



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Policy on Vitamin D Supplementation for Infants in Ireland

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1. Purpose of this Policy

The purpose of this policy is to implement the Food Safety Authority of Ireland's (FSAI's) evidence based recommendation relating to universal Vitamin D supplementation for all infants¹ from birth to 1 year of age in Ireland. The FSAI recommendation has been endorsed by the Department of Health and Children, and the HSE, Integrated Services Directorate has been given the task of implementing it.

2. The Recommendation

It is recommended that all infants, from birth to 12 months, whether breastfed or formula fed, be given a daily supplement of 5 µg (200 IU)² vitamin D. This should be provided by a supplement containing vitamin D exclusively.

3. Background

Rickets, which was thought to have been eradicated about sixty years ago, is a serious consequence of vitamin D deficiency. Recent reports indicate an increase in the number of cases of nutritional rickets among children in Ireland.

Vitamin D deficiency in infancy has long term implications for bone health throughout the life cycle (Javaid et al, 2006, Mølgaard et al, 2003, Ward, 2005) and while the primary focus of vitamin D in infancy has been on the prevention of rickets, emerging research suggests that vitamin D may play a role in protecting against other diseases also (Grant 2002; Hayes et al 1997; Holick, 2003 & 2004; Hypponen et al, 2001; Zitterman, 2003). Studies have reported low serum vitamin D among infants and children who had no other signs of vitamin D deficiency (Lawson, 1999). The HSE policy supports a population health approach to vitamin D supplementation for all infants¹ from birth to 12 months of age.

4. Summary of Rationale for Universal Vitamin D supplementation of Infants from birth to 12 months

A daily 5 µg vitamin D supplement is recommended for all infants¹ in Ireland based on the following considerations:

- Ultraviolet B (UVB) rays in sunlight are the main source of vitamin D for humans. Ireland's northerly latitude means that between the months October to March the UVB rays required to make vitamin D are inadequate, therefore vitamin D cannot be produced;
- direct sun exposure is not recommended for infants and young children;

¹ This is a population based recommendation. Some infants who, for example, were born prematurely or who are under on-going medical care may have different vitamin requirements. The specific recommendation of their doctor should be sought and followed in these cases.

² 1 µg = 40 IU or 5 µg = 200 IU

- increasing awareness of and adherence to sun protection practices, reduces the production of Vitamin D in the skin;
- there are few dietary sources of vitamin D;
- the infant diet is low in vitamin D;
- re-emergence of rickets in Ireland.

A population health approach to vitamin D supplementation is warranted because it is neither practical nor cost-effective to screen all mothers and infants for vitamin D deficiency. Administration of a daily vitamin D supplement of 5 µg can prevent vitamin D deficiency, without risk of toxicity.

The premise for this recommendation is that the intake of 5 µg of vitamin D per day is sufficient to maintain serum 25 OH D concentrations of > 27.5 nmol/L (11 ng/ml) to prevent rickets in the majority of children (Misra et al, 2008). Even when a 5 µg vitamin D supplement is combined with infant formulas already fortified with Vitamin D there is no issue concerning safety or toxicity. Vitamin D intake does not exceed the Tolerable Upper Intake Level (UL)³ (25 µg) when 5 µg vitamin D is combined with either infant formula or follow-on formula (Appendix 1). There is no risk of toxicity for any infant either when bottle-fed or breastfed, if the correct dosage of vitamin D is administered. A dose of 5 µg vitamin D per day is just one-fifth of the Tolerable Upper Intake Level. However, it is very important to adhere to the recommended dosage as per manufacturer's instructions and product information.

Infant feeding practices in Ireland range from exclusive breastfeeding/breast milk feeding to mixed breast and artificial formula feeds to solely artificial formula feeding in early infancy with the addition of complementary foods (solids) later in infancy. Introduction of solids will not improve the intake of vitamin D and supplementation should therefore be continued. Human milk is the best source of nutrition for infants. The vitamin D content of breast milk is insufficient to meet the recommended intake of vitamin D, in the majority of mothers.

5. Target Population

This policy applies to all infants, from birth to 12 months of age, living in Ireland.

