50 times longer) than light skin to manufacture an equivalent amount of vitamin D [15]. Therefore, people with darker skin have greater difficulty in obtaining vitamin D from the sun.

3.4 Sunscreen Use

Historically, it was believed that adequate sun exposure in summertime ensured that sufficient stores of vitamin D were laid down to offset the wintertime sunlight deficit. However, to reduce the risk of sun damage and skin cancer, people are strongly advised to use sunscreen on exposure to direct sunlight. To help protect the skin against sun damage, Skin Protection Factor (SPF) is commonly added to cosmetics. A sunscreen with a SPF of 15, used appropriately, can reduce the capacity of dermal vitamin D synthesis by more than 98%, which means that dietary intake of vitamin D is of increased importance.

As sun exposure is a risk factor for skin cancer, it is not recommended to expose infants to sunlight for the purpose of synthesising vitamin D.

3.5 Exposure of Bare Skin

Adults usually wear clothes that conceal most of the skin's surface and in addition, some cultural and religious practices preclude any skin exposure when outdoors. For example, some Muslim women wear full Islamic dress, covering head, arms and legs, whilst others may wear a burkha, which also covers the face.

Most adults work long hours indoors all year round, and miss the opportunity to spend time outdoors during the middle of the day when UVB rays are at their peak. Therefore, even in summertime, most adults in Ireland are not regularly exposed to the sun.

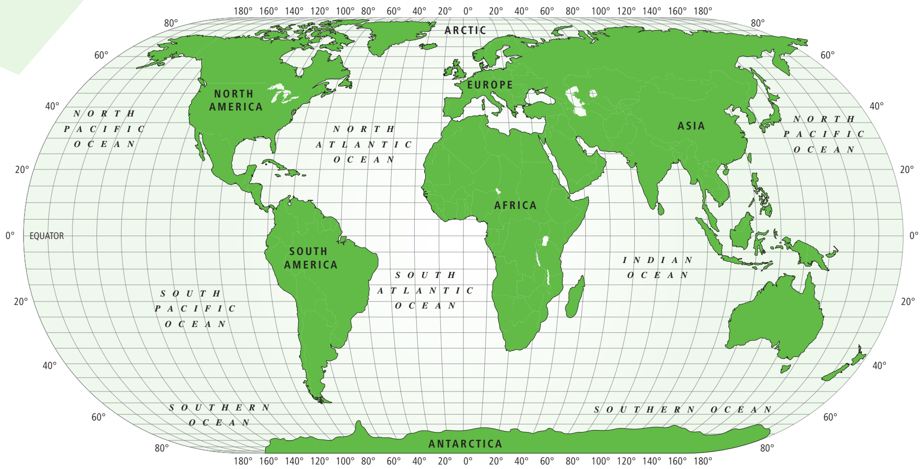
3.6 Increased Dependence on Dietary Vitamin D Intakes

The body stores of vitamin D that have accumulated by late-September/early-October (from summer sun) are lost quite rapidly [1, 18]. There is therefore increased dependence on dietary intake to maintain vitamin D status during winter.

It has been possible to assess the impact of complete lack of sunlight upon vitamin D status via studies of between 26 and 30 sailors who toured on submarines [19]. It has been found that vitamin D status (as measured by circulating 25-hydroxyvitamin D (25-OH D) levels) is reduced by up to 38% after approximately two months without any exposure to sunlight even when the sailors have consumed a diet that includes fortified milk and breakfast cereals [19]. These data highlight the difficulty in obtaining sufficient vitamin D from the diet.

Since the usual dietary intake of Northern Europeans is not sufficient to maintain adequate vitamin D levels, especially during the winter, inadequate vitamin D status during winter time is quite common in young, adolescent, adult and elderly subjects in Ireland, the UK and other Northern European countries [12,20,21,22,23,24,25,26,27]. In Britain, supplements are recommended during winter months to achieve adequate vitamin D status in preschool children especially in high-risk groups [28].

Figure 1. Map of the World by Latitude



4. VITAMIN D INTAKES AND STATUS OF THE GENERAL POPULATION LIVING IN IRELAND

Key Conclusions

- People of all ages living in Ireland have inadequate intakes of vitamin D, i.e. less than 200IU (5µg) per day, which is the recommended US Adequate Intake (AI) [1].
- Studies in Ireland also reveal that low vitamin D status and vitamin D deficiency are widespread in the population of Ireland.
- Of particular relevance to infants is the evidence which shows that women of childbearing age and adolescent girls (future potential mothers) have inadequate vitamin D intakes and low vitamin D status.

4.1 Introduction

Vitamin D status is dependent mainly on the contribution of sunlight to the synthesis of vitamin D and, to a lesser extent, on dietary intakes of vitamin D.

Chapter 3 has already outlined the reasons for the limited capacity of sunlight to provide enough vitamin D to meet the requirements of the population in Ireland.

The following section summarises the evidence which shows that adults, adolescents and children in Ireland have great difficulty in obtaining sufficient vitamin D from their diet and the widespread occurrence of vitamin D deficiency (as measured by circulating levels of 25-hydroxyvitamin D (25-OHD)).

Of particular importance is the poor vitamin D status of adolescent girls, who are the potential mothers of the future. Poor vitamin D status among young adults also has relevance to this report on infants, in so far as it impacts upon maternal nutrition, which in turn influences infant vitamin D status.

4.2 Vitamin D Intakes

There are very few natural sources of vitamin D that are commonly consumed in the UK and Ireland (see Section 2.1). Studies of adults in Ireland have found that in general, men and women aged 18-76 years have mean daily intakes of less than 5µg/day of vitamin D from both foods and supplements [12,27,29]. It has also been found that both adolescent girls and primary school children have mean daily intakes of about 2µg per day from food only, which is well below the US AI of 200IU (5µg) per day for these age groups [27,30]. A small number of schoolchildren aged 5-12 years who managed to achieve an adequate intake of 5.6µg per day, did so using supplements containing vitamin D. Therefore, Irish schoolchildren are at risk of low vitamin D status, particularly in winter.

