

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MOM Enterprises, LLC,
Petitioner,

v.

ELAINE AND REINHOLD W. VIETH,
Patent Owner,

Case IPR 2023-00726
Patent 9,066,958

DECLARATION OF REINHOLD VIETH

I, Reinhold Vieth, declare and state as follows under penalty of perjury:

1. This declaration is based on personal knowledge unless otherwise indicated. All statements made in this declaration are true and accurate. I believe that any statements made on information and belief are true and accurate. I make these statements knowing that willful false statements are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001.

2. I am the co-inventor and one of the owners of U.S. Patent No. 9,066,958 (“the ‘958 Patent”).

3. I received my B.Sc. in medical sciences. Under the supervision of Drs. Donald Fraser and Sang-Whay Kooh, who were pediatrician specialists in bone disease at the Hospital for Sick Children in Toronto. I obtained my M.Sc. in physiology, and my Ph.D. in physiology from the University of Toronto. I also received a post-graduate diploma in clinical chemistry from the University of Toronto. I have authored numerous peer-reviewed and non-peer-reviewed articles during my career. For more than thirty years, I taught at the University of Toronto, retiring in 2012 as a full professor. Attached as Exhibit A is a true and correct copy of my most recent curriculum vitae.

4. I have reviewed the Petition and exhibits filed by Petitioner in IPR2023-00726, particularly the Declaration of Robert O. Williams III, MOM-1004 (“Williams”) and the exhibits to which it refers. I also have reviewed the

transcript of Williams' deposition, taken on December 7, 2023 and referenced exhibits. A complete list of the documents I have reviewed in connection with the preparation of this declaration is attached as Exhibit B.

5. Based on my review of the various documents identified above and in Exhibit B, the Petition and Williams reflect a fundamental and erroneous misunderstanding regarding the '958 Patent, the prior art referenced by them, and more fundamentally, the difficulties and issues which the '958 Patent addresses and solves.

6. The problem of vitamin D deficiency has existed since humans started to migrate northward out of Africa. Vitamin D deficiency is the reason people of European ancestry have light-colored skin. Lighter colored skin allows for better penetration of sunlight into the skin, where vitamin D is produced. Darker skin tends to block penetration of ultraviolet light necessary for production of vitamin D. The childhood disease of the bone, known as rickets, will develop due to insufficient sunshine. The vitamin D produced due to natural exposure to ultraviolet light only occurs when the sun is high enough in the sky. This insufficiency causes health problems. For example, a woman who grew up with rickets cannot deliver an infant naturally because the rachitic pelvis becomes misshapen causing cephalopelvic disproportion, and death. This is the method for natural selection toward lighter skin, northward and away from the equator.

7. Insufficient vitamin D also causes myopathy in both children and adults. A characteristic of this is proximal muscle weakness, which makes adults need to press on their knees to stand up from a chair, for example. In infants, weak muscles contribute to lung infection because their musculature is not strong enough to cough out infection. This is also true for adults. Thus, rickets increases risk of upper respiratory disease, such as influenza and pneumonia.

8. Thus, the need for supplemental vitamin D goes back hundreds of years. Scandinavian countries started using cod liver oil in the 1700s. They referred to cod liver oil as a means to help children to thrive. They did not know the fact it provided vitamin D. (Scandinavian adults, because they lived near the sea, eat more fish which provides vitamin D, but breastfeeding infants could not eat fish.)

9. Cod liver oil, however, is disgusting. It tastes awful (fishy). It goes rancid. Moreover, the vitamin D content is highly variable. One teaspoon of cod liver oil, for example, may contain a widely disparate amount of vitamin D, perhaps anywhere from 100 international units (“IU”) to 900 IU.

10. Cod liver oil was not ideal or suitable for infants. Infants dislike the taste, often would spit any amount out, and it is very difficult to administer cod liver oil by teaspoon. You have to pour the dose into a baby’s mouth. Infants will not naturally put their mouth around a spoon.

11. Adults need more vitamin D than infants. Osteomalacia is the adult version of rickets, a disease of low calcium in the bone caused by a deficiency in vitamin D which is needed to absorb calcium from food. For adults, taking cod liver oil presents the same issues as infants and children.

12. A longstanding problem with vitamin D is that it is such a potent compound it is easy to overdose and possibly cause disease or illness. An analogy is fentanyl, which is 100 times more potent than morphine. Administered in an appropriate amount, fentanyl is useful and a licensed drug. Because of its potency, it is very easy to administer an overdose.

13. For context, a conventional aspirin dose is 300 mg. However, vitamin D is measured in micrograms (“mcg”) or IU. A microgram is 1/1000th of a milligram (“mg”). Like fentanyl, vitamin D is potent in tiny amounts, and therefore prone to misuse. The presently recommended infant dietary allowance for vitamin D is 400 IU which is equivalent to only 10 micrograms. This is a miniscule and precise amount.

14. Thus, due to its high potency, it is easy to give a human being milligram quantities of vitamin D per day instead of micrograms.

15. This is an even worse problem with infants. The risk of toxicity with infants is multiplied, especially because some infant supplements come in dose per drop, while others involve eyedroppers or teaspoons. Despite instructions on the

package, the mistakes of parents result in published case reports of infants intoxicated with vitamin D.

16. Vitamin D toxicity causes excess absorption of calcium from the gut. That raises blood and urine calcium. High blood calcium impairs neuromuscular excitability affecting the heart, intestines and brain function. High urine calcium causes kidney stones.

17. Like Warfarin (Wisconsin Alumni Research Fund), vitamin D was first isolated at the University of Wisconsin, which was seeking to discover rat poisons. Vitamin D is a highly effective rat poison. Only 1 milligram will kill a rat.

18. As is well-known in toxicology, “The dose makes the poison.”

19. As late as the 1940s, cod liver oil was still the state of the art for providing vitamin D to adults or infants.

20. Innovative attempts to provide vitamin D included a beer with vitamin D, manufactured and sold by “Schlitz” in the 1930s. Of course, this product did not address vitamin D deficiency in infants or children.

21. In the 1940s and 1950s, tablets were developed to provide vitamin D. However, infants and many children could not or would not take tablets. A risk of a toxic dose also existed due to the high potency of vitamin D.

22. In the 1950s a solution, particularly for children, was a liquid concoction, often administered by a teaspoon or an eye dropper. A teaspoon could not be used with infants, except as a means of pouring the liquid into the mouth.

23. Additionally, the amount in a teaspoon may be variable, depending on how much is poured into the teaspoon.

24. A further downside from the use of a teaspoon is the extent to which the liquid would remain on the surface of the spoon. Some of the liquid will adhere and remain on the spoon in wide variation depending on whether the spoon is made from wood, paper, plastic, silver, stainless steel, or some other substance. The size of the spoon also varies, even a so-called “teaspoon.”

25. Also, the nature of the liquid vehicle used for the vitamin D would impact the amount of vitamin D administered. Some amount of the vitamin D will definitely remain on the spoon, regardless of its construction. Any oil or syrup will remain behind on the surface after administration. For example, consider sticking your finger or hand into syrup or olive oil and not having to wash your hand after trying to lick it off.

26. The use of an eye dropper also required careful measurement, and there is always some residual amount in an eye dropper. Further, with an infant, a baby spits it out, or if the dropper is squeezed too hard, the infant may gag or inhale the liquid.

27. By the 1970s, various syrup-based products were available for vitamin D. The commercially-available product known as D-Vi-Sol, for example, is a synthetic, glycerin product that is not soluble in water. It includes an emulsifier – essentially soap. Further, D-Vi-Sol requires the careful counting of the number of drops, because it requires 30-60 drops.

28. Adults would not take vitamin D using the syrupy D-Vi-Sol style product.

29. The problem my wife and I sought to address in the early 2000s was: How do you reliably deliver vitamin D to a human being or an infant, in a form and method that is reliably safe and nutritionally effective, amenable and acceptable to the recipient?

30. This is an exceedingly complex problem. The solution is not trivial. It involved five variables: (1) a single drop; (2) the correct concentration; (3) the proper carrier; (4) the delivery means; and (5) the method of administration. These variables are all interdependent. Prior attempts to solve the problem did not recognize the interdependencies or disclose an effective solution.

31. Despite all of the efforts since the early 1800s, the problem still existed. No one had developed an elegant or effective solution to the problem.

32. In the early 2000s, I was conducting research on the use of high doses of vitamin D for clinical trials of prostate cancer and multiple sclerosis. At that

time, I became aware of medium chain triglycerides (“MCT”), which I obtained as a chemical agent.

33. In physically working in the laboratory with MCT to prepare vitamin D solutions, I observed that MCT had an interesting behavior, different from other liquids I had been working with – it was thicker than water but thinner than regular vegetable oils.

34. My wife and I had been aware of the long-standing problem identified above as a result of attending and speaking at numerous nutrition and medical conferences. Attendees often raised the question of how to give a baby vitamin D. The response from the experts at the podium was always silence; there is no particular method. If pressed, use of D-Vi-Sol type of products might be mentioned.

35. When I observed the interesting characteristics of MCT, I thought I would look into its possible use to address the breastfed-infant, vitamin D-supplementation problem identified above.

36. Attached as Exhibit C is a true and correct copy of my laboratory notebook, in which I contemporaneously entered notes and data relating to my research that led to the ‘958 Patent.

37. I gave the idea a low probability of success, that MCT would work, because my job as a clinical chemist involved method development, and I know

that a lot of new ideas about methods in the laboratory fail to work out. If the approach had not worked, others could easily say that failure should have been obvious all along. My wife and I decided it was worth the effort for us to investigate whether using MCT might be part of a solution to the breastfed-infant, vitamin D-supplementation problem.

38. I then embarked on research using MCT, which is just a delivery vehicle. I had to first determine whether a drop of liquid would stick to a small surface, such as a nipple or pacifier or the back of the hand without dripping off.

39. Next, I had to prepare a suitable solution of vitamin D in MCT: How big is one drop, how do you dispense the drop, how reproducible is the amount dispensed, and what concentration of vitamin D do you use? None of these things was straightforward, and they needed to be worked out and validated.

40. We then needed to determine if and how we could conveniently administer an efficacious and nutritionally sufficient dose not just onto an exterior surface, but also determine the efficiency of uptake from that surface into the person's body.

41. We put vitamin D-containing product on pacifiers and sucked for 30 seconds, and then measured the residual vitamin D on the pacifier as well as testing the blood of the adult subjects in the experiment to demonstrate that their blood level of vitamin D went up as a result.

42. To verify that the dose actually entered the body, we showed that the composition and method of administration appropriately increased the level of vitamin D in the blood of the persons using the method.

43. My wife and I developed a solution addressing the 5 inter-related variables. First, we decided on a single drop solution because one drop is an unambiguous, but consistent volume and would not require careful counting. Using multiple drops increases the likelihood that some amount of the product will drip-off and not be ingested. The correct concentration is linked to the volume to yield a consistent dose of vitamin D.

44. The next problem was to make sure that the target dose was consistently delivered. We discovered that by selection of the proper carrier and the delivery object from among the various options to deliver substantially all of the solution to the recipient. We thus could ensure an accurate and efficacious dose and avoid overdosing and underdosing of vitamin D.

45. We found that selecting MCT oil as the carrier allowed us to pick a delivery object that had the correct relationship. We identified this relationship as adherence. Adherence means that a drop of the substance would not immediately spread out on the object or immediately drip away.

46. Also, we gave no consideration to the use of a spoon. Use of a spoon would be stupid. You cannot place a spoon into an infant's mouth. They will gag.

Pouring liquid from a spoon still has the same deficiencies and issues identified above in the context of cod liver oil. The issue of how much will remain the surface of the spoon is amplified because a spoon has a larger surface area. Assuming the tongue even touches the drop, you do not know if the infant is simply pushing it around; licking does not mean you are actually putting something into your body. No evidence exists that infants younger than 3 months actually lick as a method to consume something.

47. An infant has not developed the ability to lick in the adult sense of it; infants do not lick. With four children – and observing others – I have never seen an infant lick to take in anything extraneous to their body.

48. Published research confirms that infants do not lick in the same way as an adult might, to pull something off a surface.

49. According to video-taped studies of how infants feed, Widström and Thingström-Paulson stated “licking movements”, defined as the tongue being frequently stretched out through the loosely closed lips” [A.M. Widström and J. Thingström-Paulsson, “The position of the tongue during rooting reflexes elicited in newborn infants before the first suckle,” 82 *Acta Pædiatrica* (1993), 281-3]. Unlike adults, infants stick their tongue out through closed lips, to serve as a probe to find the nipple but not to consume anything. It is absurd for a midwife to suggest that while an infant is held skin-to-skin at the breast, that one should stick

a spoon at that little tongue and expect any vitamin D to be taken up from there and to be pulled into the body through closed lips.

50. The rooting reflex lasts weeks to months, beyond the timeframe for any midwife to be involved. “Licking” movements by infants are part of the infant’s familiarization phase of breastfeeding, prior to suckling [A.M. Widström, G. Lilja, P. Aaltomaa-Michalias, A. Dahllöf, M. Lintula, and E. Nissen, “Newborn behaviour to locate the breast when skin-to-skin: a possible method for enabling early self-regulation,” 100 *Acta Pædiatrica* (2011) 100, 79-85]. Infants consume by suckling, and definitely not by licking off something.