6. The Policy

Further to the evidence based recommendation of the Food Safety Authority of Ireland (FSAI) which has been adopted by the Department of Health and Children and the HSE, all infants should receive a daily vitamin supplement, providing 5 µg of vitamin D, irrespective of their diet (e.g. whether they are breastfed or formula fed or whether they are receiving solid foods) (FSAI, 2007).

The FSAI expert group further recommended that the supplement to be used should contain vitamin D alone (i.e. not in combination with other vitamins) in the form of Vitamin D₃ (ibid, 2007). Since the publication of the new recommendation a number of infant vitamin D only supplements have become available on the Irish Market (others may become available at a later date). The FSAI has informed the HSE of the current available vitamin D supplements suitable for infants on the Irish market and this list can be found on www.hse.ie. These

³ **The European Tolerable Upper limit is 25µg/day (1000IU).** *The Tolerable Upper Intake Level (UL) is the highest continuing daily intake of a nutrient that is likely to pose no risks of adverse health effects for almost all individuals.*

vitamin D₃ supplements meet the policy requirement (see Appendix 2). These commercial preparations are classified as food supplements and are available without a prescription and can be purchased over the counter in pharmacies and some other outlets. The HSE does not recommend the use of one of these brand products over the other. The choice of preparation is at the discretion of the mother/care giver.

For safety reasons please ensure that:

- The vitamin preparation chosen contains Vitamin D on its own (it is not in combination with other vitamins).
- The vitamin D preparation chosen is suitable for infants and provides the recommended dose of 5 µg.
- Extreme care is taken in administering the correct dosage noting that the number of drops or amount of liquid needed to give the correct dosage is different for each product. Giving an incorrect dose may be harmful.
- The manufacturer's instructions with each individual preparation purchased must be followed.
- Health Professionals advising parents about vitamin D₃ supplements should ensure that they are familiar with the different products and different doses required by each product to provide 5 micrograms (5 µg) of vitamin D₃ per day.
- Parents should read and understand the dosage information on the packaging of their chosen product to ensure that the correct recommended dosage, as per manufacturer's instructions, is given.

7. Procedure

- Information should be given to all expectant and new mothers on the need for infant Vitamin D supplementation. This should be given in both oral and written formats on an individual basis during the health service maternity and childcare journey.
- Once the information has been given this should be documented in the mother's nursing and medical records and signed. Information leaflets have been developed by the HSE to assist in giving this information. Information leaflets are available for both health professionals and parents/carers and can be downloaded from the HSE website www.hse.ie. Copies of the parent/carer information leaflet and posters can be ordered on www.healthpromotion.ie or by contacting the local Health Promotion office(s) in each HSE Area (see Appendix 3).

8. Roles & Responsibility

8.1 Hospital Staff

- Expectant mothers should be informed of the need for infant vitamin D supplementation while they are pregnant and this should be recorded in the mother's antenatal records.
- In the early postnatal period mothers should again be given this information, while they are still in the care of the maternity unit or home birth midwife.
- Hospital managers are responsible for auditing the implementation of the policy.
- Midwifery, nursing managers and dietetic managers are responsible for informing their staff about this policy and ensure that all staff is fully compliant with it.
- Midwives, nurses and neo-natal dietitians are primarily responsible for informing parents/carers about the policy and should document this in the mother's nursing and medical records.
- Consultant Neonatologists, Consultant Obstetricians and Consultant Paediatricians are responsible for informing their staff about this policy and ensuring they fully comply with it.
- Dietitians in the course of their work will disseminate the policy where relevant.
- The policy encourages senior health professionals to ensure that their professional bodies are aware of this policy and that the policy is disseminated to their members.
- Health Professionals involved in administering vitamin D₃ supplements to babies should familiarise themselves with the range of different vitamin D₃ supplements suitable for infants on the Irish market and should read carefully the manufacturer's information and instructions to ensure that the correct dose is given.
- Health professionals advising parents about vitamin D₃ supplements should ensure that they are familiar with the different products and different doses required by each product to provide 5 micrograms (5 µg) of vitamin D₃ per day.
- Health Professionals should facilitate parents to read and understand the dosage information on the packaging of their chosen product to ensure that the correct recommended dosage, as per manufacturer's instructions, is given.