Table 4.1. The Percentages of Children (classified as non-users and users of vitamin D-containing supplements) that had Mean Daily Vitamin D Intakes Below 10, 5 and 1μg per Day

Intake Vitamin D (μg/day)	% All (n = 594)	% Non-Users of D-Containing Supplements	% Users
<10	*98*	*100*	*92*
<5	*88*	*98*	*44*
<1	*34*	*42*	*1*

Source: [30]

4.3 Vitamin D Status

There is much debate in the literature on appropriate cut off levels for defining vitamin D deficiency (see Appendix 2). For the purpose of this report, circulating levels of 25-hydroxyvitamin D (serum 25-OH D, the biomarker of vitamin D status) below 25 nmol/l are regarded as deficient and below 50nmol/l are considered inadequate or low.

In Irish studies of postmenopausal women aged 51-75 years, it has been found that up to 48% of women have low levels of vitamin D during winter [31], and approximately 4% have low levels of vitamin D during summer [32]. Vitamin D supplementation was associated with improved vitamin D status, even during summer time [32].

Table 4.2. shows data from an Irish study [12] of females aged 11 years to 75 years. Up to 55% of adolescent girls had low levels of vitamin D and 30% were deficient in the winter months. Thirty-five percent of women aged 23-50 years also had low levels of vitamin D.

Table 4.2. Percentage of Females Classified as Vitamin D Adequate or Deficient According to Serum Vitamin D Cut-off Levels

Serum Vitamin D Cut Off (nmol/l)	August/September 2002				February/March 2003			
	11-13y	23-50y	51-69y	70-75y	11-13y	23-50y	51-69y	70-75y
12.5-25	*0*	*0*	*0*	*0*	*30*	*0*	*2*	*17*
25-50	*9*	*4*	*16*	*19*	*55*	*35*	*32*	*47*
>50	*91*	*96*	*84*	*81*	*15*	*65*	*66*	*36*

Source: Adapted from [12]

Similarly, it was found that 20% of a group of older Irish women aged 70-76 years living independently, and just 1% of a sample of Irish adolescent girls had low serum vitamin D levels in summer [27]. However, in winter, the problem became more pronounced with 37% of older women and 47% of the adolescent girls having low levels.

More emerging evidence of low vitamin D status in many population subgroups, including young adults and adolescents [33, 34] suggests that strategies to increase vitamin D intakes, including fortification of food, should be investigated. Table 4.3. shows the current food fortification and supplementation programmes already in place around the world. Most countries, in the absence of a food fortification policy have at least a supplementation programme for infants.

Table 4.3 Countries With Vitamin D Supplementation and/or Mandatory Vitamin D Fortification Policies

Geographical Region	Recommended Vitamin D Supplementation Level per Day for Breastfed Infants	National Vitamin D Food Fortification Policy	Level of Fortification
North America			
Canada	*400IU (10μg) all year 800IU (20μg) in winter for high-risk infants Supplementation should be discontinued when receiving 400IU (10μg) from other dietary sources or when breasted infant reaches one year*	*Whole milk Skimmed and partly skimmed milk*	*300 – 400IU/L per reasonable daily intake 300 – 400IU/L 0.3 – 0.4IU/ml 7.5 – 10μg/L*
United States of America	*200IU (5μg) beginning during the first two months of life for: - all breastfed infants unless they are weaned to 500ml per day of vitamin D fortified formula or milk - all non-breastfed infants who are ingesting less than 500ml per day of vitamin D fortified formula or milk*	*Enriched farina Enriched macaroni products Enriched noodle products Enriched vegetable macaroni products Enriched vegetable noodle products Enriched corn meals Enriched rice Fortified nonfat dry milk (reconstituted) Evaporated milk*	*≥550IU/kg 550 – 2200IU/kg 550 – 2200IU/kg 550 – 2200IU/kg 550 – 2200IU/kg 550 – 2200IU/kg 550 – 2200IU/kg 425IU/kg 845IU/L (21.1μg/L)*

Geographical Region	Recommended Vitamin D Supplementation Level per Day for Breastfed Infants	National Vitamin D Food Fortification Policy	Level of Fortification
South America			
Brazil		*Dried skimmed milk for complementary food programmes*	*2000 – 2400IU/kg*
Guatemala		*Skim milk*	*400 – 600IU/L (10 – 12.5µg/L)*
Honduras		*Milk*	*400IU/L (10µg/L)*
Mexico		*Milk (pasteurised, ultra-pasteurised, sterilised, powder)*	*200 – 300IU/L (5 – 7.5µg/L)*
Venezuela		*Milk powder*	*400IU/L (10µg/L)*
Europe			
Austria	*400IU (10µg) during first 12 months*		
Bulgaria	*800IU (20µg)*		
Estonia	*400IU (10µg) for 0 – 2 years*		
Finland	*400IU (10µg) for 0 – 3 years*	*Milk and fluid milk products, lactose free milk, soy and cereal based fluid products, e.g. rice/oat drinks*	*200IU/100g (5µg/100g)*
France	*1000IU (25µg) – 1200IU (30µg) add 400IU (10µg) in children with dark skin*		
Germany	*D-fluorette in first few months of life*		
Iceland	*Infants from one month of age receive a vitamin A and D product; 400IU (10µg) vitamin D per day until school going age*	*Some reduced fat milks are voluntarily fortified. There is no mandatory fortification 1.5% fat milk 0.3% fat milk*	*20IU/100g (0.5µg/100g) 15.2IU/100g (0.38µg/100g)*