51. Dani, et al. showed that the feeding behavior of newborns is initiated by and involves skin-to skin contact. [Carlo Dani, Alesandra Cecchi, Arianna Commare, Gherardo Rapisardi, Rita Breschi and Simone Pratesi, “Behavior of the Newborn during Skin-to-Skin,” *Journal of Human Lactation* (2015), 1-6]. That skin-to-skin contact would make it intrusive and highly impractical to somehow get the spoon in the way. How would you do it? And the MCT oil would definitely roll around and away from the tip of a moving spoon.

52. Copies of the 3 above-mentioned peer-reviewed articles are attached as Exhibits D, E and F, respectively.

53. The inventions claimed in the ‘958 Patent represent the unexpected solution to the vitamin D nutrition problem that has existed in one form or another

for centuries, as identified above. The inventions claimed in the '958 Patent disclose a composition and method to reliably deliver vitamin D to a human being or an infant, in a form and method that is reliably safe and nutritionally effective, amenable and acceptable to the recipient.

54. After we had filed our patent application, several competitors to our product gave us unsolicited feedback. At one trade show in about 2008, I recall a representative of Enfamil, which sells D-Vi-Sol, told me, "You have a nice new technology here. It's really good."

55. On another occasion in about 2008, a sales representative for Jamieson, which sells vitamin D products, told my wife, a coincidental seat mate on an airplane traveling back from a trade show, that they wanted to figure out how to do a product like Ddrops.

56. I have reviewed the 5 prior art references identified by Williams and in the Petition.

57. Regarding the so-called Harder reference, I am aware that three different translations have been obtained and that the first one (Tinworth) does not include the words "to lick" or "lick off" or similar. Regardless of which translation is accurate, I assume for the following analysis that the Harder reference includes the phrase "to lick off" as in the third translation (Benyunes) that Petitioner obtained.

58. Harder is one of many contributors to a book which is written for midwives. It is a non-peer reviewed book for a lay audience (midwives) and is focused on the first six weeks of life. Its contents are practical, not necessarily scientifically based, and more oriented toward complementary medicine.

59. I do not believe that a researcher seeking to solve the problem and 5 inter-related variables identified above would consult or use the Harder reference in connection with their research.

60. Harder does not teach or suggest that the drop is applied “to an exterior surface of an object.” It also does not teach or suggest that the drop “adheres to the surface of said object.” Harder does not teach or suggest “having said human being suck or lick said composition directly from said object.”

61. Harder presumably states that the drop is to be placed on the “tip of a spoon,” but does not specify whether it is placed on the concave (interior) side of the tip or the convex (exterior) side of the tip.

62. Nothing in Harder suggests that administering a drop applied to a spoon is equivalent to a drop that adheres to the exterior surface of an object.

63. Harder fails to suggest or disclose that the “drop does not immediately drip or roll away from the object that enters the mouth, so that no portion would drip off the object and surface.” Paper 10, 15 Sept. 2023, p. 15. Harder does not disclose or suggest that the “drop does not coat or adhere to the object so as to

prevent efficient removal of the drop from the object.” Paper 10, 15 Sept. 2023, p. 15.

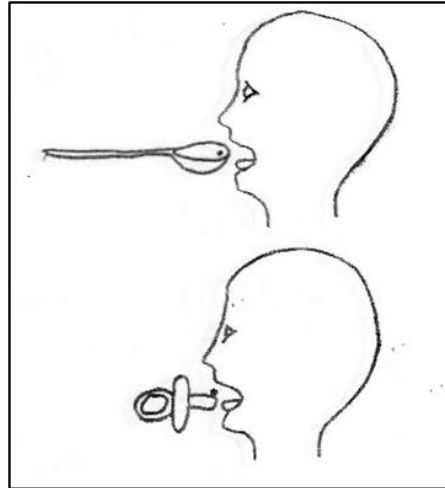
64. It is easy to demonstrate that if a single drop of MCT is applied to the tip of a spoon, that drop will quickly settle into the depth of the bowl of that spoon. If you put a drop of MCT on the tip of a steel spoon, the drop spreads out and rolls away from the tip beyond the reach of a baby’s mouth.

65. The Harder reference is not credible. Harder does not understand the basics of breastfeeding that were cited above. Any licking activity by a breastfeeding infant is related to finding the nipple of the mother and the rooting reflex. Infants do not consume anything by licking.

66. Moreover, when a spoon enters a person’s mouth, the tongue is underneath the spoon. There is no way to lick a spoon unless it is turned upside down, and that does not make sense in the context of Harder’s suggestion. Furthermore, the shape of a spoon is not something that an infant would readily suck on. A spoon is more likely to annoy an infant than stimulate licking. Harder only mentions “lick” (supposedly) and does not mention “suck.”

67. The following simple drawing makes clear the substantial and significant differences between Harder and the ‘958 Patent (Harder is illustrated at the top and the ‘958 Patent is illustrated below). The drawing does not show the fact that the drop of oil will spread across approximately half the spoon surface.

68. The upper drawing illustrates Harder's presumed suggestion. The lower drawing illustrates the '958 Patent. The dot represents the initial location of placement of the drop, which in reality is not a bead, but the oil spreads as a film coating the surface.



Harder places the drop on the tip of a spoon, which is not a size or shape that an infant can naturally suck on. Because the baby's tongue is under the spoon, the Harder reference suggestion makes it impossible to actually lick the dose, even if an infant had the ability to lick the dose to consume it. In contrast, '958 Patent places the drop on the exterior of a size, shape and material that the infant will naturally suck on.

69. The Petition and Williams' opinion is premised upon the idea that if you can place a dose of a liquid onto a spoon to be licked off, then it is obvious to put a single drop of a liquid onto a nipple or pacifier. Their thinking is simply wrong. The Petition and Williams are extrapolating the location of the drop, the interaction of the drop and the spoon, and the mechanism of transferring the drop to the infant. Harder (presumably) instructs that the baby is given the spoon "to lick off". Harder does not make sense because it is well-known that a baby does not lick in order to consume anything.

70. Harder never conceived of, did not address, and never solved the problems solved by the '958 Patent. She never showed whether a drop would not drip from a small exterior surface like a pacifier or nipple. Harder used a spoon, which is by definition a long handle with a bowl that holds any liquid. She never addressed the fundamental question of how much of the dose was left on the spoon.

71. Harder never validated her suggested approach as one that can deliver the full dose of vitamin D. In fact, much of the dose will remain stuck on the spoon. If Harder's suggested approach were widely used, there would be news reports that vitamin D deficiency was occurring despite parents trying to give drops of vitamin D to infants with a spoon.

72. The Petition and Williams' fixation on "Vigantol" mentioned in Harder is a red herring. "Vigantol" does not fix any of the deficiencies in what Harder suggests.

73. The reference to "Vigantol" had nothing to do with whether or not the liquid could stick to a small surface, whether or not the dose might drip out of the spoon, or whether it was actually removed off the surface of the spoon.

74. Furthermore, Harder first suggests dissolving a ground tablet in water and ingesting that from a spoon. ("The tablets disperse quickly in a spoonful of water and can be drunk easily from a spoon.") Her single, almost passing

suggestion, of using a drop of oil, in the context of the risk of overdose, is not a disclosure or suggestion of the inventions claimed in the '958 Patent.

75. The Petition's reliance on "Vigantol" oil is misplaced. "Vigantol" is simply the name for a particular brand of vitamin D in MCT. Harder states clearly that her use of "Vigantol" was based solely on the fact it was a simple product consisting of vitamin D in vegetable oil; her choice had nothing to do with MCT.

76. Williams opines that Harder's reference to "medium chain triglycerides (vegetable oil)" teaches that it "would be sufficiently viscous to adhere to the surface of an object (*e.g.*, nipple)." I disagree. Harder's parenthetical reference to "vegetable oil" shows that she does not appreciate that MCT is special in any way. Williams' declaration does not explain why any person of ordinary skill would have recognized the fundamental difference in physical characteristics between any vegetable oil and MCT that made possible the experimental results and the claims of the '958 Patent. According to Harder and Williams, any vegetable oil should have worked fine.

77. Moreover, "Vigantol" is just a brand name, and for many years was a tablet. It was found to cause toxicity in infants. Once it became an oil, it was (and is) available only by medical prescription in certain countries in Europe. It is not available in the United States or Canada. One cannot readily obtain a sample, and its actual composition is not readily available or listed on the product packaging.

78. Harder recognizes the risk inherent in using “Vigantol” when she strenuously cautions to use only one drop and to wipe the spoon and start over if more than one drop is applied.

79. The Wolf reference relied on by Williams lists many liquid vitamin D products. There were many liquid options for delivering vitamin D to choose from, most of which were not dissolved in MCT.

80. Wolf does not address the complex interrelated variables solved by the ‘958 Patent.

81. More significantly, Wolf states, “Drops or tablets should not be added to the bottle, but administered to the baby on a spoon with some liquid.” (Emphasis added.) The fact that Wolf adds liquid to the single-drop products recognizes the difficulty of efficiently delivering the full dose of a single drop from a surface. By adding extra liquid, Wolf understands that some liquid, and thus some of the dose, is left behind and not consumed. Williams glosses over this critical point and has no response.

82. Wolf is a peer-reviewed publication that therefore teaches away from the single-drop method claimed in the ‘958 Patent.

83. Wolf also teaches away from the carrier recited in the claims of the ‘958 Patent.

84. The Blass reference suggests that by sucking on something sweet, an infant is distracted from an acute pain it otherwise is suffering.

85. Nothing in Blass mentions or suggests delivery of any agent into the body. Blass describes the method as “nonpharmacological”.

86. Blass is irrelevant. It does not address any of the five inter-related variables that were solved by the ‘958 Patent.

87. Williams’ reliance on *European Pharmacopoeia* is also misplaced. First, it relates only to MCT and does not mention any active ingredient, vitamin D or otherwise.

88. Williams says *European Pharmacopoeia* shows the “qualitative and quantitative composition of and the test to be carried out” on medicines. Some of the characteristics of MCT are stated in terms of references to standards and tests. However, the standards and test procedures are not contained in the referenced part of *European Pharmacopoeia*. No pharmacopoeia exists that compares the efficiencies with which a person can readily lick or suck off the oil from a surface.

89. The Gartner reference simply discloses the minimum daily dose recommendation for vitamin D. It, too, does not address any of the 5 inter-related variables solved by the ‘958 Patent.

90. I disagree with Williams that a researcher in the field would have been motivated to combine Harder, Wolf, and *European Pharmacopoeia* to solve the 5

inter-related variables of the invention. Williams provides no rational reasons why anyone would be motivated to address the problem the ‘958 Patent solves.

91. Moreover, as explained above, these 3 references do not disclose or suggest the solution to the 5 inter-related variables problem solved in the ‘958 Patent. Indeed, Wolf teaches away from the one drop solution and adds a carrier.

92. Williams is wrong to argue that a researcher would read Wolf and Harder “to deliver a nutritional and therapeutic amount of vitamin D in an oil composition to a baby by applying the oil to an object, such as the tip of a spoon, in a manner that would allow the baby to lick it off.”

93. Firstly, Wolf argues against using a single drop, such as on a spoon. Secondly, breastfeeding infants do not “lick” anything from surfaces, because sticking out their tongue through closed lips is simply part of the rooting reflex to find the nipple and to latch.

94. In my opinion, a person of ordinary skill in the art, which according to Williams [paragraph 84] includes a person with a doctorate degree in pharmaceuticals, would not look to a baby care book (Harder) for midwives in attempting to solve the problem solved in the ‘958 Patent.

95. Harder never offers any evidence that her method actually delivers any vitamin D to the infant. Wolf recognizes the inefficiency of pulling a single drop from a spoon and advises adding additional liquid. *European Pharmacopoeia*

offers no insight of why MCT is any different from any other oil so far as delivery efficiency to lick it from a surface. Likewise, Harder fails to distinguish characteristics between MCT and vegetable oil, and she incorrectly equates the two. Harder's understanding of the licking behavior of a breastfeeding infant is wrong, and she contradicts the published peer-reviewed literature on the subject.

96. Adding the Blass reference does not solve the deficiencies in Harder, Wolf, and *European Pharmacopoeia*. Blass never demonstrates that the solution being sucked on ever enters the body of an infant or human being. At best it shows that having something sweet in the mouth may distract from the baby's immediate pain of the heel prick necessary to obtain a blood sample.

97. Substituting Gartner for Blass in the above combination similarly does not solve the 5 inter-related variables of the problem. Gartner does not suggest anything about delivery of vitamin D other than "currently available" multivitamins that include vitamin D or vitamin D-fortified milk or formula. Gartner does not even address the fact there is a problem with how to administer vitamin D to a human being.

98. I have read Williams' declaration and the transcript of his deposition. Among many issues with his opinions, I am particularly surprised that his declaration apparently was written for him by Petitioner's attorneys. The five prior

art references discussed above were selected for him by the attorneys, and the specific combinations of prior art had been laid out for him.

99. Williams admitted that the prior art reference combinations do not disclose how many licks are necessary to get a nutritional or therapeutic amount of vitamin D. Williams knows nothing about breastfeeding and there is no indication that he has made any effort at all to understand the mechanisms of breastfeeding.

