

Testimony for HB1328 Main Points Summary

- Traditional Epidemiological Model: A susceptible host equals a vulnerable person (body, host).
- Research demonstrates vitamin D is critical to cellular function.
- Research demonstrates that vitamin D deficiency compromises the host by impairing cellular function and the innate immune response.
- Research shows that every North Dakotan is at risk for vitamin D deficiency
- Research shows that vitamin D deficiency has very serious health consequences and is costly to employers
- There is no lack of research. The problem lies in moving research into practice.
- Fears of toxicity have been addressed by the research and the information has not moved into practice.
- Screening and Supplements are both inexpensive.
- Each person responds to supplementation differently, so testing is necessary for best practice.
(Research has found that the same dose can produce ranges from 20ng/ml to 120ng/ml)
- Barriers to moving research into practice and implement equity in vitamin D screening and testing for our vulnerable population can be easily address with this legislation and partnerships with key stake holders.
- Since research shows that all North Dakotans are at risk and the consequences to vitamin D deficiency are so high, it could be argued that it is discriminatory and unethical to continue cover vitamin D testing for some and not others.

Testimony for HB1328

Testimony for HB1328 Increased insurance reimbursement for Vitamin D screening and testing. This bill will give health care providers the option of ordering a screening test or follow up with their patient for vitamin D testing.

Story behind the bill

- Personal Experience
- Daughter's Experience
- Pandemic—Long Term Care
- Turned to the experts: Vitamin D Society of Canada and Grassroots Health Research Institute
- Alaska Resolution 2011
- Norwegian Resolution 2014
- Ireland, Scotland, UK
- Dr. Andy McLean's recommendations (see Dr. Andrew McLean's testimony)
- Why weren't the recommendations followed? (see Michael Curtis's testimony)
- Here we are today: Lack of insurance coverage for vitamin D screening and testing
- Without evaluating blood levels, it is very difficult to get people into the 40-60ng/ml range and everyone responds to supplementation differently.

The Importance of the Host in the Epidemiological Model

- Epidemiological Model <https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section10.html>

Host

The final link in the chain of infection is a susceptible host. Susceptibility of a host depends on genetic or constitutional factors, specific immunity, and nonspecific factors that affect an individual's ability to resist infection or to limit pathogenicity. An individual's genetic makeup may either increase or decrease susceptibility. For example, persons with sickle cell trait seem to be at least partially protected from a particular type of malaria. Specific immunity refers to protective antibodies that are directed against a specific agent. Such antibodies may develop in response to infection, vaccine, or toxoid (toxin that has been deactivated but retains its capacity to stimulate production of toxin antibodies) or may be acquired by transplacental transfer from mother to fetus or by injection of antitoxin or immune globulin. Nonspecific factors that defend against infection include the skin, mucous membranes, gastric acidity, cilia in the respiratory tract, the cough reflex, and nonspecific immune response. Factors that may increase susceptibility to infection by disrupting host defenses include **malnutrition, alcoholism, and disease or therapy that impairs the nonspecific immune response.**

Figure 1.19 Chain of Infection

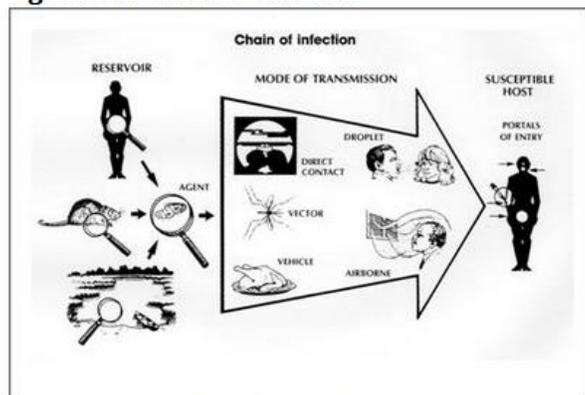


Image Description

Source: Centers for Disease Control and Prevention. *Principles of epidemiology*, 2nd ed. Atlanta: U.S. Department of Health and Human Services;1992.

Main Point: A susceptible host equals a vulnerable person (body, host).