Geographical Region	Recommended Vitamin D Supplementation Level per Day for Breastfed Infants	National Vitamin D Food Fortification Policy	Level of Fortification
Europe			
Norway	*Cod liver oil from four weeks of age. Increase from 2.5ml (200IU/5µg) to 5ml (400IU/10µg) during the first six months. From the age of six months 5ml cod liver oil is recommended daily. Children and infants not getting cod liver oil should instead be supplemented with vitamin D droplets*		
Romania	*400IU (10µg)*		
Sweden	*400IU (10µg) for up to two years old*	*Restoration of vitamin D to milk with fat content of 1.5% or lower*	*3.8 – 5.0IU/L (0.1 – 0.13µg/L)*
The Netherlands	*400 – 600IU (10 – 15µg) from two weeks for exclusively breastfed infants 400 – 600IU (10-15µg) from six months to four years unless infant is receiving a follow on formula, infant formula or a combination of both*		

Geographical Region	Recommended Vitamin D Supplementation Level per Day for Breastfed Infants	National Vitamin D Food Fortification Policy	Level of Fortification
United Kingdom	*Healthy Start scheme for families on income support: 300IU (7.5µg) vitamin D per day for breastfed babies aged six months to four years and for formula-fed babies from six months to four years who are taking <500ml formula per day. Particularly important for fussy eaters, children from Asian, African, Afro-Caribbean or Middle-Eastern backgrounds or those who live in the north of the country. Pregnant and breastfeeding women to receive 400IU (10µg) vitamin D daily.*		
Asia			
Philippines		*Filled milk, sweetened or unsweetened*	*≥973IU/L (≥24µg/L)*
Middle East			
Saudi Arabia		*Enriched wheat and enriched treated flour*	*≥551.15IU/kg*
Bahrain		*Enriched and enriched treated wheat flour*	*≥551.15IU/kg*

Table adapted from various sources: Canada [35], USA [36], South America, Asia and Middle East [37]; Austria [38], Bulgaria and Romania [39], Estonia [40], Finland [41], France [42], Germany [43], Iceland [44], Norway [45], Sweden [46], Netherlands [47], United Kingdom [48].

Please note the fortification of margarines and other butter like replacements were not included in this table as such fortification is to ensure that the butter replacements are compositionally close to butter.

5. VITAMIN D LEVELS DURING PREGNANCY, LACTATION AND INFANCY

Key Conclusions

- Rickets, the consequence of vitamin D deficiency has re-emerged as a public health problem in Ireland over the last four to five years.
- There is evidence from other countries as well as from Ireland which demonstrates that poor vitamin D status is a problem amongst pregnant women.
- Infants are dependent on maternal vitamin D status, as they have 50-60% of their mother's vitamin D stores at birth.
- Breast milk is commonly low in vitamin D, regardless of maternal vitamin D status.
- Infant formulas have vitamin D added to take into account the particular needs of infants.
- As infants should not be exposed to sunlight, (for protection against skin cancer), infants are dependent on dietary sources of vitamin D, which is difficult to obtain from most weaning diets. Therefore, all infants are at risk of vitamin D deficiency.
- Most other countries at latitudes similar to our own already have in place strategies to supplement infants aged 0-12 months with vitamin D.
- All infants in Ireland aged 0-12 months would benefit from supplementation of at least 200IU (5μg) per day of vitamin D.

5.1 Introduction

Maternal micronutrient status from the periconceptual period through lactation will have an impact on infant nutrition [49]. Vitamin D is of particular relevance, as marginal status is widespread in the general population.

It is known that metabolites of vitamin D can cross the placenta, and infants at birth typically have circulating vitamin D levels that are only approximately 50-60% of maternal levels [50]. Newborns are therefore afforded limited protection from vitamin D deficiency during the first few weeks of life. Infants are at particular risk of sub-optimal vitamin D status if there is maternal deficiency resulting in inadequate placental transfer (Appendix 3 provides detail of vitamin D metabolism during pregnancy and lactation).

The potential long term effects of vitamin D insufficiency at the crucial stages of development between birth and six months are currently being investigated. What is known is that rickets, which were thought to be a feature of the past, have recently been observed in young children in Canada [51] and the US [52] as well as in Ireland, and that vitamin D deficiency is increasingly common in breastfed infants who do not receive supplemental vitamin D, particularly in winter [53].

Tables 5.1. and 5.2. describe the profiles of ten infants with rickets at a national children's hospital in Dublin from 2000 to 2005 [8]. The age at which rickets is most common is between three and 18 months, and the established risk factors are:

- exclusive breastfeeding without vitamin D supplementation
- low maternal vitamin D status
- low calcium intakes
- living in temperate climates and
- dark skin.

The infants described in Tables 5.1 and 5.2 include children with dark-skin, fair-skinned children born in winter [8] and those who were exclusively breastfed.

Table 5.1. Demographic Profile, Diet and Serum Indicators of Nutritional Rickets Amongst In-patients of Less than 12 Months of Age Admitted to a National Children's Hospital between the Years 2000 to 2005

No.	Ethnic Group	Sex	Age (mo)	Diet	Child Serum Vitamin D (nmol/l)	Mother Serum Vitamin D > 50 Oct – May > 70 Jun – Sep
1	*Black – Kenya*	*F*	*5*	*Exclusively breastfed*	*1.5*	*26.9*
2	*Caucasian – Caribbean*	*M*	*11*	*Breastfed for eight months Vegan and rice milk*	*N/A*	*N/A*
3	*Black – South Africa*	*F*	*4*	*Exclusively breastfed*	*3.9*	*N/A*
4	*Black – African*	*F*	*4*	*Exclusively breastfed*	*6.8*	*26.0*

Sex: F – female, M – male, N/A – not available/analysed

Source:[8]

Table 5.2. Demographic Profile, Diet and Serum Indicators of Nutritional Rickets Amongst In-patients of Greater than 12 months of Age Admitted to a National Children's Hospital between the Years 2000 and 2005