100. Contrary to Williams' leap in logic, no amount of "common sense and human experience" will inform about the efficiency with which sucking or licking will pull a nutritional or therapeutic dose of vitamin D in an oil off a surface, much less a pacifier or nipple.

I, Reinhold Vieth declare and state that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code.

Dated: 3 February 2024.



Reinhold Vieth

Exhibit A

Curriculum Vitae of Reinhold Vieth January, 2024

Reinhold Vieth, BSc MSc PhD, Dipl Clinical Chemistry, FCACB (Fellow of Canadian Academy of Clinical Biochemists), Professor Emeritus, University of Toronto
27 Chester Hill Road, Toronto M4K 1X4
Cell 416-992-9389

Email reinhold.vieth@utoronto.ca

B. BIOGRAPHICAL INFORMATION

1. Degrees:

DEGREE	UNIVERSITY	DEPARTMENT	YEAR
B.Sc.	University of Toronto	Medical Sciences	1974
M.Sc.	University of Toronto	Physiology	1975
Ph.D.	University of Toronto	Physiology	1980
Diploma	University of Toronto	Clinical Chemistry	1982

Professional Certifications

Certification by Canadian Society of Clinical Chemists,	1983
Fellow of Canadian Academy of Clinical Biochemists (F.C.A.C.B.*)	1987

*Professional certification indicating scientific and technical competence to oversee the operation of hospital or private laboratory biochemical laboratory service for diagnostic testing of human blood samples.

Distinctions

Canadian Association for Clinical Chemistry Award for Excellence in Research, presented at the CSCC Annual Conference in Quebec City, June 17-20, 2012

2. Employment

Date	Rank and Position	Department	Institution
2012-	Professor Emeritus, Department of Pathobiology and Laboratory Medicine, University of Toronto, and Department of Nutritional Sciences, University of Toronto		
2005-2015	Professor, Dept of Nutritional Sciences	U of Toronto	
2005-2012	Professor. Primary departmental appointment, Dept of Laboratory Medicine and Pathobiology, Faculty of Medicine, University of Toronto		
1990- 2012	Clinical Chemist and Director, Bone and Mineral Lab		Mount Sinai Hospital
2009-	2012 Clinical Chemist and Director, Point-of-Care Testing, Mount Sinai Hospital		
2004	Assoc Prof. Cross-appointment, Dept of Nutritional Sciences		U of Toronto
1999- (4 yrs)	Associate Professor	Pathobiology and Laboratory Medicine	U of Toronto
1985-1999 and Lab Medicine, U of T	(14 yrs)	Assistant Professor	Pathobiology

1982-1985 Biochemistry	(3 yrs) U of Toronto	Lecturer	Clinical
1982-90 U of Toronto	(8 yrs)	Laboratory Director Bone and Mineral Group	
1988- 1990 U Puerto Rico	(2 yrs)	Collaborating Scientist	Caribbean Primate Res Ctr

Teaching Appointments Held:

2002-2017: Course Coordinator sole instructor, LMP1407: Introductory Biostatistics and Clinical Investigation (annual enrollment 120 postgraduate MSc, PhD, clinical chemistry, medical and dentistry residents)

1995 to 2002 (7 yrs) Course Coordinator, LMP1407: From Bench to Bedside: Design, Measurement and Analysis for Clinical Investigators.

2007-10 (3 yrs) Guest lecturer, LMP404: Bone and Skeletal Disorders.

2002 – 2007 (5 yrs) Course Co-Coordinator with Dr W Vogel, LMP404: Bone and Skeletal Disorders.

1995 -Dec/97 (2.5 yrs) Graduate Studies Coordinator, Department of Clinical Biochemistry, U of Toronto

1992 . 1994 (2 yrs) Course co-coordinator with Dr AD Baines, JCL1406: Methods in Clinical Investigation

1995 – 1998 (3 yrs) Course Coordinator, CLB405: Undergraduate Project Course.

1998 - 2002 (5 yrs) Course Co-Coordinator with Dr H Yeger, LMP405: Undergraduate Project Course.

Professional Affiliations and Activities:

Member, American Society for Bone and Mineral Research

Member, Canadian Society of Clinical Chemists

Member, The Endocrine Society

Member, American Society for Nutrition

: **Journal Reviewer** I have served as a peer reviewer of manuscripts submitted to each of the following journals (minimum one manuscript each, including their revisions)

- American Journal of Clinical Nutrition
- European Journal of Clinical Nutrition
- British Journal of Nutrition
- Calcified Tissue International
- European Journal of Pediatrics
- Food and Nutrition
- Journal of Bone and Mineral Metabolism
- Journal of Rheumatology
- Journal of the American Geriatric Society
- Journal of Clinical Endocrinology and Metabolism
- New England Journal of Medicine
- Osteoporosis International
- Nutrition
- Nutrition Research
- Public Health Nutrition
- Steroid Biochemistry and Molecular Biology

C. ACADEMIC HISTORY

1. Completed double-blind randomized clinical trial of vitamin D during the weeks leading to radical prostatectomy (I am PI, the first grant application for this work was submitted in 2005, and this has taken 7 years to complete). Our late-breaking abstract was promoted to an oral presentation at the recent American Association for Cancer meeting and was one of only 7 selected for press release. The presentation is available online <http://webcast.aacr.org/console/player/18186?mediaType=slideVideo>
The main achievement of that work was the development by my graduate student, Dennis Wagner, of an assay for calcitriol (the active vitamin D metabolite) in tissue, and it was those tissue calcitriol results that correlated with the key cancer-related outcome changes in the prostate.
2. We published two more papers reporting on our clinical trial of vitamin D in patients with Multiple Sclerosis (see 7, 10 of publications). The trial for which I was co-PI with Paul O'Connor was completed in 2010, , St Michael's Hospital. This work led Merck-Serono to fully-fund a multicenter clinical trial of our average vitamin D-dosage in MS patients on beta interferon. <http://clinicaltrials.gov/ct2/show/NCT01285401> I am on the organizing group for this trial.
3. Served on two vitamin D panels to advise policy: American Geriatric Society, and Canadian Academy of Health Sciences.

2. Research Awards (Operating Grants)

Year	Individual(s) or Group	Grantor
Amount		

Research Grants:

Held Grants

2014 Vitamin D Society. Quantification of the effect of Canadian tanning facility practices on the concentration of serum 25-hydroxyvitamin D. \$60,000

2014-2018 Dairy nutrition and risk of diabetes in vulnerable populations: novel insights from biomarkers, measures of marginalization, and their interaction. Dairy Farmers of Canada, Dairy Research Cluster 2 Program. January 1, 2014- March 2018. Investigators: A. Hanley, R. Bazinet, S. Harris, D. Cole, B. Zinman, R. Retnakaran, J. Gittelsohn, S. Bruce, L. Wagenknecht, C. Lorenzo, J. Norris, A. Brown, L. Maple-Brown, **R. Vieth**, C. Lee. Total budget, \$928,000.

2010-2012 Dairy Farmers of Canada. Improved Retention of vitamin D in cheese based on casein-specific binding. 2-yr total, \$246,740.00

2010-2011 Direct-MS. Analysis of samples and data collected in Phase 1-2 clinical trial of high-dose vitamin D in the treatment of multiple sclerosis. \$45,000

2006-2010 National Cancer Institutes of Canada. Vitamin D-dose effects on prostate immunohistochemical markers at prostatectomy, \$129485.00; 2007-8, \$133245.00

Co-Investigator.

Arnaout, Angel (PI) A Phase 2 Randomised, Double-blind, Window of Opportunity Trial Evaluating Clinical and Correlative Effects of Vitamin D in Patients with Breast Cancer (The ICARUS Study) Canadian Breast Cancer Foundation – Ontario Chapter. \$275,050 over 3 year

Tom Wolever PI. Effect of vitamin D supplementation on indices of insulin sensitivity and β -cell function in humans at risk for type 2 diabetes with marginal vitamin D status Dairy Farmers of Canada 3 years \$260,000.

Jonathan Maguire PI, DO IT: Vitamin D Outcomes and Interventions in Toddlers. CIHR Priority Announcement - INMD Startup Funds (Bridge funding) 1 year \$100,000

Dr. Ravi Rajan Retnakaran PI Vitamin D and the Early Pathophysiology of Type 2 Diabetes in Women with a History of Gestational Diabetes CIHR, \$98,000

Raymond Hupperts PI. Sponsor Merck-Serono Merck KgAA Supplementation of Vigantol® Oil Versus Placebo as Add-on in Patients With Relapsing Remitting Multiple Sclerosis Receiving Rebif® Treatment (SOLAR) 3 years Funding at 6 million Euro.

Previous Support

- 2006-2008 Multiple Sclerosis Foundation of Canada. Vitamin D in predicting risk for and prognosis in multiple sclerosis, \$164300.00; 2007-8, \$112300.00
- 2006-2007 Dairy Farmers of Canada. DEC Cole, R Vieth. 2006-7, \$68060.00; 2007-8, \$68060.00.
- 2006-2007 **Vieth R**, O'Connor P. Phase 1B study of vitamin D in patients with multiple sclerosis. \$200,000.00 , DirectMS, Calgary.
- 2006-2007. Clemons M, Cole DEC, **Vieth R**. Vitamin D as in the palliative care of patients with metastatic breast cancer. \$100,000.00. Vitamin D Society, Research Donation.
- 2004-2006 M Grynpas, R Vieth, R Kandel. Can vitamin D delay or arrest the progression of Osteoarthritis in an animal model? Canadian Institutes for Health Research. \$83897.00/yr (I am co-applicant)
- 2005-2007 R Vieth, D Rousseau. Bioavailability of Vitamin D from fortified cheese, ice cream and yogurt. Dairy Farmers of Canada, \$38,000 per year. (I am PI)
- 2004-2006 David Cole, Reinhold Vieth. Genetics influences on the variability of response to vitamin D supplementation. Dairy Farmers of Canada. I am co-applicant.
- 2003-2006 Julia Knight, R Vieth. A study of normal light exposure and melatonin in healthy women. \$325,665.00 per year. Canadian Breast Cancer Research Initiative (I am co-investigator)
- 2003-2004 George Ebers. Vitamin D nutritional status as a risk factor for multiple sclerosis: a pilot study. The Multiple Sclerosis Society of Canada. \$50,000. (I am collaborator)
- 2002-2004 Derrick Rousseau and R Vieth. Approaches to the Fortification of Dairy Foods with Vitamin D. Dairy Farmers of Canada, \$38,000 per year. (I am co-applicant)
- 2003-2006 A.M. Cheung, G. Hawker, R. Josse, P. Massicotte, T. Murray, L. Thompson, R. Vieth. Evaluation of the use of vitamin K in postmenopausal women with osteopenia – ECKO trial. CIHR, \$152 563/yr (I am one of 6 coapplicants)
- 2001-2003 El Haj-Fuleihan and R Vieth. Clinical trial of the efficacy of greater vitamin D supplementation for school children in Lebanon. Nestle Foundation, US\$160,000/yr (I am co-applicant)
- 2001-2003 R Vieth, Rubin L, Josse R, Cole DEC. Vitamin D and osteoporosis prevention, healthy postmenopausal women (The POWDER Study). CIHR, Oct 1, 2000 – Sept 30, 2003. \$94,180.00 (I am PI) Funds sufficient to Mar 2005 (subject recruitment was slow, and so was rate of expenditure)
- 2001-2001 R. Vieth. Human Vitamin D Nutrition and its Effects on Gene Expression in Whole Blood. Dairy Farmers of Canada Operating Grant. \$40,000, one-year pilot study (I am PI)
- 2000-2001 R. Vieth. The effects of vitamin D supplementation on immune function of normal adults and responses of patients with metastatic prostate cancer. Centrum Foundation, \$25,000.00. (I am PI)
- 1998-2000 P Walfish, R. Vieth Characterization of vitamin D status in endocrine clinic outpatients. \$15,000/yr. Merck KGaA, Darmstadt, Germany (I am co-PI)
- 1996-97 R.Vieth Ciba-Geigy Canada Operating Grant \$85,000/yr. Renewal, bisphosphonate assays (I am PI)

1995-97 R. Vieth Dairy Farmers of Canada Operating Grant .\$.48,000/yr. D. Cole ; R Vieth was principal investigator. Effects of vitamin D supplementation on normal subjects and kidney stone patients. (I am PI)

1995-97 D. Cole , L Rubin, R. Vieth Dairy Farmers of Canada Operating Grant .\$.83,000/yr. Principal investigator, Dr Cole; Genetics of calcium-sensing receptor (I am collaborator)

1994-96 R.Vieth Ciba-Geigy Canada Operating Grant \$60,000/yr. Development of bisphosphonate assays in bone (I am PI)

1994 R.Vieth Ciba-Geigy Canada Equipment Grant \$60,000 1992-94 R.Vieth Medical Research Council of Canada. Operating Grant \$58,000/yr. (I am PI)

1990-92 R.Vieth Medical Research Council of Canada Operating Grant. \$52,003.00/yr. Adaptation dynamics in the vitamin D endocrine system (I am PI)

1989-90 S.W. Kooh, Abbott Laboratories, Canada Operating Grant \$25,000 (I am one of two coapplicants)

1988-89 R. Vieth Research Institute of the Queen Elizabeth Hospital. \$7,773.00 To study the metabolic fate of oral vs intracardial 25(OH)D in rats. (I am PI)

1988-89 S.W. Kooh, The Kidney Foundation Operating Grant \$39,800 R. Vieth , J.W. Balfe I was primary author of the resulting paper Publication 14. (I am one of two coapplicants)

1987-1988 Kessler MJ, Pritzker KPH, **Vieth R.** United States Dept. of Health and Human Services. \$5,000.00 support for The Caribbean Primate Research Center Program. (I am collaborator)

1986-87 R. Vieth. Medical Research Council of Canada. \$10,250.00 "Control of 25(OH)D3-24-hydroxylase activity". (I am PI)

1984-86 R. Vieth. Medical Research Council of Canada. \$41,000.00/yr. "Control of 25(OH)D3-24-hydroxylase activity". (I am PI)

D. PUBLICATIONS

REFEREED PUBLICATIONS

Published since retirement:

UVB-emitting cloth to prevent low serum 25-hydroxyvitamin D caused by clothing.