Research behind vitamin D and how it protects the body (host)

- **Nutrient Journal Issue Dedicated to Vitamin D**
https://www.mdpi.com/journal/nutrients/special_issues/Vitamin_D_in_the_New_Decade
- Scientists' Call to D*Action for Public Health <https://www.grassrootshealth.net/project/our-scientists>
- Vast body of research

- >600 RCT https://vitamindwiki.com/tiki-index.php?page_id=6329
- >400 meta-analyses https://vitamindwiki.com/tiki-index.php?page_id=4267

How do proper levels of vitamin D protect the host?

Vitamin D is created by our body in response to UVB rays (angle of the sun (10-2pm); shadow is shorter than a person's height).

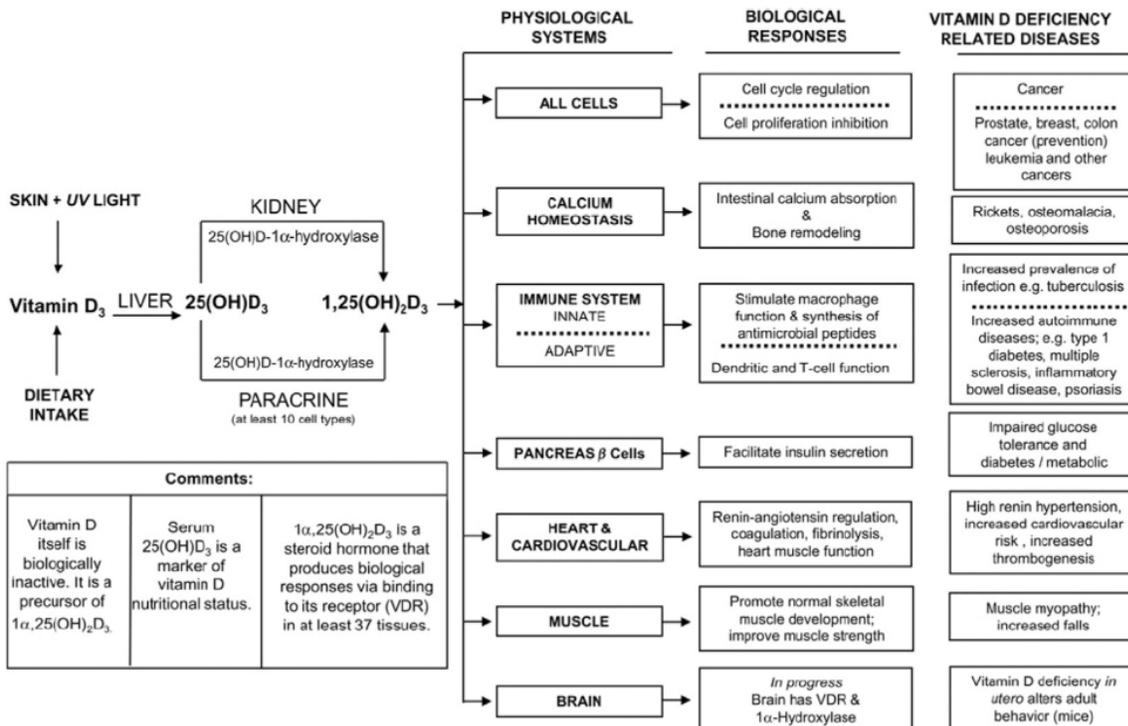
- <https://www.grassrootshealth.net/document/sunshine-calendar/>
- North Dakota: four months of the year not enough sunshine for adequate amounts of D (I would beg to differ that the people who created this calendar haven't been to ND in the winter—October to April)

Vitamin D has a critical role in cellular function and the immune system

Dr. Carsten Carlberg from the University of Eastern Finland School of Medicine Institute in Biomedicine, Kuopio, Finland. The vitamin D receptor: "VDR is primarily involved in the **control of cellular metabolism** but in addition **modulates processes** important for **immunity**, such as **anti-microbial defense** and the induction of **T cell tolerance**." ---Dr. Carsten Carlberg from the University of Eastern Finland School of Medicine Institute in Biomedicine, Kuopio, Finland.