No.	Ethnic Group	Sex	Age (mo)	Diet	Infant Serum Vitamin D (nmol/l)	Mother Serum Vitamin D > 50 Oct – May > 70 Jun – Sep
5	*Black – African*	*M*	*27*	*Exclusively breastfed for eight months dairy free allergies*	*7.7*	*36.1*
6	*Black – African (Burkha)*	*F*	*29*	*Breastfed for one year 300ml cows milk/day and mixed diet*	*8.5*	*N/A*
7	*Black – Libyan (Burkha)*	*M*	*24*	*Breastfed twice per day and mixed diet*	*20.6*	*10.4*
8	*Black – Nigerian*	*F*	*13*	*Exclusively breastfed for four months Mixed low calcium diet Cows milk and breastfed from ten months*	*6.1*	*15.1*
9	*Black – Sudan*	*M*	*18*	*Breastfed five times per day Allergy to dairy and poor diet*	*8.5*	*N/A*
10	*Caribbean – Irish*	*M*	*24*	*Exclusively breastfed for eight months Vegan diet*	*48.9*	*N/A*

Sex: F – female, M – male, N/A – not available analysed

Source: [8]

5.2 Vitamin D Status During Pregnancy

There is evidence that vitamin D deficiency is widespread during pregnancy [54,55]. Immigrant subgroups to countries in the northern hemisphere [56] and their breastfed infants [57] have also been found to have vitamin D deficiency. This is of significance in Ireland as there has been a relatively recent increase in the immigration of people from places such as Asia, Africa and the Middle East.

It has been found that between 59 and 84% of women of non-European origin living in The Hague, Netherlands, (a country with a more southerly latitude than Ireland) had very low levels of serum 25-hydroxyvitamin D during their 12th week of pregnancy [58]. However, even in a sunny country like Greece, low levels of vitamin D in mother/cord pairs have been reported and it has been noted that vitamin D status is problematic during pregnancy [59].

In a recent review of the literature, it was found that 35 out of 76 studies reported deficiency of vitamin D amongst pregnant women [60]. The countries where deficiency was reported included: North America, Europe, the UK, Africa, the Middle East and Asia. This provides compelling evidence that low vitamin D status in pregnant women is endemic in many parts of the world, regardless of race.

Evidence is steadily accumulating that vitamin D deficiency during pregnancy is a significant problem in Ireland. Preliminary data from a study of 265 women, 90% of whom were Irish, attending antenatal services in Cork city between 2004 and 2006 [2] show that the prevalence of vitamin D deficiency (serum 25(OH)D<25nmol/L) in women during winter (November-March) was 24% and during summer (April-October), when deficiency would not be expected, was 17%. The prevalence of low levels of vitamin D (25(OH)D<50 nmol/l) in women was 77% during winter and 68% during summer. Vitamin D status was lower in women during their third trimester, regardless of season. This is to be expected due to the increase in blood volume during pregnancy, which dilutes serum biomarkers, as well as the increased metabolic demand for vitamin D. These data show that compared to international data, pregnant women in Ireland are very vulnerable to low vitamin D status regardless of season or ethnicity [2].

In summary, pregnant women in Ireland, like their non-pregnant counterparts, are at high risk of low vitamin D status. Due to Ireland's geographic position, this risk is heightened during the months from November to April. Groups at further risk are dark-skinned women and women whose dietary practices mean that their intakes of vitamin D and calcium are low.

5.3 Factors Affecting Vitamin D Status in Infancy

Even when mothers have optimal vitamin D status, newborns will have no more than about 50-60% of their mother's vitamin D stores at birth. They will therefore only have limited protection against deficiency and will need to obtain adequate intakes of vitamin D from dietary sources, as infants should never be exposed to sunlight.

Children born to mothers who have low vitamin D status (and evidence suggests that this is a widespread occurrence) will have low vitamin D status themselves, and will be at even further risk of rickets from the start. Risk factors for very low vitamin D status in mothers are dark skin, immigration to northerly countries with comparatively long winters, limited sun exposure and vegetarianism [61].

There is no doubt that breast milk is the optimum food for babies between birth and six months. However, exclusively breastfed babies are more vulnerable to low vitamin D status, as infant formula is fortified with vitamin D to take account of the need to supplement this age-group. A Greek study on vitamin D status, recently concluded that babies exclusively breastfed during the first six months are in need of vitamin D supplementation irrespective of the season, even in a sunny country where foods are not supplemented [62].

Even when breastfeeding mothers are not deficient in vitamin D themselves, and assuming that many breastfeeding mothers are more "health conscious" and therefore likely to have good diets, it is recognised that breast milk contains low levels of vitamin D, i.e. approximately 25IU per litre [63]. The Food and Agriculture Organisation (FAO) of the United Nations and the World Health Organization (WHO) [64] have noted that breastfed infants are particularly at risk of vitamin D deficiency because of the low concentrations of vitamin D in breast milk

However, all infants aged 0 -12 months would benefit from having extra vitamin D as foods containing vitamin D are rarely included in weaning diets [17]. Other countries on a latitude similar to Ireland (UK, Canada) and even those who are more southerly (Netherlands, United States) have already recognised and dealt with the problem of vitamin D deficiency in infants by recommending supplementation programmes (see Table 3).

In summary, all infants in Ireland are potentially at risk of having low vitamin D status due to the period of rapid growth, our geographic position and to various combinations of factors that adversely affect vitamin D intake and status amongst women and children.

A recommendation to increase vitamin D intake in infants should apply to all infants aged 0-12 months irrespective of how they are fed. Supplementation to the level of 200IU (5μg) per day would ensure that all infants would be receiving at least the Adequate Intake (AI) recommended by the US Food and Nutrition Board of the Institute of Medicine (IOM), and this would be sufficient to prevent vitamin D deficiency, although an intake of up to 400IU (10μg) per day would be more ideal.

With this recommendation, breastfed babies will not be provided with as much vitamin D as those who are fed on infant formula. However, breastfed babies will be getting sufficient vitamin D to prevent deficiency, whilst at the same time they will be gaining the enormous health advantages derived from breastfeeding.