Vieth R. Eur J Clin Nutr. 2023 Mar;77(3):405-406. doi: 10.1038/s41430-022-01253-9. Epub 2022 Dec 9. PMID: 36494476 No abstract available.

2

An Appraisal to Address Health Consequences of Vitamin D Deficiency With Food Fortification and Supplements: Time to Act!

Reichrath J, März W, DE Gruijl FR, **Vieth R**, Grant WB, Slominski AT, Holick MF, Vogt T, Pilz S. Anticancer Res. 2022 Oct;42(10):5009-5015. doi: 10.21873/anticancer.16008. PMID: 36192012 Review.

3

Critique of Public Health Guidance for Vitamin D and Sun Exposure in the Context of Cancer and COVID-19.

Vieth R. Anticancer Res. 2022 Oct;42(10):5027-5034. doi: 10.21873/anticancer.16011. PMID: 36191997 Review.

4

Mistakes in terminology cause false conclusions: Vitamin D does not increase the risk of dementia.

Vieth R. Aging Cell. 2022 Oct;21(10):e13722. doi: 10.1111/acer.13722. Epub 2022 Sep 29. PMID: 36173739 Free PMC article.

5

Individual participant data (IPD)-level meta-analysis of randomised controlled trials with vitamin D-fortified foods to estimate Dietary Reference Values for vitamin D.

Cashman KD, Kiely ME, Andersen R, Grønberg IM, Madsen KH, Nissen J, Tetens I, Tripkovic L, Lanham-New SA, Toxqui L, Vaquero MP, Trautvetter U, Jahreis G, Mistry VV, Specker BL, Hower J, Knoll A, Wagner D, **Vieth R**, Öhlund I, Karlsland Åkeson P, Brett NR, Weiler HA, Ritz C. Eur J Nutr. 2021 Mar;60(2):939-959. doi: 10.1007/s00394-020-02298-x. Epub 2020 Jun 15. PMID: 32556447

6

Supplemental Vitamins and Minerals for Cardiovascular Disease Prevention and Treatment: JACC Focus Seminar.

Jenkins DJA, Spence JD, Giovannucci EL, Kim YI, Josse RG, **Vieth R**, Sahye-Pudaruth S, Paquette M, Patel D, Blanco Mejia S, Viguiliouk E, Nishi SK, Kavanagh M, Tsirakis T, Kendall CWC, Pichika SC, Sievenpiper JL. J Am Coll Cardiol. 2021 Feb 2;77(4):423-436. doi: 10.1016/j.jacc.2020.09.619. PMID: 33509399 Free article.

7

Vitamin D supplementation: cholecalciferol, calcifediol, and calcitriol.

Vieth R. Eur J Clin Nutr. 2020 Nov;74(11):1493-1497. doi: 10.1038/s41430-020-0697-1. Epub 2020 Jul 23. PMID: 32704098 Review.

8

Correction to: Weaker bones and white skin as adaptations to improve anthropological "fitness" for northern environments.

Vieth R. Osteoporos Int. 2020 Apr;31(4):803-804. doi: 10.1007/s00198-019-05251-9. PMID: 31970437 Free PMC article.

9

Weaker bones and white skin as adaptations to improve anthropological "fitness" for northern environments.

Vieth R. Osteoporos Int. 2020 Apr;31(4):617-624. doi: 10.1007/s00198-019-05167-4. Epub 2019 Nov 6. PMID: 31696275 Free PMC article. Review.

10

Neither human nor mouse is hypercalcaemic with 250 nmol/l 25-hydroxyvitamin D.

Vieth R. Brain. 2020 Feb 1;143(2):e9. doi: 10.1093/brain/awz388. PMID: 31848581 No abstract available.

11

The Paleolithic Nutrition Model in Relation to Ultraviolet Light and Vitamin D.

Vieth R. Adv Exp Med Biol. 2020;1268:409-419. doi: 10.1007/978-3-030-46227-7_21. PMID: 32918231 Review.

12

Randomized trial of daily high-dose vitamin D₃ in patients with RRMS receiving subcutaneous interferon β -1a.
Hupperts R, Smolders J, **Vieth R**, Holmøy T, Marhardt K, Schluep M, Killestein J, Barkhof F, Beelke M, Grimaldi LME; SOLAR Study Group. *Neurology*. 2019 Nov 12;93(20):e1906-e1916. doi: 10.1212/WNL.0000000000008445. Epub 2019 Oct 8. PMID: 31594857 Free PMC article. Clinical Trial.

13

Randomized window of opportunity trial evaluating high-dose vitamin D in breast cancer patients.

Arnaout A, Robertson S, Pond GR, **Vieth R**, Jeong A, Hilton J, Ramsey T, Clemons M. *Breast Cancer Res Treat*. 2019 Nov;178(2):347-356. doi: 10.1007/s10549-019-05392-9. Epub 2019 Aug 9. PMID: 31399931 Clinical Trial.

14

Hypercalcemia and a "no observed adverse effect level" intake of vitamin D.

Vieth R. *CMAJ*. 2019 Jul 8;191(27):E768. doi: 10.1503/cmaj.72512. PMID: 31285382 Free PMC article. No abstract available.

15

25-Hydroxyvitamin D variability within-person due to diurnal rhythm and illness: a case report.

French CB, McDonnell SL, **Vieth R**. *J Med Case Rep*. 2019 Feb 4;13(1):29. doi: 10.1186/s13256-018-1948-9. PMID: 30712514 Free PMC article.

16

Rationale and Plan for Vitamin D Food Fortification: A Review and Guidance Paper.

Pilz S, März W, Cashman KD, Kiely ME, Whiting SJ, Holick MF, Grant WB, Pludowski P, Hilgsmann M, Trummer C, Schwetz V, Lerchbaum E, Pandis M, Tomaschitz A, Grubler MR, Gaksch M, Verheyen N, Hollis BW, Rejnmark L, Karras SN, Hahn A, Bischoff-Ferrari HA, Reichrath J, Jorde R, Elmadfa I, **Vieth R**, Scragg R, Calvo MS, van Schoor NM, Bouillon R, Lips P, Itkonen ST, Martineau AR, Lamberg-Allardt C, Zittermann A. *Front Endocrinol (Lausanne)*. 2018 Jul 17;9:373. doi: 10.3389/fendo.2018.00373. eCollection 2018. PMID: 30065699 Free PMC article. Review.

17

Supplemental Vitamins and Minerals for CVD Prevention and Treatment.

Jenkins DJA, Spence JD, Giovannucci EL, Kim YI, Josse R, **Vieth R**, Blanco Mejia S, Viguiliouk E, Nishi S, Sahye-Pudurath S, Paquette M, Patel D, Mitchell S, Kavanagh M, Tsirakis T, Bachiri L, Maran A, Umatheva N, McKay T, Trinidad G, Bernstein D, Chowdhury A, Correa-Betanzo J, Del Principe G, Hajizadeh A, Jayaraman R, Jenkins A, Jenkins W, Kalaichandran R, Kirupaharan G, Manisekaran P, Qutta T, Shahid R, Silver A, Villegas C, White J, Kendall CWC, Pichika SC, Sievenpiper JL. *J Am Coll Cardiol*. 2018 Jun 5;71(22):2570-2584. doi: 10.1016/j.jacc.2018.04.020. PMID: 29852980 Free article.

18

1: Kimball SM, Lee J, **Vieth R**. Sunbeds with UVB radiation can produce physiological levels of serum 25-Hydroxyvitamin D in healthy volunteers. *Dermatoendocrinol*. 2017 Oct 17;9(1):e1375635. doi: 10.1080/19381980.2017.1375635. eCollection 2017. PubMed PMID: 29484099; PubMed Central PMCID: PMC5821157.

2: Brisson J, Bérubé S, Diorio C, Mâsse B, Lemieux J, Duchesne T, Delvin E, **Vieth R**, Yaffe MJ, Chiquette J. A Randomized Double-Blind Placebo-Controlled Trial of the Effect of Vitamin D(3) Supplementation on Breast Density in Premenopausal Women. *Cancer Epidemiol Biomarkers Prev*. 2017 Aug;26(8):1233-1241. doi: 10.1158/1055-9965.EPI-17-0249. Epub 2017 May 17. PubMed PMID: 28515107.

3: Darling AL, Hart KH, Gossiel F, Robertson F, Hunt J, Hill TR, Johnsen S, Berry JL, Eastell R, **Vieth R**, Lanham-New SA. Higher bone resorption excretion in South Asian women vs. White Caucasians and increased bone loss with higher seasonal cycling of vitamin D: Results from the D-FINES cohort study. *Bone*. 2017

May;98:47-53. doi: 10.1016/j.bone.2017.03.002. Epub 2017 Mar 7. PubMed PMID: 28286239.

4: Dambal S, Giangreco AA, Acosta AM, Fairchild A, Richards Z, Deaton R, Wagner D, **Vieth R**, Gann PH, Kajdacsy-Balla A, Van der Kwast T, Nonn L. microRNAs and DICER1 are regulated by 1,25-dihydroxyvitamin D in prostate stroma. *J Steroid Biochem Mol Biol*. 2017 Mar;167:192-202. doi: 10.1016/j.jsbmb.2017.01.004. Epub 2017 Jan 12. PubMed PMID: 28089917; PubMed Central PMCID: PMC5304339.

5: Moreira-Lucas TS, Duncan AM, Rabasa-Lhoret R, **Vieth R**, Gibbs AL, Badawi A, Wolever TM. Effect of vitamin D supplementation on oral glucose tolerance in individuals with low vitamin D status and increased risk for developing type 2 diabetes (EVIDENCE): A double-blind, randomized, placebo-controlled clinical trial. *Diabetes Obes Metab*. 2017 Jan;19(1):133-141. doi: 10.1111/dom.12794. Epub 2016 Nov 9. PubMed PMID: 27717236.

6: Al-Khalidi B, Chiu W, Rousseau D, **Vieth R**. Bioavailability and Safety of Vitamin D3 from Pizza Baked with Fortified Mozzarella Cheese: A Randomized Controlled Trial. *Can J Diet Pract Res*. 2015 Sep;76(3):109-16. doi: 10.3148/cjdpr-2015-015. PubMed PMID: 26280790.

7: Daley P, Jagannathan V, John KR, Sarojini J, Latha A, **Vieth R**, Suzana S, Jeyaseelan L, Christopher DJ, Smieja M, Mathai D. Adjunctive vitamin D for treatment of active tuberculosis in India: a randomised, double-blind, placebo-controlled trial. *Lancet Infect Dis*. 2015 May;15(5):528-34. doi: 10.1016/S1473-3099(15)70053-8. Epub 2015 Apr 8. PubMed PMID: 25863562.

8: Chow E, DeAngelis C, Chen BE, Azad A, Meyer RM, Wilson C, Kerba M, Bezjak A, Wilson P, Nabid A, Greenland J, Rees G, **Vieth R**, Wong RK, Hoskin P. Effect of re-irradiation for painful bone metastases on urinary markers of osteoclast activity (NCIC CTG SC.20U). *Radiother Oncol*. 2015 Apr;115(1):141-8. doi: 10.1016/j.radonc.2015.02.025. Epub 2015 Mar 14. PubMed PMID: 25782738.

9: Giangreco AA, Dambal S, Wagner D, Van der Kwast T, **Vieth R**, Prins GS, Nonn L. Differential expression and regulation of vitamin D hydroxylases and inflammatory genes in prostate stroma and epithelium by 1,25-dihydroxyvitamin D in men with prostate cancer and an in vitro model. *J Steroid Biochem Mol Biol*. 2015 Apr;148:156-65. doi: 10.1016/j.jsbmb.2014.10.004. Epub 2014 Oct 8. PubMed PMID: 25305352; PubMed Central PMCID: PMC4361379.

10: Muscogiuri G, Mitri J, Mathieu C, Badenhoop K, Tamer G, Orio F, Mezza T, **Vieth R**, Colao A, Pittas A. Mechanisms in endocrinology: vitamin D as a potential contributor in endocrine health and disease. *Eur J Endocrinol*. 2014 Sep;171(3):R101-10. doi: 10.1530/EJE-14-0158. Epub 2014 May 28. Review. PubMed PMID: 24872497.