Figure 1 of 2

Figure 1 Overview of vitamin D and its role on physiological systems and the biological responses as well as possible vitamin D-related diseases. The three columns on the right side, respectively, indicate the following: physiological systems (the six physiological systems that the essential nutrient vitamin D₃ supports by its metabolism to 25(OH)D₃ and 1α,25(OH)₂D₃); biological responses (examples of biological responses generated by 1α,25(OH)₂D₃ in the six physiological systems); and vitamin D-deficient related diseases (identifies for each system some of the disease states that are associated with an inadequate vitamin D nutritional status) (8).



Top 25 Vitamin D Publications in 2020

<https://orthomolecular.activehosted.com/index.php?action=social&chash=4c5bde74a8f110656874902f07378009.186&s=a58e917b86647ba1e0e0ead2f130ed2>

Main point: research demonstrates that Vitamin D deficiency compromises the host by impairing cellular function and the innate immune response.

According to the vast body of research, who is at risk for vitamin D deficiency?

(see attached reference list for articles)

- People living in northern latitudes (UV Index: above 3 needed for adequate opportunity for UVB) <https://www.mdpi.com/2072-6643/12/12/3805>
- People of darker skin tones
- Lifespan: Elderly
- Genetic
- Disease processes preventing absorption of fat-soluble vitamins (alcoholism, intestinal disorders)
- Institutionalized populations such as Elderly and Prisons
- Indoor lifestyles
- Shift workers
- Women who wear veils and full body coverings
- Certain pharmaceuticals disrupt vitamin D processes

Public Health Officials and Legislators of other vulnerable populations are aware of the risks of vitamin D deficiency

- Alaska 2011
- Scandinavia 2014; update 2020 (Cultural foods: Cod Liver Oil)
- UK: Scotland, Northern Ireland, and Britain
 - Testimony before parliament https://www.youtube.com/watch?v=Gog5mgBv0hM&feature=emb_logo
- Germany (research conference coming up in February 2021)

Main Point: Research shows that every North Dakotan is at risk for vitamin D deficiency, just like our northern latitude counterparts.

Research shows that vitamin D deficiency has very serious health consequences and is costly to employers

- Iceberg sheet for the general population <https://www.grassrootshealth.net/document/vitamin-d-deficiency-iceberg-handout-general/>
- Iceberg sheet for pregnant women https://www.grassrootshealth.net/wp-content/uploads/2016/11/poc-iceberg-handout.pdf?_ga=2.76544405.1818723904.1611468139-435831200.1611115281

Examples of vitamin D deficiency, common health conditions and cost to employer

Vitamin Deficiency and adverse outcomes for mom and baby

- Premature birth <https://www.grassrootshealth.net/blog/important-attack-preterm-birth/>
 - costs employers 12.7 billion dollars per year (March of Dimes)
 - \$5,085 for a healthy, full-term baby
 - \$55,393 for a premature or low birth weight baby
 - 25 days in NICU for one pre-term birth \$144,000

- Pregnancy <https://www.grassrootshealth.net/blog/when-headlines-mislead/>
 - Maternal Hypertension (can lead to deadly preeclampsia) <https://www.grassrootshealth.net/blog/vitamin-d-protects-complications-pregnancy/>
- Type 1 Diabetes in Children <https://health.ucsd.edu/news/releases/Pages/2012-11-15-vitamin-D-and-type-1-diabetes-link.aspx>
- Frequently sick children (sick leave days) “Observational studies predominantly reported statistically significant associations between low vitamin D status and increased risk of both upper and lower respiratory tract. infections. <https://www.sciencedirect.com/science/article/abs/pii/S0960076012002506?via%3Dihub>