6. CONSIDERATIONS IN RECOMMENDING A SUPPLEMENT

Key Conclusions

- A supplement for use in infants aged 0-12 months in Ireland that contains vitamin D only needs to be made available.
- Use of currently available multi-vitamin supplements to obtain 200IU (5µg) of vitamin D would not be safe, as there is a risk of exceeding the tolerable upper limits for vitamin A when taken in combination with 500ml or more per day of infant formula.
- The cost of a new vitamin D supplement needs to be addressed to ensure that it does not pose a barrier to implementation of the recommendations.

6.1 Introduction

Before deciding on recommendations to supplement infants, the issue of safety needs to be addressed. Since infant formula is used to a great extent in Ireland, consideration needs to be given to the effects of a combination of a vitamin D containing supplement with infant formula.

There is a need for a new supplement which would be suitable for all infants aged 0-12 months containing vitamin D only in Ireland. Other supplemental forms of vitamin D such as cod liver oil or other preparations which also contain vitamin A would be unsuitable, as the combination of these with infant formula would exceed tolerable upper limits for vitamin A (see Appendix 4 for supplements available in other countries).

6.2 Infant Formula Composition and Content of Currently Available Vitamin D Supplements

Infant formulas have vitamin D already added. The average vitamin D content per 100ml for infant formula is 1.3µg and for follow-on formula is 1.5µg. Appendix 5 shows the quantity of formula that needs to be consumed to obtain between 200-500IU (5-12.5µg) of vitamin D.

Currently there is only one vitamin D supplement on the Irish market (Abidec) that is suitable for infants and this is in multi-vitamin format (see Table 6.1). This supplement (Abidec) provides 200IU (5µg) vitamin D at the recommended dosage for infants of 0.3ml. The UK supplement (Brand B) recommended dose for infants is 0.14ml and this provides 300IU (7.5µg) of vitamin D along with vitamins A, B, and C (see Table 6.1).

Table 6.1. Composition of Abidec Supplement (Ireland) and Brand B Supplement (UK)

Recomm-ended Dose	A μg (IU)	D μg (IU)	Thiamin (B_1) (mg)	Riboflavin (B_2) (mg)	Pyridoxine HCL (B_6) mg	C (mg)	Niacina-mide (mg)
Abidec (Ireland)							
0.3ml (0-1yr)	*200μg (666.5IU)*	*5μg (200IU)*	*0.2*	*0.4*	*0.4*	*20*	*4*
Brand B (UK)							
0.14ml (5 drops)	*233μg (776.7IU)*	*7.5μg (300IU)*				*20*	

6.3 Safety of Multi-vitamin Supplements When Combined With Infant and Follow-on Formula

There is an issue concerning safety when infant formulas are combined with the currently available multi-vitamin supplements containing both vitamins A and D.

Vitamin A intakes do exceed Tolerable Upper Intake Levels when an infant consumes more than 500ml of infant formula and follow-on formula (see Tables 6.2. and 6.3.) in addition to either of the multi-vitamin infant supplements available in Ireland and the UK (Abidec and Brand B). This means that partially breastfed babies who are consuming no more than 500ml of infant formula per day can safely take these supplements.

Appendix 6 provides data on the intakes of vitamins D and A provided by various levels of infant and follow-on formula (at minimum and maximum levels of formula fortification) when combined with 0.3ml Abidec or 0.14ml Brand B. These data show that in the case of both supplements at their recommended dosage for infants, there are no concerns about exceeding the tolerable upper limit for vitamin D even if the infant consumes large quantities (1,000ml) of formula.

Table 6.2. Proportion (%) of Tolerable Upper Levels for Vitamins D and A when Supplements are Combined with Infant Formula at Intakes of 200ml, 500ml, 700ml, 800ml and 1,000ml

	European Tolerable Upper Level for Vitamin D of 25μg*				North American Tolerable Upper Level for Vitamin D of 25μg**			
	Vitamin D with Abidec		Vitamin D with Brand B		Vitamin D with Abidec		Vitamin D with Brand B	
Infant formula	Min. Vit. D	Max. Vit. D	Min. Vit. D	Max. Vit. D	Min. Vit. D	Max. Vit. D	Min. Vit. D	Max. Vit. D
200ml	*29%*	*32%*	*39%*	*42%*	*29%*	*32%*	*39%*	*42%*
500ml	*42%*	*50%*	*52%*	*60%*	*42%*	*50%*	*52%*	*60%*
700ml	*51%*	*62%*	*61%*	*72%*	*51%*	*62%*	*61%*	*72%*
800ml	*55%*	*68%*	*65%*	*78%*	*55%*	*68%*	*65%*	*78%*
1,000ml	*64%*	*80%*	*74%*	*88%*	*64%*	*80%*	*74%*	*88%*
	European Tolerable Upper Level for Vitamin A not established*				**#North American Tolerable Upper Level for Vitamin A of 600μg****			
	Vitamin A with Abidec		**Vitamin A with Brand B**		**Vitamin A with Abidec**		**Vitamin A with Brand B**	
Infant formula	**Min. Vit. A**	**Max. Vit. A**	**Min. Vit. A**	**Max. Vit. A**	**Min. Vit. A**	**Max. Vit. A**	**Min. Vit. A**	**Max. Vit. A**
200ml					*51%*	*59%*	*57%*	*65%*
500ml					*78%*	*98%*	*84%*	*104%*
700ml					*96%*	*124%*	*102%*	*130%*
800ml					*105%*	*137%*	*111%*	*143%*
1,000ml					*123%*	*163%*	*129%*	*169%*

Note: Minimum and maximum levels of vitamins D and A refer to the minimum and maximum levels of these nutrients in infant formulas on the market in Ireland in 2007, with the addition of the supplement (Abidec or Brand B).