11: American Geriatrics Society Workgroup on Vitamin D Supplementation for Older Adults. Recommendations abstracted from the American Geriatrics Society Consensus Statement on vitamin D for Prevention of Falls and Their Consequences. *J Am Geriatr Soc*. 2014 Jan;62(1):147-52. doi: 10.1111/jgs.12631. Epub 2013 Dec 18. PubMed PMID: 24350602.

12: Mocanu V, **Vieth R**. Three-year follow-up of serum 25-hydroxyvitamin D, parathyroid hormone, and bone mineral density in nursing home residents who had received 12 months of daily bread fortification with 125 µg of vitamin D₃. *Nutr J*. 2013 Oct 11;12:137. doi: 10.1186/1475-2891-12-137. PubMed PMID: 24120120; PubMed Central PMCID: PMC3874673.

13: Darling AL, Hart KH, Gibbs MA, Gossiel F, Kantermann T, Horton K, Johnsen S, Berry JL, Skene DJ, Eastell R, **Vieth R**, Lanham-New SA. Greater seasonal cycling of 25-hydroxyvitamin D is associated with increased parathyroid hormone and bone resorption. *Osteoporos Int*. 2014 Mar;25(3):933-41. doi: 10.1007/s00198-013-2493-4. Epub 2013 Aug 28. PubMed PMID: 23982802.

14: Al-Shaar L, Nabulsi M, Maalouf J, El-Rassi R, **Vieth R**, Beck TJ, El-Hajj Fuleihan G. Effect of vitamin D replacement on hip structural geometry in adolescents: a randomized controlled trial. *Bone*. 2013 Oct;56(2):296-303. doi: 10.1016/j.bone.2013.06.020. Epub 2013 Jun 28. PubMed PMID: 23810841.

15: Giangreco AA, Vaishnav A, Wagner D, Finelli A, Fleshner N, Van der Kwast T, **Vieth R**, Nonn L. Tumor suppressor microRNAs, miR-100 and -125b, are regulated by 1,25-dihydroxyvitamin D in primary prostate cells and in patient tissue. *Cancer Prev Res (Phila)*. 2013 May;6(5):483-94. doi: 10.1158/1940-6207.CAPR-12-0253. Epub 2013 Mar 15. PubMed PMID: 23503652; PubMed Central PMCID: PMC3644314.

16: Chow EC, Quach HP, **Vieth R**, Pang KS. Temporal changes in tissue 1α,25-dihydroxyvitamin D₃, vitamin D receptor target genes, and calcium and PTH levels after 1,25(OH)₂D₃ treatment in mice. *Am J Physiol Endocrinol Metab*. 2013 May 1;304(9):E977-89. doi: 10.1152/ajpendo.00489.2012. Epub 2013 Mar 12. PubMed

PMID: 23482451.

17: Wagner D, Trudel D, Van der Kwast T, Nonn L, Giangreco AA, Li D, Dias A, Cardoza M, Laszlo S, Hersey K, Klotz L, Finelli A, Fleshner N, **Vieth R**. Randomized clinical trial of vitamin D3 doses on prostatic vitamin D metabolite levels and ki67 labeling in prostate cancer patients. *J Clin Endocrinol Metab*. 2013 Apr;98(4):1498-507. doi: 10.1210/jc.2012-4019. Epub 2013 Mar 5. PubMed PMID: 23463655.

18: Kayaniyil S, Harris SB, Retnakaran R, **Vieth R**, Knight JA, Gerstein HC, Perkins BA, Zinman B, Hanley AJ. Prospective association of 25(OH)D with metabolic syndrome. *Clin Endocrinol (Oxf)*. 2014 Apr;80(4):502-7. doi: 10.1111/cen.12190. Epub 2013 Apr 1. PubMed PMID: 23452164.

19: **Vieth R**. The future of "vitamin D", i.e. 25-hydroxyvitamin D, testing. *Clin Biochem*. 2013 Feb;46(3):189. doi: 10.1016/j.clinbiochem.2012.12.018. PubMed PMID: 23298561.

20: Briggs AD, Kuan V, Greiller CL, Maclaughlin BD, Ramachandran M, Harris T, Timms PM, Venton TR, **Vieth R**, Norman AW, Griffiths CJ, Martineau AR. Longitudinal study of vitamin D metabolites after long bone fracture. *J Bone Miner Res*. 2013 Jun;28(6):1301-7. doi: 10.1002/jbmr.1855. PubMed PMID: 23281057.

21: Choo R, Lukka H, Cheung P, Corbett T, Briones-Urbina R, **Vieth R**, Ehrlich L, Kiss A, Danjoux C. Randomized, double-blinded, placebo-controlled, trial of risedronate for the prevention of bone mineral density loss in nonmetastatic prostate cancer patients receiving radiation therapy plus androgen deprivation therapy. *Int J Radiat Oncol Biol Phys*. 2013 Apr 1;85(5):1239-45. doi: 10.1016/j.ijrobp.2012.11.007. Epub 2012 Dec 19. PubMed PMID: 23265571.

Publications prior to retirement:

1. Greenfield JA, Park PS, Farahani E, **Vieth R** et al. Solar ultraviolet-B radiation and vitamin D: a cross-sectional population-based study using data from the 2007 to 2009 Canadian Health Measures Survey. *BMC Public Health* 2012;12:660. doi: 10.1186/1471-2458-12-660.:660-12.
2. Parlea L, Bromberg IL, Feig DS, **Vieth R**, Merman E, Lipscombe LL. Association between serum 25-hydroxyvitamin D in early pregnancy and risk of gestational diabetes mellitus. *Diabet Med* 2012;29:e25-e32.

3. Tripkovic L, Lambert H, Hart K et al. Comparison of vitamin D2 and vitamin D3 supplementation in raising serum 25-hydroxyvitamin D status: a systematic review and meta-analysis. *Am J Clin Nutr* 2012;95:1357-64.
4. **Vieth R.** Implications for 25-Hydroxyvitamin D testing of public health policies about the benefits and risks of Vitamin D fortification and supplementation. *Scand J Clin Lab Invest Suppl* 2012;243:144-53.
5. Wagner D, Dias AG, Schnabl K, Van der KT, **Vieth R.** Determination of 1,25-dihydroxyvitamin D concentrations in human colon tissues and matched serum samples. *Anticancer Res* 2012;32:259-63.
6. Banwell B, Bar-Or A, Arnold DL et al. Clinical, environmental, and genetic determinants of multiple sclerosis in children with acute demyelination: a prospective national cohort study. *Lancet Neurol* 2011;10:436-45.
7. Heaney RP, **Vieth R**, Hollis BW. Vitamin D efficacy and safety. *Arch Intern Med* 2011;171:266.
8. Kayaniyil S, **Vieth R**, Harris SB et al. Association of 25(OH)D and PTH with metabolic syndrome and its traditional and nontraditional components. *J Clin Endocrinol Metab* 2011;96:168-75.
9. Kayaniyil S, Retnakaran R, Harris SB et al. Prospective associations of vitamin D with beta-cell function and glycemia: the PROspective Metabolism and ISlet cell Evaluation (PROMISE) cohort study. *Diabetes* 2011;60:2947-53.
10. Kayaniyil S, **Vieth R**, Harris SB et al. Association of 25(OH)D and PTH with metabolic syndrome and its traditional and nontraditional components. *J Clin Endocrinol Metab* 2011;96:168-75.
11. Kimball S, **Vieth R**, Dosch HM et al. Cholecalciferol plus calcium suppresses abnormal PBMC reactivity in patients with multiple sclerosis. *J Clin Endocrinol Metab* 2011;96:2826-34.
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16. Smolders J, Hupperts R, Barkhof F et al. Efficacy of vitamin D(3) as add-on therapy in patients with relapsing-remitting multiple sclerosis receiving subcutaneous interferon beta-1a: A Phase II, multicenter, double-blind, randomized, placebo-controlled trial. *J Neurol Sci* 2011;311:44-9.
17. **Vieth R.** The Pharmacology of Vitamin D. In: Feldman D, Pike JW, Adams JS, eds. *Vitamin D*. New York: Academic Press 2011:1041-66.
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108. **Vieth R.**, Bayley TA, Walfish PG, Rosen IB, Pollard A. (1991) Relevance of vitamin D metabolite concentrations in supporting the diagnosis of primary hyperparathyroidism. *Surgery* 110: 1043-1047. (SRA)
109. **Vieth R.** (1990) The mechanisms of vitamin D toxicity. *Bone and Mineral* 11:267-272.
110. **Vieth R.** (1990) Presystemic 24-hydroxylation of oral 25-hydroxyvitamin D₃ in rats. *J Bone and Mineral Research* 11:1177-1182. (SRA)
111. **Vieth R**, Kooh SW, Balfe JW, Tinmouth WW and Rawlins M. (1990) Tracer kinetics and actions of oral and intraperitoneal 1,25-dihydroxyvitamin D₃ administration in rats. *Kidney Int* 38: 857-861. (SRA)
112. **Vieth R**, Kessler MJ and Pritzker KPH. (1990) Species differences in the binding kinetics of 25-hydroxyvitamin D₃ to vitamin D binding protein. *Canadian Journal of Physiology and Pharmacology* 68: 1368-1371. (SRA)
113. **Vieth R**, McCarten K and Norwich KH. (1990) Role of 25-hydroxyvitamin D₃ dose in determining rat 1,25-dihydroxyvitamin D₃ production. *Am. J. Physiol.* 258:E780-E789. (SRA)
114. Bayley TA, Muller C, Harrison JE, Basualdo J, Sturtridge WC, Josse RG, Murray TM, Pritzker KPH, **Vieth R**, Goodwin S, and Strauss AL (1990) The long-term treatment of steroid osteoporosis with fluoride. *J. Bone and Mineral Res.* 5 (Suppl 1):S157-S161. (Coll)
115. Bayley TA, Harrison JE, Josse RG, Sturtridge WC, Pritzker KPH, Strauss AL, **Vieth R**, and Goodwin S (1990) Fluoride-induced fractures: relation to osteogenic effects. *J. Bone and Mineral Res.* 5 (Suppl 1):S217-S222. (Coll)
116. Murray, T.M., Harrison, J.E., Bayley, T.A., Josse, R.G., Sturtridge, W.C., Chow R, Budden F, Laurier L, Pritzker K P H, Kandel R, **Vieth R.**, Strauss A L, and Goodwin, S. (1990) Fluoride therapy of osteoporosis: dose, age and other clinical factors in the osteogenic response. *J. Bone and Mineral Res.* 5 (Suppl 1):S27-S35. (Coll)
117. **Vieth R**, Ledermann SE, Kooh SW and Balfe JW (1989). Losses of calcitriol to peritoneal dialysis bags and tubing. *Peritoneal Dialysis International* 9: 277-280. (PA)
118. Watson AR, Kooh SW, Tam CS, Reilly BJ, Balfe JW and **Vieth R** (1989) Renal osteodystrophy in children on CAPD: A prospective trial of 1-alpha-hydroxycholecalciferol therapy. *Childhood Nephrology and Urology* 9:220-227. (Coll)

119. Budden, F.H., Bayley, T.A., Harrison, J.E., Josse, R.G., Murray, T.M., Sturtridge, W.C., Kandel, R., Vieth, R., Strauss, A.L. and Goodwin, S. (1988) The effect of fluoride on bone histology in postmenopausal osteoporosis depends on fluoride absorption and retention. *J. Bone and Mineral Res.* 3: 127-132. (Coll)
120. Vieth, R., Kessler, M.J., Pritzker, K.P.H.. Serum concentrations of vitamin D metabolites in Cayo Santiago rhesus macaques. (1987) *J. Med Primatol* 16: 349-357. (SRA)
121. Vieth, R., Fraser, D., Kooh, S.W. (1987) Low dietary calcium reduces 25-hydroxycholecalciferol in plasma. *J. Nutrition*, 117:914-918. (PA)
122. Kooh, S.W. and Vieth, R. (1980) 25-Hydroxyvitamin D metabolism in the sheep fetus and lamb. *Pediat. Res.*, 14:360-363. (CPA)
123. Vieth, R. and Fraser, D. (1979) Kinetic behavior of 25-hydroxyvitamin D-1-hydroxylase and -24-hydroxylase in rat kidney mitochondria. *J. Biol. Chem.*, 254:12455-12460. (PA)
124. Vieth, R., Fraser, D., Jones, G. (1978) Modified photography tank for continuous development of thin-layer chromatographic plates. *Analytical Chemistry*, 50:2150-2152. (PA)

Non-Refereed Publications (not updated)

Invited editorials and commentaries in peer-reviewed journals:

1. **Vieth R**, Fraser D. Vitamin D insufficiency: no recommended dietary allowance exists for this nutrient. *CMAJ.* 2002;166:1541-2. (SAR)
2. Vieth, R. AND Carter, G (2001). Difficulties With Vitamin D Nutrition Research: Objective Targets Of Adequacy, And Assays For 25-Hydroxyvitamin D. *European Journal Of Clinical Nutrition* 55: 221-222. (SRA)
3. Vieth, R. (2001) Reply to J Hathcock and I Munro. Upper intake limit for nutrients. *Am J Clin Nutr* 74: 866-867. (SRA)
4. Vieth, R. (2001) Reply to FAJ Muskiet et al. Do we really need >100 ug vitamin D daily, and is it safe for all of us? *Am J Clin Nutr* 74: 862-863. (SRA)

Published Letters to Editor, in peer-reviewed journals:

1. **Vieth R**, Scragg R. Vitamin D nutrition does not cause peripheral artery disease. *Arterioscler Thromb Vasc Biol* 2005;25:e41-e42.
2. Barthel, H. R. & VIETH, R. (2004) Lack of generalizable evidence of the superiority of alfacalcidol over plain vitamin D in the treatment of glucocorticoid-induced osteoporosis: comment on the article by Ringe et al. *Rheumatol*
3. **Vieth R**. Enzyme kinetics hypothesis to explain the U-shaped curve for prostate cancer vs 25-hydroxyvitamin D in Nordic countries. *Int J Cancer*, 2003
4. **Vieth R**. Dairy products, calcium, and prostate cancer risk in the Physicians' Health Study. *Am J Clin Nutr* 2002;76:490-1.