8.2 PCCC staff

- HSE Primary Care units will be responsible for disseminating the relevant information to General Practitioners, to Community Pharmacists and to practice nurses so that further opportunities are available to reinforce key messages with mothers/carers at these locations e.g. at antenatal, at postnatal and at the infant 6 week check.
- Directors of Public Health Nursing and Dietitian Managers are responsible for informing their staff about the policy and ensuring their compliance with it.
- Public Health Nurses are primarily responsible for giving information about the policy to mothers/carers of infants at the first post-natal check following discharge from maternity care, or as soon as possible for infants who are older at the time of commencement of the policy.
- Dietitians in the course of their work will disseminate the policy where relevant.
- Health Professionals advising parents about vitamin D₃ supplements should ensure that they are familiar with the different products and different doses required by each product to provide 5 micrograms (5 µg) of vitamin D₃ per day.
- Health Professionals should facilitate parents to read and understand the dosage information on the packaging of their chosen product to ensure that the correct recommended dosage, as per manufacturer's instructions, is given.

8.3 Health Promotion Staff

- The Assistant National Director, Health Promotion will ensure that standardised appropriate written resources on vitamin D supplementation are developed and made available to relevant services for dissemination to health professionals and the general public.
- Health promotion offices are responsible for facilitating the distribution of information materials relating to this policy as requested.
- Dietitians in the course of their work will disseminate the policy where relevant.
- The policy will be disseminated to training and continuing professional development programmes.
- Health Professionals advising parents about vitamin D₃ supplements should ensure that they are familiar with the different products and different doses required by each product to provide 5 micrograms (5 µg) of vitamin D₃ per day.
- Health Professionals should facilitate parents to read and understand the dosage information on the packaging of their chosen product to ensure that the correct recommended dosage, as per manufacturer's instructions, is given.

9. Implications for Practice

The recommendation to supplement all infants in Ireland with 5 µg vitamin D daily conforms to current best research based practice. The HSE & Department of Health and Children seeks the cooperation of all health care staff in promoting and implementing this recommendation at national, regional and local levels.

The current recommendation to supplement all infants with 5 µg Vitamin D daily applies to all infants from birth until 1 year of age.

10. Stakeholder Involvement

The policy was developed by a multidisciplinary group involved in child health. The group membership included:

Ms. Catherine Murphy, Assistant National Director Health Promotion (Chair)
Dr. Davida deLa Harpe, Assistant National Director Health Intelligence
Dr. Philip Crowley, Deputy Chief Medical Officer, Department of Health & Children
Dr. Mary Flynn, Chief Specialist Public Health Nutrition, Food Safety Authority of Ireland
Ms. Kate Mulvenna, Chief Pharmacist, HSE National Contracts Office
Dr. Teresa Bennett, Project Officer, Health Promotion
Ms. Sheilagh Reaper-Reynolds, Health Promotion Functional Manager, DML
Ms. Sarah O' Brien, Project Officer, HSE Health Promotion Information
Ms. Maureen Fallon, HSE National Breastfeeding Co-Ordinator
Ms. Leonie O' Neill, HSE National Planning Specialist (Social Inclusion), Office of the Chief Executive Officer
Ms. Emma Ball, Community Dietitian Manager, HSE West
Ms. Patricia Hughes, Director of Nursing and Midwifery, Coombe Women & Infants University Hospital
Dr. Margaret Sheridan-Pereira, Consultant Neonatologist/Paediatrician, Faculty of Paediatrics, Royal College of Physicians of Ireland
Dr. Joe Clarke, GP Advisor, HSE
Ms. Kathy Maher, Community Pharmacist

The draft documents were circulated to all relevant stakeholders for review before finalisation.

Thanks to Marie Roddy, Senior Paediatric Dietitian, Adelaide Meath and National Children's Hospital and to Margaret O' Donovan, Director of Public Health Nursing, Dublin South East, for comments on drafts of this policy document.

11. Implementation Plan

Each National Director will be contacted and will be requested to distribute this policy to relevant staff members (see sections 7, 8 & 9 of this policy).

12. References

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Ward (2005). Vitamin D deficiency in the 21st century: a persistent problem among Canadian infants and mothers. *CMAJ*; Mar 15; 172(6):769-70.

Zitterman A (2003). Vitamin D in preventive medicine: are we ignoring the evidence? *Br J Nutr* 2003;89:552-572.