*European – European Food Safety Authority (EFSA) [65]

**North American Institute of Medicine (IOM) [1]

Based on Retinol Equivalent Activity for children up to three years of age

Table 6.3. Proportion (%) of Tolerable Upper Levels for Vitamins D and A when Supplements are Combined with Follow-on Formula at Intakes of 200ml, 500ml, 700ml, 800ml and 1,000ml

	European Tolerable Upper Level for Vitamin D of 25µg*				**North American Tolerable Upper Level for Vitamin D of 25µg****			
	Vitamin D with Abidec		**Vitamin D with Brand B**		**Vitamin D with Abidec**		**Vitamin D with Brand B**	
Follow-on formula	**Min. Vit. D**	**Max. Vit. D**	**Min. Vit. D**	**Max. Vit. D**	**Min. Vit. D**	**Max. Vit. D**	**Min. Vit. D**	**Max. Vit. D**
200ml	*32%*	*35.2%*	*42%*	*45.2%*	*32%*	*35.2%*	*42%*	*45.2%*
500ml	*50%*	*58%*	*60%*	*68%*	*50%*	*58%*	*60%*	*68%*
700ml	*62%*	*73.2%*	*72%*	*83.2%*	*62%*	*73.2%*	*72%*	*83.2%*
800ml	*68%*	*80.8%*	*78%*	*90.8%*	*68%*	*80.8%*	*78%*	*90.8%*
1,000ml	*80%*	*96%*	*90%*	*106%*	*80%*	*96%*	*90%*	*106%*
	European Tolerable Upper Level for vitamin A not established*				**#North American Tolerable Upper Level for Vitamin A of 600µg****			
	Vitamin A with Abidec		**Vitamin A with Brand B**		**Vitamin A with Abidec**		**Vitamin A with Brand B**	
Follow-on formula	**Min. Vit. A**	**Max. Vit. A**	**Min. Vit. A**	**Max. Vit. A**	**Min. Vit. A**	**Max. Vit. A**	**Min. Vit. A**	**Max. Vit. A**
200ml					*56%*	*60%*	*61.5%*	*65.2%*
500ml					*90%*	*99%*	*95.5%*	*104.7%*
700ml	*European Tolerable Upper Level for vitamin A not established*				*113%*	*126%*	*118.2%*	*131.0%*
800ml					*124%*	*139%*	*129.5%*	*144.2%*
1,000ml					*147%*	*165%*	*152.2%*	*170.5%*

Note: Minimum and maximum levels of vitamins D and A refer to the minimum and maximum levels of these nutrients in infant formulas on the market in Ireland in 2007, with the addition of the supplement (Abidec or Brand B).

*European – European Food Safety Authority (EFSA) [65]

**North American Institute of Medicine (IOM) [1]

Based on Retinol Equivalent Activity for children up to three years of age

6.4 Need for a New Supplement

Appendix 6 details the various vitamin D supplements used in other countries. To ensure the safety of a vitamin D supplementation programme involving all infants aged 0-12 months, a new supplement will need to be made available which only contains vitamin D providing 200IU (5µg) per dose. It may be more beneficial to produce a supplement which contains vitamin D_3 (cholecalciferol) rather than vitamin D_2 (ergocalciferol) due to its greater potency.

6.5 Cost of a New Supplement

It is crucial that a new supplement be easily accessible and available to all infants in Ireland. To this end, it is important that the issue of cost of a new supplement be addressed in order to ensure that it does not pose a barrier to implementation of the recommendations.

6.6 Dissemination of Recommendations

Representatives from the various relevant health professional groups (public health nurses, nurses, GP's, dietitians, pharmacists) and the general public, (including bodies which represent the interests of ethnic minorities and immigrants in Ireland) need to be identified and consulted on:

- the best way to implement the policy
- appropriate methods of communication of the recommendations
- how to ensure compliance and
- how to monitor feedback on effectiveness.

APPENDIX 1. METABOLISM OF VITAMIN D

The two major physiologically relevant forms of vitamin D are vitamin D_2, known as ergocalciferol (form found in supplements) and vitamin D_3 or cholecalciferol (see Figures 2 and 3). Although the chemistry and metabolism of both D_2 and D_3 are similar, there is some evidence from human intervention studies that vitamin D_3 potency may have greater potency than that of vitamin D_2 [9,10,11].

As vitamin D and calcium are inextricably linked in human nutrition, vitamin D metabolism is viewed in the context of homeostasis. The mechanisms have been elucidated in detail elsewhere [15].

On exposure to UVB light (290-320nm), vitamin D_3 is synthesised in the skin from 7-dehydrocholesterol, a precursor of cholesterol in cell membranes. Vitamin D from foods and from supplements enters the circulation via gastrointestinal absorption.

Once either formed in the skin or absorbed from the gut, vitamin D is transported to the liver and metabolised to 25-hydroxyvitamin D (25-OH D). It is this form that is most often used as a marker to determine vitamin D status in humans. The half-life of serum 25-hydroxyvitamin D is approximately 2-3 weeks.

In response to serum calcium levels and parathyroid hormone (PTH), further metabolism of 25-OH D takes place in the kidney and other tissues to form 1,25-dihydroxyvitamin D_3 ($1,25(OH)_2D_3$), the biologically active form of vitamin D.

When serum calcium levels are reduced, $1,25(OH)_2D_3$ works to conserve calcium in the body by:

- promoting its absorption in the intestine
- inhibiting renal calcium excretion in favour of phosphate and
- mobilising calcium from bone.

When serum calcium levels return to normal, the hormone, calcitonin is released and these activities are reversed, i.e. renal excretion of calcium increases and mobilisation of calcium from bone decreases.