5. **Vieth R**, Rao DS. Inaccuracies in relating 25-hydroxyvitamin D to ischemic heart disease. *Eur.J.Epidemiol.* 2003;18:461-2.
6. Vieth,R. (2000) Problems With Direct 25-Hydroxyvitamin D Assays And The Target Amount Of Vitamin D Nutrition Desirable For Patients With Osteoporosis. *Osteoporosis International* 2000, 11, Pp. 635-636. (SRA)
7. Peltekova VD, Rubin LA, Uterlinden AG, Hawker G, **Vieth R**, Trang H, Cole DEC. (1997) . *J Bone and Mineral Research.* 12:494. R. Vieth was a collaborator
8. **Vieth R.**, Kooh SW, Murray T, Houpt J (1993) Vitamin D supplementation. *Can Med Assoc J*; 149:396-397. (SRA)
9. **Vieth R.** (1990) Letter to the editor Re. Alteration of vitamin D metabolism in Mexican-Americans. *J Bone and Mineral Research.* 5:791. (SRA)
10. **Vieth R.** (1982) Statistics in "Clinical Biochemistry" papers. *Clinical Biochemistry* 15: 268

Publications in non-peer-reviewed journals. (Not updated)

1. Optimizing vitamin D supplementation. **Vieth R**, Taha N. *Clinical Laboratory* 2011
2. National Post, June National Post Tuesday, June 14, 2005 Page: FP23 Section: Financial Post: Comment Byline: Reinhold Vieth. Financial Post Edition: National Story Type: Business; Opinion: A healthy tan: Excess exposure may be hard on the skin, but the healthful effects of UV outweigh skin cancer and melanoma risks
3. National Post, June National Post Tuesday, June 15, 2005 Page: FP23 Section: Financial Post: Comment Byline: Reinhold Vieth. Financial Post Edition: National Story Type: Business; Opinion: 'D' depravation: There's no problem with vitamin D intakes to at least 10,000 units per day. But the junkiest science rules with an official safe limit of only 1,000 units
4. OUR VOICE: Living with prostate cancer in Canada (magazine for cancer patients). *Winter 2003, pg12-14.* Sunshine and Supplements: An update on vitamin D. Peter Hyde and Reinhold Vieth
5. R. Vieth. Update on vitamin D nutrition. Whitehall-Robbins Report. Feb 2001 issue (Canadian circulation, 15,000 health professionals)
6. **Vieth R.** A Review of the Evidence on Vitamin D Supply, Serum 25-Hydroxyvitamin D, and Safety. *Bone Depeche, Excerpta Medica*, 1999

BOOK CHAPTERS (total, 17)

1. **Vieth R.** Defining thresholds for vitamin D II: Justification for serum 25-hydroxyvitamin D >74 nmol/L. In "Feldman and Pike's Vitamin D" Vol 2 Chapter 52 pp 11-30. 2024
<https://doi.org/10.1016/B978-0-323-91338-6.00002-1>
- 2.
3. **Vieth R**, Holick MF. The IOM—Endocrine Society Controversy on Recommended Vitamin D Targets: In Support of the Endocrine Society Position. *Chapter 57, pp 1091-*

1107 in Feldman, *Vitamin D, Volume 1: Biochemistry, Physiology and Diagnostics*, Fourth Edition Elsevier, 2018 <http://dx.doi.org/10.1016/B978-0-12-809965-0.00059-8>

4. **Vieth R.** The pharmacology of Vitamin D. in *Vitamin D*, 3rd edition, edited by D Feldman, JW Pike, J Adams. Eslevier, 2011
5. **Vieth R.** Unique Features of the Enzyme Kinetics for the Vitamin D System, and the Implications for Cancer Prevention and Therapeutics. D.L. Trump and C.S. Johnson (eds.), *Vitamin D and Cancer*, Springer Science Business Media, LLC 2010
6. **Vieth R.** Toxicity of Vitamin D. in *Vitamin D: Physiology, Molecular Biology, and Clinical Applications*, 2nd edition, editet by Holick MF, Humana Press, 2010.
7. **Vieth R**, and Sidhom G. Chapter 12. Basic Aspects of Vitamin D Nutrition. In. *Contemporary Endocrinology: Osteoporosis: Pathophysiology and Clinical Management*. Edited by Robert A. Adler. 2010
8. **Vieth R.** Chapter: Vitamin D. *Encyclopedia of Public Health*, 2009
9. **Vieth R** (2005). The pharmacology of Vitamin D. in *Vitamin D*, 2nd edition, edited by D Feldman, JW Pike. Eslevier, 2005
10. VIETH,R. (2004) What is the optimal amount of vitamin D for osteoporosis? In: *Nutritional Aspects of Osteoporosis* (Ed. by P.Burckhardt, R.Heaney & B.Dawson-Hughes). Academic Press, San Diego. Elsevier SRA)
11. Dawson-Hughes, B., Heaney, R., Lips, P., Meunier, P., & VIETH, R. (2004) Vitamin D Round Table. In: *Nutritional Aspects of Osteoporosis* (Dawson-Hughes, B., Heaney, R., & Burckhardt, P., eds.), Academic Press, New York.
12. R VIETH. Effects of Vitamin D on Bone and the Consequent Evolution of Skin Color. Chapter, in *Age Related Bone Loss, an Anthropological Perspective*, American Association for Physical Anthropology. (Ed by SC Agarwal and SD Stout) 2003 Kluwer Academic/Plenum Publishers, New York.(SRA)
13. Dawson-Hughes, B., Heaney, R., Lips, P., Meunier, P., & VIETH, R. (2004) Vitamin D Round Table. In: *Nutritional Aspects of Osteoporosis* (Dawson-Hughes, B., Heaney, R., & Burckhardt, P., eds.), Academic Press, New York.
14. VIETH,R. (2004) What is the optimal amount of vitamin D for osteoporosis? In: *Nutritional Aspects of Osteoporosis* (Ed. by P.Burckhardt, R.Heaney & B.Dawson-Hughes). Academic Press, San Diego. (SRA)
15. VIETH,R. (2001) Would prehistoric human 25-hydroxyvitamin D concentrations be beneficial, and how much vitamin D do we need to ensure desirable nutritional targets? In: *Nutritional Aspects of Osteoporosis* (Ed. by P.Burckhardt, R.Heaney & B.Dawson-Hughes), pp. 173-195. Academic Press, San Diego. ..(SRA)
16. **Vieth R** and Cole DEC. (1996) The vitamin D endocrine system. in *CRC Handbook of Endocrinology, Volume II*, 2nd Edition. Gass and Kaplan, editors. CRC Press, Boca Raton, Florida pp 33-60..(SRA)
17. Trang H, Cole DEC, Pierratos A, **Vieth R** (1997) Relative effectsof vitamin D2 and vitamin D3 at increasing serum 25-(OH)D pp 727-728. In : *Vitamin D: Chemistry, Biology and Clinical Applications of the Steroid Hormone*. Printing and Radiographics, University of California, Riverside (SRA).

18. **Vieth R.** and Pierratos A. (1991) Urinary calcium and serum 1,25(OH)₂D correlate in kidney stone patients. Eighth Workshop on Vitamin D. pp 907-908. in Vitamin D. Chemical, Biochemical and clinical update. ed AW Norman, M Thomasset and R Bouillon. W de Gruyter, Berlin. (SRA)
19. Vieth, R. (1988) Evidence that rat kidney 25-hydroxyvitamin D-24-hydroxylase can exist in an inactive state. in Vitamin D. Chemical, Biochemical and clinical update. ed AW Norman. W de Gruyter, Berlin. pp 196-197. (SRA)

PRESENTATIONS AND SPECIAL LECTURES

Podium Presentation co-author: ASBMR, ECTRIMS

Continuing Medical Education (CME) Presenter

Nutrition for Docs. Faculty of Medicine, University of Toronto. Continuing Medical Education (CME) McCloud Auditorium MSB, 2011

- Lecture 1 SUNSHINE VITAMIN D AND HEALTH.
- Lecture 2: Overview of statistical analysis in biomedical research.

Course Coordinator, Faculty representative. Continuing Medical Education Day. Conference title, Diagnosis & Treatment of Vitamin D Deficiency. Nov 3, 2009

Nutrition for Docs. Faculty of Medicine, University of Toronto. Continuing Medical Education (CME) McCloud Auditorium MSB

- Lecture 1. April 26, 2009: SUNSHINE VITAMIN D AND HEALTH.
- Lecture 2: May 30, 2009: Overview of statistical analysis in biomedical research.

Toronto Western Hospital Dermatology Journal Club Speaker Reinhold Vieth, Ph.D., F.C.A.C.B

IMPORTANCE OF THE SKIN TO VITAMIN D And GENERAL HEALTH PLUS:

RELEVANCE OF VITAMIN D TO SKIN. October 28, 2008

Medical Grand Rounds, Sunnybrook Hospital Medical Center, Invited guest presentation: Vitamin D. May 23, 2008

Koffler Student Health Services Professional Staff CME. Vitamin D. University of Toronto, May 23, 2008

Nutrition for Docs, Medical Sciences Building, October 4, 2008. Accredited U of T CME event for physicians.

Mount Sinai Hospital Research Institute. A short overview of biostatistics. June 3, 2008

Princess Margaret Hospital, Urologic Oncology Seminars. Randomized trial of the effects of cholecalciferol on prostate cancer-associated lesions and on cholecalciferol metabolites in prostate tissue April 2, 2008

St Michaels Hospital CME course for physicians. April 4 2008. Reinhold Vieth. Vitamin D – Skeletal and Non-Skeletal Effects SHOULD WE BE ADVISING ALL PATIENTS TO TAKE VITAMIN D SUPPLEMENTS? The “YES” argument Reinhold Vieth

Sponsored professional CME lectures:

Merck: Rheumatology Journal Club, Richmond Hill Ontario, July 16 2008 Octagon Restaurant

Merck: Family Practitioner Journal Club, Windsor Ontario, April 10 2008

Merck: Family Practitioner Journal Club, Kingston Ontario, March 6, 2008

Scarborough Osteoporosis Patient Support Group. Update on vitamin D and osteoporosis. April 28 2008

CONFERENCE PRESENTATIONS

The Case for Paleolithic 25-Hydroxyvitamin D Levels as Optimal for Modern-Day Humans. R Vieth Joint International Symposium Vitamin D in Prevention and Therapy and Biologic Effects of Light...June 05-07, 2019 Schlossberg Hotel Homburg/Saar, Germany

Challenge and Promise: The Risks and Benefits of Vitamin D Supplementation and Fortification. R Vieth. International Workshop on Vitamin D and Cancer. Invited workshop lecture Homburg Germany, June 2017..

Double-blind randomized clinical trial of vitamin D3 showing effects on tissue calcitriol levels, gene expression and proliferation immunohistochemistry in prostate cancer. Abstract promoted to oral presentation at international meeting. American Association for Cancer Research April 3, 2012

Three presentations (I) **Optimal nutritional levels of 25 OH Vitamin D: How we measure them, safety and risk of supplementation** (II) **Vitamin D and gynecological cancer.** (III) **Classical And Non-Classical Actions Of Vitamin D.** The conference of Argentinean Society of Gynecological and Reproductive Endocrinology (SAEGRE) Congress, in Buenos Aires city, Argentina, in April 22- 24, 2012 Three separate Invited lectures

Benefits and Risk of Vitamin D Supplements. International Federation of Clinical Chemistry, Bergmeyer Conference, held in Garmish Partenkirchen, Germany March 7, 2012. Invited Lecture.

The Vitamin D Debate: Asserting the Position that “The Institute of Medicine (IOM) guidance for vitamin D is a soothing fairy tale, NOT objective scientific advice to prevent disease” University of Calgary, Department of Kinesiology, Invited expert for academic discussion and debate

Evidence Based Medicine for a Vitamin D RDA when all the evidence is in Shades of Grey. Florida Dietetic Association. Orlando Florida. July 20, 2011. Invited presentation for dietetic professionals

Dosing with vitamin D. National Multiple Sclerosis Society USA. Chicago, USA December 12, 2011. Scientific experts meeting to attempt to design a large-scale trial to “prove” efficacy of vitamin D in preventing Multiple Sclerosis.