13. Policy Reviewer Statement

Reviewer: *The purpose of this statement is to ensure that a policy and procedure for implementation of **Vitamin D Supplementation for Infants in Ireland** is circulated to people who have a stake in the policy and procedure or protocol.*

Policy on Vitamin D Supplementation for Infants

I acknowledge the following:

- *I have been supplied with a copy of the policy/procedure described above*
- *I have read the policy/procedure document*
- *I agree with the implementation of the policy/procedure*
- _____ *[insert name person responsible for implementing this policy to staff e.g. Hospital management or Director of Public Health Nursing or Community Dietitian Manager or other relevant Manager etc.,]*

Name

Signature

Date

Please retain this form for record, evaluation/audit purposes

15. Evaluation and Audit

Evaluation and audit of the implementation of the policy is necessary to ensure its success. A person nominated by Ms. Catherine Murphy, chair of the national steering group, will be responsible to lead the evaluation and audit process.

The Chair (Ms. Catherine Murphy) and Project Officer (Dr. Teresa Bennett) of the National Steering Group on Vitamin D will be responsible for reviewing and updating this policy on a yearly basis or sooner if appropriate.

Appendix 1 Amounts of vitamin D provided by Infant formula and Follow-on formula alone and when combined with a vitamin D supplement of 5 µg vitamin D per day.

Vitamin D intake does not exceed the Tolerable Upper Intake Level (UL)³ of 25 µg when a 5 µg vitamin D supplement is combined with either infant formula (Table 1) or follow-on formula (Table 2).

Table 1: Total Amounts of Vitamins D Provided by Infant Formula[†] alone and when Combined with a Vitamin D supplement 5 µg vitamin D per day.

Levels of Infant Formula	Amount of Vitamin D from Infant Formula (µg)	Amount of Vitamin D from supplement per day (µg)	Total Amount of Vitamin D provided by Infant Formula + vitamin D supplement (µg)
200ml	2.6	5	7.6
500ml	6.5	5	11.5
700ml	9.1	5	14.1
800ml	10.4	5	15.4
1,000ml	13.0	5	18.0
1,250ml	16.25	5	21.25

[†]For infants up to the age of 12 months who are consuming infant formula, the average vitamin D content per 100 ml for infant formula is 1.3 µg. This information is correct at date of print. Content of formulas are subject to change depending on manufacturer's adherence to European Commission Directive 2006/141/EC.

Fluid requirements for infants aged 0-6 Months is 150 mls/Kg.

Table 2: Total Amounts of Vitamins D Provided by Follow-On Formula^{††} alone and when Combined with a Vitamin D supplement 5 µg vitamin D per day.

Levels of Infant Formula	Amount of Vitamin D from Follow-on Formula (µg)	Amount of Vitamin D from supplement per day (µg)	Total Amount of Vitamin D provided by Follow-on Formula + vitamin D supplement (µg)
200ml	3.0	5	8.0
500ml	7.5	5	12.5
700ml	10.5	5	15.5
800ml	12.0	5	17.0
1,000ml	15.0	5	20.0
1,250ml	18.25	5	23.25

^{††}For infants up to the age of 12 months who are consuming follow-on formula, the average vitamin D content per 100 ml is 1.5 µg. This information is correct at date of print. Content of formulas are subject to change depending on manufacturer's adherence to with European Commission Directive 2006/141/EC.

Fluid requirements for infants aged 7-12 Months is 120 mls/Kg.

³ **The European Tolerable Upper limit is 25µg/day (1000IU).** The Tolerable Upper Intake Level (UL) is the highest continuing daily intake of a nutrient that is likely to pose no risks of adverse health effects for almost all individuals

Appendix 2 Vitamin D supplements available for infants in Ireland

A list of the current range of vitamin D only supplements available for infants on the Irish market is available on www.hse.ie.

The FSAI is a statutory independent science based body whose role is to take all reasonable steps to ensure that food, including food supplements, produced, distributed or marketed in the State meets the highest standards of food safety and hygiene and complies with legal requirements, or where appropriate with recognised codes of practice.