Figure 2 Chemical Structure of Vitamin D_2 (Ergocalciferol)

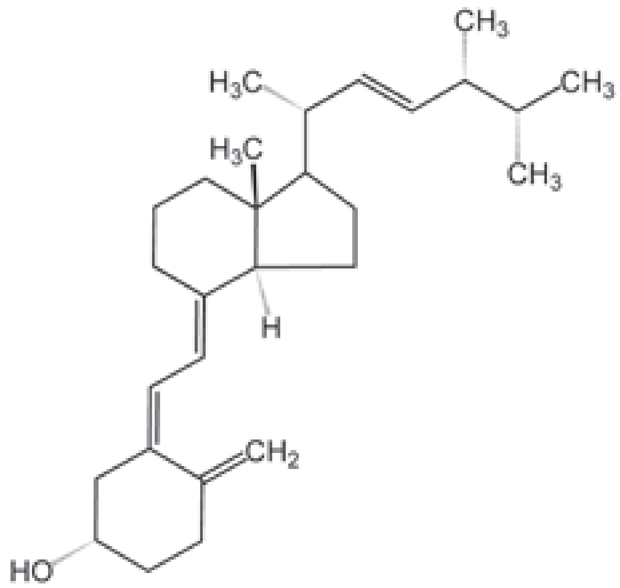
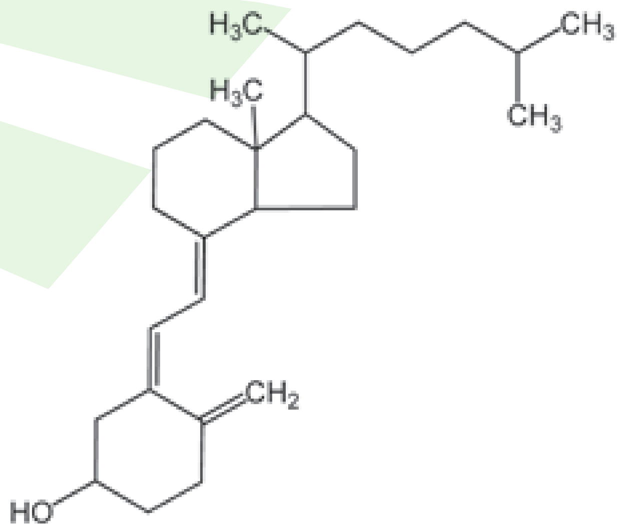


Figure 3 Chemical Structure of Vitamin D_3 (Cholecalciferol)



APPENDIX 2. CUT-OFF POINTS USED TO DETERMINE VITAMIN D DEFICIENCY (based on serum 25-hydroxy vitamin D levels)

Author	Year	Vitamin D Cut-off Points Used to Define Status			
Hill et al [12] *Lips* [66]	*2006* *2004*	*> 50nmol/ – adequate*	*25 – 50nmol/l – mildly deficient*	*12.5 – 25nmol/l – moderately deficient*	*< 12.5nmol/l – severely deficient*
Van der Meer et al [58]	*2006*	*<25nmol/l – deficient*			
Laaksi et al [67]	*2006*	*40nmol/l – insufficient*		*<25nmol/l – deficient*	
Hochberg [68]	*2003*	*<62.4nmol/l – low*			
Vieth et al [69]	*2001*	*25- 40 nmol/l – marginally deficient*		*<20-25mnol/l - severely deficient*	
Heaney [70]	*2004*	*>80nmol/l – adequate*	*20 – 80nmol/l insufficient*	*<20nmol/l-osteomalacia*	

APPENDIX 3. METABOLISM OF VITAMIN D DURING PREGNANCY AND LACTATION

During pregnancy, maternal mineral metabolism adapts to compensate for the requirements of the growing foetus, e.g. approximately 25-30g of calcium are transferred to the foetal skeleton by the end of pregnancy, much of it in the last trimester, by increased intake, enhanced gut absorption, renal conservation or mobilisation of body stores [71]. While increased bone turnover is evident from the early stages of pregnancy, there is also a marked increase in intestinal calcium absorption, from ~35% in the non-pregnant state to ~60% during the third trimester [72]. This is facilitated by a 50-100% increase in circulating 1,25(OH)2D3 over the course of the pregnancy [73], which is thought to be largely independent of PTH and in response to placental hormones that upregulate hydroxylation of 25-OH D [72,74]. This increase in $1,25(OH)_2D_3$ is a normal physiological adaptation to pregnancy in response to increased calcium requirements, however the success of the adaptation is dependent on the availability of a sufficient pool of 25-OH D and adequate dietary calcium. Low vitamin D status during pregnancy leads to secondary hyperparathyroidism and hypocalcaemia in the neonate [74]. During lactation, maternal vitamin D status is determined by the same factors as during pregnancy, or indeed in the nonpregnant state, i.e. sun exposure, skin colour, diet and supplementation. There is no evidence that lactation increases the requirement for vitamin D in the mother although there is transfer of vitamin D metabolites into breast milk [71].

APPENDIX 4. INFANT VITAMIN D SUPPLEMENTS AVAILABLE IN EUROPE

(1) Abidec multi-vitamin drops for babies and children

Available in: Ireland and the UK Price: €5.18

Method of presentation is a 1 x 25 ml bottle and 1 syringe. This quantity of Abidec equates to the following number of single daily doses ~ 42 doses at 0.6ml and ~83 doses at 0.3ml.

Abidec is an over the counter registered medicine.

Active ingredients

Age Group		**Under 1 year**	**1 – 12 years**
Dose	**Unit**	**0.3ml**	**0.6ml**
Ergocalciferol (vitamin D_2)	*IU*	*200.0*	*400.0*
	µg	*5.0*	*10.0*
Retinol (as vitamin A palmitate)	*IU*	*666.5*	*1333.0*
	µg RE	*133.3*	*266.6*
Thiamine HCL (vitamin B_1)	*mg*	*0.2*	*0.4*
Riboflavin (vitamin B_2)	*mg*	*0.4*	*0.8*
Pyridoxine HCl (vitamin B_6)	*mg*	*0.4*	*0.8*
Ascorbic Acid (vitamin C)	*mg*	*20.0*	*40.0*
Niacinamide (nicotinamide)	*mg*	*4.0*	*8.0*

Excipients
Sodium hydroxide, sucrose, polysorbate 60, nitrogen (oxygen free) and water

The vitamin A is dissolved in Arachis oil (peanut oil).