Application of Risk-Benefit Analysis in Nutrition Policy: Vitamin D as an example of the policy issues. International Food Technology Conference. New Orleans June 14, 2011 Invited presentation to food-industry professionals.

Dietary Guidelines for Vitamin D and their Implications for Laboratory Testing. Ontario Society of Laboratory Technologists. Annual Meeting, Niagara Falls, Ontario. September 24, 2011. Invited presentation to medical-laboratory professionals.

Minimising the population risk of micronutrient deficiency and overconsumption: The role of food (dietary) supplements. International Alliance of Dietary Supplement Associations. Conference to inform government policy makers from countries in Central and South America. September 1,2 2011 Buenos Aires Argentina. Invited speaker.

Vitamin D safety and toxicity in the context of pregnancy, preterm birth and preeclampsia. Center for Disease Control, Atlanta Georgia USA. April 26 2011. Invited expert for presentation on government information session on vitamin D and pregnancy.

Treatment & Toxicity – Benefits and dangers of supplementing with Vitamin D. Wellcome Trust, London UK. April 7 2011. Workshop sponsored by private trust. Industry-sponsored Workshop Presentation

Vitamin D supplementation during pregnancy & breastfeeding: Effects on gestational diabetes, plus a review of safe and toxic blood serum levels. Wellcome Trust, London UK. May 17. 2011. Workshop sponsored by private trust. Invited Workshop Presentation

Hypovitaminosis D. Medical Grand Rounds, IWK Hospital Halifax Nova Scotia. April 13, 2011

Vitamin D in Pregnancy and Lactation. Nutrition and Dietetics Rounds. IWK Hospital, April 13, 2011

Institute of Medicine Dietary Recommendations in Relation to Serum 25-Hydroxyvitamin D. EuroMedLab Exposition. International Federation of Clinical Chemistry (IFCC) annual conference. May 18, 2011.

Vitamin D and Cancer: U-Shaped-Risk Curves in relation to Serum 25(OH)D. Homburg Germany. R Vieth. International Workshop on Vitamin D and Cancer. Invited workshop lecture.

High-dose oral vitamin D3 administration to prostate cancer patients increases intra-prostate levels of vitamin D metabolites. D Wagner and R Vieth International Workshop on Vitamin D and Cancer. Free communication promoted to oral presentation.

Vitamin D in prevention or treatment of disease. Sioux Lookout regional medical staff of physicians and nurses. Telemedicine Conference. Jan 27, 2011

4th International Vitamin D Symposium on "Vitamin D and Analogs in Cancer Prevention and Therapy" held in Homburg/Saar Germany, May 20/21, 2011. Presenter and sessions Chair.

Euromedlab – International Federation of Clinical Chemistry conference in Berlin (May 18 2011). Discussion of the recently released guidelines from the Institute of Medicine (IOM) and their impact in clinical chemistry practice.

The Wellcome Trust, London, England. Vitamin D during Pregnancy and Lactation. May 16, 2011

Charite Universitätsmedizin Berlin. Berlin, Germany CME for Endocrinologists. Correction of vitamin D deficiency through supplementation. April 9, 2010.

The Wellcome Trust, London, England. Treatment & Toxicity – Benefits and dangers of supplementing with Vitamin D. April 7, 2011

Telemedicine conference Controversies about dietary guidelines and the correction of vitamin D deficiency through supplementation. Sioux Lookout Ontario, physicians and nurses, January 25, 2011

Controversies about dietary guidelines and the correction of vitamin D deficiency through supplementation. University of Rome, Italy, March 28, 2011.

Continuing Medical Education day, Presentation: Hypovitaminosis D. Foggia Italy, March 25, 2011.

Invited expert presenter, "Vitamin D Physiology in Pregnancy: Implications for Preterm Birth and Preeclampsia." Meeting held on April 26-27, 2011 Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, USA.

American Association for Clinical Chemistry (AACC) 2011 Annual Meeting "Vitamin D: Challenges and Opportunities" Atlanta, GA July 27, 2011

Nova Scotia Health, Halifax, Nova Scotia. April 12 and 13, 2011. Lecture to Dietetics Department: The pro's and con's of the latest RDA's for vitamin D.

Grand Rounds, IWK Hospital. Vitamin D and its potential role in pregnancy, and in childhood, and the clinical utility of serum 25D assays, and the question of whether provincial health insurance should continue to fund them for "healthy?" individuals.

Academic debate: The Great Vitamin D Debate. New Guidelines: Agree or not. The Florida Dietetic Association. 76th Annual Symposium July 17-20, 2011

Academic debate: The new Vitamin D Guidelines: Agree or not. University of Calgary, Alberta. Dept of Kinesiology, Markin USRP in Health & Wellness Tuesday, February 8, 2011

Public Broadcasting System (PBS), USA. Panelist on Second Opinion, Topic, Vitamin D, Half-hour, First Episode for this 2011 season. (NB.this is the only program on broadcast television that counts toward CME credits for the American Medical Assoc)

Canadian Society of Clinical Chemists. 14-16 2010 Saskatoon, Saskatchewan. Workshop Presenter: Vitamin D (sponsored by DiaSorin Inc).

American Association of Clinical Chemistry. Anaheim CA. July 27, 2010 Symposium: 'Vitamin D revisited. Invited speaker Defining Optimal Vitamin D Levels: Reinhold Vieth

American Association of Clinical Chemistry. Anaheim CA. July 27, 2010 Invited speaker, sponsored by DiaSorin Inc. Invited speaker Reinhold Vieth . Role of the clinical laboratory in vitamin D toxicity.

Ohio River Regional Chapter of the American Association of Clinical Endocrinologists Annual Meeting July 30-31, 2010 Indianapolis, IN. Invited speaker, Reinhold Vieth. Update on Vitamin D. (2nd time invited in 5 yrs to present to this group)

Ortho-Clinical Diagnostics, Inc, Rochester NY. June 24, 2010. Invited speaker, Reinhold Vieth. Clinical utility of serum 25-hydroxyvitamin D testing.

National Institutes of Allergy & Infectious Diseases, Bethesda, MD Conference on IMPACT OF MICRONUTRIENTS ON RESPIRATORY INFECTIONS. May 10-11, 2010. Invited speaker, Reinhold Vieth. Where do we want to be in terms of 25(OH) D, and how do we get there?

Third International Course on Endocrinology. Bogota, Colombia. April 16, 2010. Invited keynote speaker. Reinhold Vieth. Endocrine aspects of cancer: The role of Vitamin D.

Ross University Research Day. Medical School Dominica Caribbean. CME May 21, 2010. Reinhold Vieth, guest faculty lecture.

University of Minnesota. Department of Nutrition. Invited speaker. March 9, 2010. Reinhold Vieth Clinical Nutrition of Vitamin D in the Context of Cancer and Multiple Sclerosis

14th Workshop on Vitamin D - Brugge, Belgium, 4 - 8 October 2009. Reinhold Vieth. Podium Debate to defend the position: OPTIMAL HEALTH REQUIRES HIGH 25OHD LEVELS >40NG/ML (>100 NMOL/L).

Symposium "Vitamin D deficiency, hype or threat" Oktober 2, 2009 , De Eenhoorn, Amersfoort, NL. Reinhold Vieth, keynote speaker. Efficacy and safety of vitamin D3.

American Association of Clinical Chemistry, Chicago, July 22, 2009. Sponsored lecture, DiaSorin Inc. The Role of the Laboratory in Assessing Concerns Over Vitamin D Toxicity. Reinhold Vieth

IOM Committee to Review the DRIs for Vitamin D and Calcium, Invited presentation to the committee during its Information Gathering Workshop' held August 4, 2009, in Washington DC. Reinhold Vieth. Safety of Vitamin D

National Osteoporosis Society, United Kingdom. Annual meeting Manchester, June 29, 2009, Plenary Invited Speaker, Reinhold Vieth. Podium Debate with Dr Roger Francis: optimal requirements for vitamin D.

Nutrition Society, United Kingdom. Annual Meeting, Surrey, UK. June 30, 2009 Vitamin D: Worldwide insufficiency and effects on health outcomes. Invited lecture Reinhold Vieth.

RANK FORUM ON VITAMIN D July 2-3 2009 University of Surrey, Guildford. Reinhold Vieth Invited speaker. Optimal 25-hydroxyvitamin D.

University of Saskatchewan. Edith Simpson Lecture, January 26, 2009. Sponsored lecture, Department of Pharmacy and Nutrition. Wonderful health news about vitamin D, and why the powers that be are not ready to accept it. Reinhold Vieth With followup lecture in the evening at Saskatoon Public Library for the general public.

Public Health Agency of Canada. Invited presentation. March 12, 2009. Reinhold Vieth. The problem of establishing the "proof" that vitamin D prevents multiple diseases.

International Association for Dietary and Supplements Associations. April 22, 2008. Evidence-Based medicine: Are clinical trials the only answer? Reinhold Vieth

Scripps Institute CME: Natural Supplements: An Evidence-Based Update. Lecture title: The Role of Vitamin D and Calcium in Bone Health January 17 - 20, 2008 Paradise Point Resort San Diego, California

Third International Symposium on Vitamin D Analogs in Cancer Prevention and Therapy. Invited Speaker. Optimal Vitamin D for the prevention of Cancer. Krefeld, Germany. **May 17 – 18, 2008**

Invited guest speaker, DSM Human Nutrition Advisory Board Meeting, Basel, Switzerland, Nov 27, 2007

American Association of Clinical Chemists, Sponsored Lecture: Analytical and clinical aspects of vitamin D. Meeting In Washington, July 28-31, 2008

14th Vitamin D Workshop, Bruegge, Belgium. Member of organizing committee. 2008 Planning for October 4-8, 2009.

Brazilian Society for Food and Nutrition October 24-28, 2007, Sao Paolo, Brazil. Keynote Speaker, Reinhold Vieth.

5th International Conference of the European Society of Skin Cancer Prevention, EUROSKIN "Reducing the Health Risks of Sunbed Use-Needs for Further European Harmonization of Regulations" 14. – 17. October 2007 Steigenberger Hotel Hamburg Germany. Invited presenter, Reinhold Vieth, "How much vitamin D is needed for health?"

Symposium on Vitamin D in Mother and Neonate. Cleveland, Ohio, October 6, 2007. Invited speaker, Reinhold Vieth, "Vitamin D Requirements in Adults and Toxicity Issues"

NIH Conference on Vitamin D and Health in the 21st Century. Bethesda, Maryland, USA, September 4-5, 2007. Reinhold Vieth, invited speaker, "Potential Adverse Outcomes of Vitamin D"

Center for Bone Health at Childrens Hospital of Philadelphia, Nutrition Seminar Series. May 2, 2007. Reinhold Vieth, Guest speaker, "A fixation on preventing rickets may have led to a neglect of Vitamin D nutrition through the early years of life"

American Academy of Clinical Endocrinology, Ohio River Regional Chapter of "9th Annual Symposium and Business Meeting" August 17-19, 2007, Cincinnati Riverfront Marriott. Invited faculty, Reinhold Vieth, "Vitamin D Deficiency and How to Correct It"

Canadian Laboratory Medicine Congress, Symposium on Biomarkers in Metastatic Bone Disease June 9-13, 2007 Toronto, Ontario, Canada. Reinhold Vieth, invited speaker: "Vitamin D in Cancer – for Diagnosis Only? ... or also for Treatment?"

Merck Latin American Speakers' Forum, Cancun, Mexico, June 1-3 Reinhold Vieth, Invited Faculty, Vitamin D: Its Importance in the Treatment of Osteoporosis

Merck National Osteoporosis Experts Forum, New York NY, May 18, 2007. Reinhold Vieth, presenter and discussion facilitator. Vitamin D: The Potential for Toxicity

National Kidney Foundation, 2007 Spring Clinical Meetings, Orlando Florida, April 11, 2007. Reinhold Vieth, invited faculty, "Role of Vitamin D Nutrition in Health and Renal Disease."

Aurora Health Care, St Luke's Medical Center, Hospital Grand Rounds, Milwaukee, WI, April 5, 2007. Reinhold Vieth, Invited speaker, The spectrum of vitamin D relevance to health and disease in adults.

Novartis, Vitamin D Advisory Board Zürich, Switzerland. 26 January 2007 Invited expert presenter, Reinhold Vieth. Pharmacology of vitamin D.

American Society for Bone and Mineral Research. Vitamin D Toxicity, Policy and Science. Washington, DC. December 4, 2006, available as a webcast
<http://app2.capitalreach.com/esp1204/servlet/tc?cn=asbmr&c=10169&s=20343&e=6950&&>

Tanning World Expo, Nashville, TN. Saturday, October 28 Mid-Conference General Session: Vitamin D and Indoor Tanning. Keynote Speaker, Reinhold Vieth.