Vitamin D deficiency and Cancer

- Cancer costs \$264 billion dollars in healthcare costs and lost productivity
- **All Cancer**
 - 71% reduction in all cancers
 - https://www.grassrootshealth.net/blog/71-reduction-in-all-cancer-risk/?_ga=2.50781481.1818723904.1611468139-435831200.1611115281
- **Breast Cancer**
 - Cost of treating one woman for breast cancer: \$100,000-300,000
 - Prevention: 80% reduction of breast cancer if in optimal range compared to 20ng/ml <https://www.grassrootshealth.net/document/breast-cancer-prevention-brochure/>
 - Survival rates: 60% more women survived if their levels within optimal range
 - <https://www.grassrootshealth.net/document/improving-breast-cancer-patients-survival/>
 - <https://www.grassrootshealth.net/document/does-vitamin-d-help-survival-rates-for-breast-cancer/>

Diabetes 2

- \$20 billion dollars cost to employers <https://www.grassrootshealth.net/blog-category/diabetes/>
- The role of vitamin D in preventing Type 2 Diabetes <https://www.grassrootshealth.net/blog/role-vitamin-d-preventing-type-2-diabetes/> by influencing insulin secretion and response. **Overall, vitamin D is needed for insulin to be made and it is needed for cells to respond to insulin.**

COVID-19

- <https://www.grassrootshealth.net/blog/dont-let-covid-19-patients-die-vitamin-d-deficiency-medpagetoday/>
- <https://www.grassrootshealth.net/blog/vitamin-d-secret-weapon-covid-19/>
- Professor Sunil Wimalawansa COVID & Vitamin D <https://youtu.be/9HEPmuzNDJ0>

Grassroots Health Research Institute was awarded the 2016 Humanitarian of the Year award by the American College of Nutrition to honor their tireless efforts of moving vitamin D research into practice.

<https://www.grassrootshealth.net/grassrootshealth-receives-humanitarian-award-american-college-nutrition>

Main Point: There is no lack of research. The problem lies in moving research into practice.

Vitamin D “Mythbusters”

- Do we really need to test? <https://www.grassrootshealth.net/blog/vitamin-d-testing-necessary/>
- Current Recommendations are adequate <https://www.grassrootshealth.net/blog/current-recommendations-low/>
 - Statistical Data error in recommendation; current recommendations far too low. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4210929/>
- Vitamin D supplements cause kidney stones <https://www.grassrootshealth.net/blog/vitamin-d-kidney-stones-myth/>
- <https://www.grassrootshealth.net/blog/vitamin-d-fat-soluble-storage-debate/>
- <https://www.grassrootshealth.net/blog/watch-vitamin-d-build-fat-can-toxic-toxicity-debate-pt-1/>
- <https://www.grassrootshealth.net/blog/watch-much-vitamin-d-can-toxic-toxicity-debate-pt-2/>
- <https://www.grassrootshealth.net/blog/can-taking-vitamin-d-unmask-underlying-nutrient-imbbalances/>
- <https://www.grassrootshealth.net/blog/vitamin-d-primary-hyperparathyroidism/>
- <https://www.grassrootshealth.net/blog/granulomatous-disorders-vitamin-d-hypersensitivity/>
- Toxicity example: Iron supplements can be toxic. Screenings can monitor blood levels to avoid toxicity.

Main points: Fears of toxicity have been addressed by the research and the information has not moved into practice.

Discriminatory and ethical concerns of inequities in coverage

The example provided is typical of reimbursement for health insurance companies.

<https://www.bcbsnd.com/providers/policies-precertification/medical-policy/vitamin-d-assay>

“Vitamin D deficiency is defined as a 25(OH)D below 20 ng/ml (50 nmol/liter), and vitamin D insufficiency as a 25(OH)D of 21–29 ng/ml(525–725 nmol/liter).

Criteria (copied and pasted from the document above)

Measurement of cholecalciferol 25-hydroxyvitamin D [25 (OH) D] levels may be considered medically necessary for individuals with (not all inclusive):

- Clinically documented underlying disease that is specifically associated with vitamin D deficiency, decreased bone density; **or**
- Individuals considered at high risk for vitamin D deficiency (see list below) **and** vitamin D supplementation is being taken per the recommended daily amounts; **or**
 - African-American and Hispanic children and adults
 - Pregnant and lactating women
 - Older adults greater than 65 years with history of falls or non-traumatic fractures
 - Obesity; children and adults (BMI greater than or equal to 30)
- Chronic kidney disease (CKD), stage 3 or greater; **or**