(2) Supplements used in other countries

(i) Norway

Nutrients in Möller's Tran (cod liver oil)		
Nutrients	**per 2.5ml**	**per 5ml**
Vitamin D	*5.0μg*	*10.0μg*
Vitamin A	*125.0μg*	*250.0μg*
Vitamin E	*5.0μg*	*10.0μg*
Omega-3 fettsyrer	*0.6g*	*1.2 g*
- derav DHA	*0.3g*	*0.6 g*
- derav EPA	*0.2g*	*0.4 g*
Ingredients: Tran (cod liver oil), (aromastoffer), dl-α-tokoferylacetat (vitamin E), naturlige tokoferoler (antioksidant)		

Source: [43]

(ii) Germany

D – Flourette which is a prescription medicine containing fluoride and Vitamin D 41

(iii) Iceland

There are two products on the market (Ein a dag and Multitabs) plus cod liver oil:

- Ein a dag (an Icelandic product) A,-D-vitamins drops
  1 drop = 50μg vitamin A and 2.5μg vitamin D in coconut oil

- Multitabs (a Danish product) ACD vitamins
  1 ml =300μg vitamin A, 35mg vitamin C and 10μg Vitamin D

- Cod liver oil, Lysi (an Icelandic product) - a product for children
  1ml = 50μg vitamin A, 1μg vitamin D and 0.6mg vitamin E [42]

APPENDIX 5. THE QUANTITY OF INFANT FORMULA NEEDED TO OBTAIN 200-500IU OF VITAMIN D

For infants up to the age of 12 months who are consuming infant formula, the average vitamin D content per 100ml for infant formula is 52IU (1.3µg) and for follow-on formula, 60IU (1.5µg). Please see below for the quantity of formula that needs to be consumed to obtain between 200 – 500IU (5-12.5µg) of vitamin D.

Quantity of infant formula needed to meet requirements	
To obtain:	**Need to consume (ml):**
200IU (5.0µg)	*384.6*
300IU (7.5µg)	*576.9*
400IU (10.0µg)	*769.2*
500IU (12.5µg)	*961.5*

Quantity of follow-on formula needed to meet requirements	
To obtain:	**Need to consume (ml):**
200IU (5.0µg)	*333.3*
300IU (7.5µg)	*500.0*
400IU (10.0µg)	*666.7*
500IU (12.5µg)	*833.3*

APPENDIX 6. AMOUNT OF VITAMINS D AND A PROVIDED BY INFANT FORMULA IN COMBINATION WITH MULTI-VITAMIN SUPPLEMENT

Total Amounts of Vitamins D and A Provided by Various Levels of Infant Formula (at minimum and maximum levels of formula fortification) when Combined with 0.3ml Abidec* or 0.14ml Brand B**

Levels of Infant Formula	Vitamin D in Infant Formula + 0.3ml Abidec		Vitamin D in Infant Formula + 0.14ml Brand B	
	Minimum	Maximum	Minimum	Maximum
200ml	*7.2μg*	*8.0μg*	*9.7μg*	*10.0μg*
500ml	*10.5μg*	*12.5μg*	*13.0μg*	*15.0μg*
700ml	*12.7μg*	*15.7μg*	*15.2μg*	*18.0μg*
800ml	*13.8μg*	*17.5μg*	*16.2μg*	*19.5μg*
1,000ml	*16.0μg*	*20.0μg*	*18.5μg*	*22.5μg*

Levels of Infant Formula	Vitamin A in Infant Formula + 0.3ml Abidec		Vitamin A in Infant Formula + 0.14ml Brand B	
	Minimum	Maximum	Minimum	Maximum
200ml	*308μg*	*356μg*	*341μg*	*389μg*
500ml	*470μg*	*590μg*	*503μg*	*623μg*
700ml	*578μg*	*746μg*	*611μg*	*779μg*
800ml	*632μg*	*824μg*	*665μg*	*857μg*
1,000ml	*740μg*	*980μg*	*773μg*	*1,013μg*

* 0.3ml of Abidec supplement= 200IU (5μg) vitamin D/200IU vitamin A

** 0.14ml of Brand B supplement = 300IU (7.5μg) vitamin D/233IU vitamin A

Total Amounts of Vitamins D and A Provided by Various Levels of Follow-on Formula (at minimum and maximum levels of formula fortification) when Combined with 0.3ml Abidec* or 0.14ml Brand B**

Levels of Follow-on Formula	Vitamin D in Follow-on Formula + 0.3ml Abidec		Vitamin D in Follow-on Formula + 0.14ml Brand B	
	Minimum	Maximum	Minimum	Maximum
200ml	8.0µg	8.8µg	10.5µg	11.3µg
500ml	12.5µg	14.6µg	15.0µg	17.1µg
700ml	15.5µg	18.3µg	18.0µg	20.8µg
800ml	17.0µg	20.2µg	19.5µg	22.7µg
1,000ml	20.0µg	24.0µg	22.5µg	26.5µg

Levels of Follow-on Formula	Vitamin A in Follow-on Formula + 0.3ml Abidec		Vitamin A in Follow-on Formula + 0.14ml Brand B	
	Minimum	Maximum	Minimum	Maximum
200ml	336µg	358µg	369µg	391µg
500ml	540µg	595µg	573µg	628µg
700ml	676µg	753µg	709µg	786µg
800ml	744µg	832µg	777µg	865µg
1,000ml	880µg	990µg	913µg	1,023µg

* 0.3ml of Abidec supplement= 200IU (5µg) vitamin D/200IU vitamin A

** 0.14ml of Brand B supplement = 300IU (7.5µg) vitamin D/233IU vitamin A

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