All Food supplements marketed in Ireland for the first time must be notified to the FSAI. The FSAI has informed the HSE of the available vitamin D₃ supplements that are currently available on the Irish market that are suitable for infants and support the national policy on Vitamin D Supplementation for Infants aged 0 to 12 months in Ireland. A list of these Vitamin D₃ supplements can be found on www.hse.ie. This list will be updated in accordance with the FSAI informing the HSE of other Vitamin D₃ Supplements suitable to support this policy becoming available on the Irish market.

It is important to note the following:

- **The HSE does not recommend the use of one brand over the other*. The choice of preparation is at the discretion of the mother/care giver.**
- **The dose of each product differs and care must be taken to ensure that the correct recommended dose, as per manufacturer's instructions, is given. Giving an incorrect dose may be harmful.**
- **The vitamin D₃ supplement chosen must be suitable for infants and provide the recommended dose of 5 µg.**
- **The vitamin preparation chosen should contain Vitamin D₃ on its own (it is not in combination with other vitamins).**

*** All vitamin D food supplements suitable for infants that are introduced to the Irish market are notified to the Food Safety Authority of Ireland where they are checked in terms of compliance with relevant legislation (including all regulations applicable to food supplements, food labelling, health claims). In addition to this, all vitamin D₃ supplements suitable for providing infants with 5 µg of vitamin D are now included in the Food Safety Authority of Ireland annual monitoring surveys.**

Appendix 3 List of Health Promotion Offices

DML

Health Promotion Department,
3rd Floor,
52 Broomhill Road,
Tallaght,
Dublin 24.

Tel: 01 4632800

DNE

Health Promotion Department, Dublin North East
Health Service Executive
Railway Street
Navan
Co. Meath

Tel: 046 907 6400

South

Health Promotion Department,
HSE South
Eye, Ear and Throat Hospital
Western Road,
Cork

Tel. 021 492 1642

West

Health Promotion Services
1st Floor, West City Centre,
Seamus Quirke Road,
Galway

Tel: 091 548320

Appendix 4 Definitions

Exclusive Breastfeeding: The infant has received only breast milk from his/her mother or a wet nurse, or expressed breast milk and no other liquids, or solids with the exception of drops or syrups consisting of vitamins, mineral supplements, or medicines (Menon et al, 2003).

Exclusive Formula Feeding: the infant is given formula milk only.

International Unit: is abbreviated as **IU** and is a unit of measurement for the amount of a substance, based on measured biological activity or effect. The unit is used for vitamins, hormones, some medications, vaccines, blood products, and similar biologically active substances.

For **Vitamin D**, **1 IU = 0.025 µg** cholecalciferol or ergocalciferol
Or **200 IU = 5 µg**

Other countries may use the term IU instead of µg. In Ireland, under EU law [Directive 2002/46/EC], food supplements for sale in Ireland use µg instead of IU to denote the amount of a nutrient in a product. For example, the amount of Vitamin D₃ in a food supplement will be given in µg.

µg: is the abbreviation for microgram. A microgram (µg) is equal to one-millionth (10⁻⁶) of a gram. Also abbreviated to mcg.

Or **1 µg = 1 X 10⁻⁶ g**

ng: is the abbreviation for nanogram. A nanogram (ng) is equal to one billionth (10⁻⁹) of a gram.

Or **1 ng = 1 X 10⁻⁹ g**

Rickets: a disorder caused by Vitamin D deficiency and marked by bending and distortion of the bones under muscular action, by the formation of nodular enlargements on the ends and sides of the bones, by delayed closure of the fontanelles, pain in the muscles and sweating of the head.

Vitamin D: a fat soluble vitamin necessary for healthy bone growth.

Vitamin D₃: also called **Cholecalciferol**. It is a form of Vitamin D. Cholecalciferol is manufactured in the skin from the action of ultraviolet B light in sunlight.

Vitamin D₂: also called **Ergocalciferol** is a form of Vitamin D. Ergocalciferol is derived from plant sources by activating ergosterol with ultraviolet light. Ergocalciferol is only half as potent as cholecalciferol (vitamin D₃).

25 (OH): also called **25-hydroxycholecalciferol** or calcidiol. **25 (OH)** is produced in the liver by hydroxylation of cholecalciferol (Vitamin D₃) to calcidiol (25-hydroxycholecalciferol). Blood levels of **25 (OH)** largely reflect the amount of vitamin D₃ produced in the skin or the vitamin D₂ or D₃ ingested.