- Granuloma forming diseases; **or**
 - Sarcoidosis
 - Tuberculosis
 - Histoplasmosis
 - Coccidiomycosis
 - Berylliosis
- Hepatic disease or failure; **or**
- Hyperparathyroidism; **or**
- Long term use of anticonvulsants, glucocorticoids, rifampicin, acquired immune deficiency syndrome (aids) medications, antifungals, cholestyramine and other medications known to lower vitamin d levels; **or**
- Malabsorption states; **or**
 - Cystic fibrosis
 - Inflammatory bowel disease (i.e. Crohn's disease, Ulcerative colitis)
 - Bariatric surgery
 - Radiation enteritis
- Individuals receiving hyperalimentation; **or**
- Osteomalacia; **or**
- Osteoporosis or at risk for osteoporosis; **or**
- Osteogenesis imperfecta; **or**
- Rickets; **or**
- Vitamin D deficiency on replacement therapy; to monitor the efficacy of treatment

25-OH Vitamin D-3 may be tested up to four (4) times per year for Vitamin D deficiencies when the above criteria are met.

Testing and screening for vitamin D deficiency with 25-hydroxyvitamin D [25(OH)D] serum testing is considered not medically necessary for all other indications.

Professional Statements and Societal Positions Guidelines

The Endocrine Society

The Endocrine Society recommends screening for vitamin D deficiency in individuals at risk for deficiency. The society does not recommend population screening for vitamin D deficiency in individuals who are not at risk. **It is recommended using the serum circulating 25-hydroxyvitamin D [25(OH)D] level, measured by a reliable assay to evaluate Vitamin D status in patients who are at risk for vitamin D deficiency.** The society recommends using the serum 1,25-dihydroxyvitamin D [1,25(OH)2D] assay in monitoring certain conditions, such as acquired and inherited disorders of vitamin D and phosphate metabolism.

American Society for Clinical Pathology and Choosing Wisely

American Society for Clinical Pathology and Choosing Wisely recommends not performing population-based screening for 25-OH-Vitamin D deficiency. **Vitamin D deficiency is common in many populations, particularly in patients at higher latitudes, during winter months and in those with limited sun exposure.** Over the counter Vitamin D supplements and increased summer sun exposure are sufficient for most otherwise healthy patients. Laboratory testing is appropriate in higher risk patients when results will be used to institute more aggressive therapy (e.g., osteoporosis, chronic kidney disease, malabsorption, some infections, obese individuals)?

Main point: Research shows that all North Dakotans are at high risk and the consequences to vitamin D deficiency are so high, it could be argued that it is discriminatory and unethical to continue cover vitamin D testing for some and not others.

Barriers to implanting vitamin D research in North Dakota

Two Key Partnerships

- Partnership with key stake holders to educate Health Care Professionals and the public
 - Researchers recommend to adopt a prevention model of public health by increasing awareness about vitamin D deficiency, testing, and supplementation and address fears of toxicity.
- Partnership with Insurance companies to address inequities in screening and testing for our vulnerable population.

Main Point: Barriers can be easily address with this legislation and partnerships with key stake holders.

Costs

An annual screening for vitamin D: \$25-50 dollars

- Boston Heart Lab = \$26
- Everlywell (internet) = \$50
- Grassroots Health Research Institute = \$65
- McKenzie County Health Care Systems Birthday Labs=\$15 add on

Bottom line: Annual screening for vitamin D: \$25-50 dollars

Supplementations costs: 5,000IU =three cents per day.

Why not just supplement? Research shows that every person responds differently to supplementation.

Summary

Our people perish for lack of knowledge. In this case specifically, for lack of moving existing research into practice. Researchers report that on average it takes 17 years to move research into current healthcare practice. It is impossible to gauge an individual's vitamin D level without blood testing. The consequences of vitamin D deficiency are devastating. The costs to the state are enormous, but it is the costs to our people in terms of loss of quality of life that are immeasurable. Let's partner together: researchers, health experts, insurance companies, and

legislators to bring the best research into practice that we can for the sake of our people.

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