New Hampshire Falls Risk Reduction Task Force. Evidence Based Falls Risk Reduction in the Elderly: Taking it Back to Your Community and Making it Work, Phase II. Reinhold Vieth, Vitamin D. June 2, 2006 Mountain Club on Loon, Lincoln, New Hampshire

Hennipen County Medical Center, Department of Medicine, Noon Grand rounds: TITLE: Vitamin D is a pleiotropic nutrient, and adults around the world will benefit from intakes of it that are much higher than current recommendations. November 30, 2006

Henepin County Medical Center, Minneapolis: City-wide endocrine seminars: TITLE: Problems with the way some of the basic principles about the vitamin D endocrine system have been traditionally imagined. November 30, 2006

University of Minnesota, College of Pharmacy. Special Lecturer, graduate program, Natural Medicines Course. Two lectures: 1. Safety and Toxicity of vitamin D. 2. Calcium and Vitamin D controversies. (Host, Professor Rick) February 22, 2006

13th Vitamin D Workshop, Victoria, British Columbia, Canada. Invited Speaker, plus coauthor on two abstracts promoted to oral sessions. April 7 to 12, 2006.

13th Vitamin D Workshop, Victoria, British Columbia, Canada. Member of organizing committee. April 7 to 12, 2006.

House of Commons, London England, Meeting on Sunlight, Vitamin D and Health; organised by Health Research Forum, and sponsored by Ian Gibson MP, Wednesday 2nd November 2005 in the Atlee Room, Portcullis House**

International Workshop on UV Exposure Guidance, Munich, Germany, Joint meeting with WHO and Euroskin,: Sun-protection guidelines, implications with vitamin D. October 17-18, 2005.

Direct-MS. Invited speaker: The biology of vitamin D, and its implications for the health of Canadians. Calgary Alberta. Two presentations. October 12 and 13 2005. available as webcast, www.direct-ms.org

Council for Responsible Nutrition. Annual meeting, Palm Springs CA, USA. Invited speaker, "Calcium, Vitamin D and Health". September 26, 2005

Italian Endocrine Society. The endocrinology and nutrition of vitamin D. Invited speaker, Lecture for continuing education. Rome, Italy, July 14, 2005.

30th Public Health Nutrition Update, University of North Carolina. Keynote Lecture: Evaluation of Nutritional Risk for Vitamin D: An Evolving Issue. May 12, 2005

Experimental Biology 2005. R Vieth. Invited speaker for Vitamin D Symposium, to address the topic: Issues and considerations for the safe upper limits of vitamin D intake. San Diego USA April 2-6 2005

Harvard School of Public Health, Boston USA. Jan 28 2005. R Vieth one of 13 experts (the only non US invitee). Symposium called by Dr Walter Willett to request companies to increase the amount of vitamin D in multivitamins and supplements.

National Dairy Council (USA). Vitamin D and PSA levels in men with relapsed prostate cancer. R. Vieth, R Choo, T Woo. Chicago IL, January 13, 2005.

Israel Endocrine Society. The endocrinology and nutrition of vitamin D. Plenary Lecture and one symposium session. December 20-21, 2004, at the Tel Aviv Dan Panorama Hotel & Convention Center.

Cancer Chemoprevention & Cancer Treatment: Is there a role for vitamin D, 1,25(OH)₂-vitamin D₃, or new analogs (deltanoids)? Session II: *Vitamin D, nutrition, and cancer* Session Chairs: R. Bouillon, R. Vieth NIH Campus, Bethesda, Maryland USA November 17-19, 2004.

Harvard School of Public Health, Boston USA. Why vitamin D deficiency will be the “evolving” public health emergency of this decade. R Vieth, Invited Speaker. September 27, 2004.

Wake Forest University, Winston-Salem NC. Grand Rounds, and seminar presentation to Prostate-Cancer Research Group. Mar 17, 2004.

Twelfth Workshop on Vitamin D. July 6-10, 2003, Maastricht, The Netherlands. Debate and Round-Table Discussion: Vitamin D requirements, The High, presented by R. Vieth

5th International Symposium on Nutritional Aspects of Osteoporosis. Presentation, and round-table discussant: “optimal requirements for vitamin D and osteoporosis.” Lausanne/Switzerland, May 14-17, 2003.

32nd Annual Conference, Nutritional Medicine Today. International Society for Orthomolecular Medicine, Toronto, Canada, April 10, 2003

Center for Nutrition Science, Whitehall International. Global Nutrition Advisory Board Meeting, Quebec City, PQ. Sept 30-Oct 2, 2002. Efficacy, safety, and optimal dose of vitamin D for human nutrition.

Joint meeting of the Finnish Society for Nutrition Research and the Finnish Bone Society: Vitamin D – There is more to it than meets the eye. Helsinki, Finland. November 16, 2001. Plenary lecture by R Vieth, Canada: Vitamin D intake and optimal vitamin D status.

Effects of Vitamin D on Bone and the Consequent Evolution of Skin Color. American Association for Physical Anthropology, Kansas City MO, March 28-31, 2001.

4th International Symposium on Nutrition and Osteoporosis, Lausanne, Switzerland, May 17-20, 2000. Invited Lecture. “Estimating the vitamin D requirement and evaluating vitamin D status in patients and populations.” Chapter in the published proceedings, Academic Press, 2001.

First Merck (Germany) Conference on Life Cycle Management In the Middle East. Cairo, Egypt, May 8-10, 2000. “Rationale for improving vitamin D nutrition in sunny countries, and its relation to calcitriol in the management of osteoporosis.”

The role of vitamin D and the vitamin D receptor polymorphism in patients with idiopathic hypercalciuria. Mineral Metabolism and Endocrine Research Laboratory. University Hospital, Erlangen, Germany. January, 1996.

Local, Ontario presentations

Vitamin D requirements during pregnancy and Onwards: The global evidence. Cleveland Clinic Toronto. December 8, 2011. Invited presentation to professional medical staff.

Sunshine Vitamin D And Health. City-Wide Endocrine Rounds Sept 16, 2011. Academic presentation to endocrinologists from across Toronto.

Sunshine Vitamin D And Health. Presented as accredited continuing medical education at Nutrition for Docs. Medical Sciences Building September 17 2011.

George Brown College, Toronto. Dietitian educational event to discuss the new Recommended Dietary Allowance for Vitamin D. April 5, 2010.

Vitamin D Recent Developments for Prevention in Women . Ontario Medical Association, Women's Health Seminar Apr 29, 2010

Vitamin D – Vitamin or Hormone? Diabetes/Endocrine Update CME Program Chatham, Ontario October 2, 2010

Review of the evidence about vitamin D in prevention or treatment of cancer. Thunder Bay Medical Society CME Thunder Bay Ontario, November 12, 2010.

Crons and Cholitis Foindation. CNIB Conference Centre, Toronto April 25, 2010. Invited speaker to patients and families. Reinhold Vieth, Vitamin D and inflammatory bowel disease.

Cleveland Clinic, Toronto. Wonderful health news about vitamin D, and why the powers that be are not ready to accept it.. Reinhold Vieth. Invited lecture, Feb 12, 2009

Faculty Club, University of Toronto. Continuing Medical Education Day. Conference title, Diagnosis & Treatment of Vitamin D Deficiency. Titles of R Vieth lectures: 9 am Introduction. 2:30pm Solving the D Deficiency--a Safety Profile.

Peterborough General Hospital, Peterborough Ontario. Grand Rounds. Clinical Features of the Vitamin D Story. April 24, 2009

Womens College Hospital, Grand Rounds, September 26, 2007. Reinhold Vieht, The clinical fundamentals of Vitamin D in health and disease.

Womens Health Seminar Series, Centre for Girls' and Women's Health and Physical Activity September 25th, 2006 University of Toronto Athletic Centre, "Sunshine, Vitamin D, Neuromuscular Performance and Health".

June 7, 2006 Osteoporosis Canada summary update for physicians about highlights of the Internationl Osteoporosis Federation Meeting Toronto.

Michener Institute and Osteoporosis Canada Update Course "OSTEOPOROSIS SYMPOSIUM 2006 – MOVING FORWARD" Reinhold Vieth, Vitamin D, November 18, 2006.

PUBLIC LECTURES

Senior Alumni University of Toronto - Canadian Perspectives lecturer series: April 20, 2011: Emmanual College, 75 Queens Park - Room 001 (South Of The Gardiner Museum Of Ceramic Art) TOPIC: VITAMIN D AND OSTEOPOROSIS

University of Toronto Womens' Club Luncheon Lecture. November 16, 2010. Nutrition and Osteoporosis.

Scarborough Osteoporosis Support Group. April **2008-2011**. Vitamin D and osteoporosis. Invited Lecture to approximately 75 lay public

Yonge and St Clair Osteoporosis Patient Support Group annually May, **2007-2011**, organizer, Mrs Debbie Howe

West Toronto Patient Osteoporosis Support Group annually May, **2007-2011** organizer, Mrs Debbie Howe

Oakville Patient Osteoporosis Support Group annually May, **2007-2011** organizer, Mrs Debbie Howe

Osteoporosis Society of Hamilton. May 31, 2007. Reinhold Vieth, Keynote Speaker VITAMIN D: Why do you need it? How much do you need ? How best to take it?

Osteoporosis Canada, Bone China Tea, Keynote Speaker: Reinhold Vieth, Vitamin D: Bone and Beyond. Bracebridge, Ontario, May 28, 2007

Yonge and St Clair Osteoporosis Patient Support Group May, 2007, organizer, Mrs Debbie Howe

West Toronto Patient Osteoporosis Support Group May, 2007, organizer, Mrs Debbie Howe

Oakville Patient Osteoporosis Support Group May, 2007, organizer, Mrs Debbie Howe

Scarborough Osteoporosis Support Group. April 23, 2007. Vitamin D and osteoporosis. Invited Lecture to approximately 75 lay public (invited back for 3rd year).

Osteoporosis Canada, Bone China Tea, Keynote Speaker: Nutrition and Osteoporosis, Royal York Hotel, Toronto, November 5, 2006

Yonge and St Clair Osteoporosis Support Group May, 2006

West Toronto Osteoporosis Support Group May, 2006

Oakville Osteoporosis Support Group May, 2006

Scarborough Osteoporosis Support Group. April 25, 2006. Vitamin D and osteoporosis. Invited Lecture to approximately 75 lay public (invited back for 2nd year).

Grand Rounds, St Joseph's Hospital Toronto, "Vitamin D, Victorian vitamine or orphan drug" April 18, 2006.

Grand Rounds, North York General Hospital, "Vitamin D, Victorian vitamine or orphan drug" April 18, 2006.

Scarborough Osteoporosis Support Group. April 24, 2006, and annually until 2019. Vitamin D and osteoporosis. Invited Lecture to the public, Scarborough Village Recreation Center.

University of Toronto Endocrine Day, November 18, 2005. Invited Speaker, "Osteoporosis fracture risk and vitamin D"

Nutrition for Docs, Continuing education program, Faculty of Medicine, University of Toronto. Vitamin D and Cancer. November 13, 2005.

Waterloo, Ontario: Invited presentation for health professionals. November 9, 2005. Update on role of vitamin D in Osteoporosis and General Health.

Bone and Mineral Group Day, May 27, 2005. University of Toronto. Keynote speaker. Vitamin D and Bone Disease. (this is traditionally for outside invited speakers -- hence, an honour to be a local and invited to speak)

Scarborough Osteoporosis Support Group. April 25, 2005. Vitamin D and osteoporosis. Invited Lecture to approximately 50 lay public.

Osteoporosis Update. Vaughn Estates, Sunnybrook Campus. Organized by Dr R Josse, St Michael's Hospital, for continuing education of physicians about osteoporosis. April 1, 2005

Mount Sinai Hospital. R Vieth: Why you should prefer to be diagnosed with cancer during summer than during winter. April 26 2005, Continuing education sessions for National Medical Technology week.

Womens Health Matters (an annual show of consumer health products) at Toronto Convention Center. Public lecture, sponsored by Wyeth Pharmaceuticals, R Vieth, Nutrition and Osteoporosis. January 15, 2005, Toronto.

Mount Sinai Hospital. R Vieth: Nutrition and Osteoporosis. October 28 2004, Continuing education sessions for laboratory technologists.

Sunnybrook and Womens' College Hospital. Continuing education sessions for laboratory technologists (TML) Noon Rounds, May 12, 2004. Laboratory testing for Osteoporosis, and the clinical nutrition of osteoporosis prevention.

University Health Network. Continuing education sessions for laboratory technologists (TML) Noon Rounds, April 2003. Laboratory testing for Osteoporosis, and the clinical nutrition of osteoporosis prevention.

Complementary Medicine Physicians' Conference (OMA Workshop) 2004, Invited Speaker, Vitamin D and Nutrition. Bahen Center, University of Toronto, May 29, 2004

Healthy Living Lecture Series: Preventing Osteoporosis. March 19, 2003. Sponsored by Mount Sinai Hospital, Community Relations, Evening lecture, held at Lea Posluns Theatre, North York: audience 500 general public.

Etobicoke Osteoporosis Society, Vitamin D and Osteoporosis. April 5, 2003

University Health Network. Continuing education sessions for laboratory technologists (TML) Noon Rounds, April 2003. Laboratory testing for Osteoporosis, and the clinical nutrition of osteoporosis prevention.

Citywide Rheumatology Rounds. Bone markers, the science and what we have available for the clinician. Hospital for Sick Children, Dec 17, 2002

Mount Sinai Hospital. Endocrinology Rounds. March 10, 2002

University Health Network. Osteoporosis Noon Rounds, February 16, 2001. The story of vitamin D nutrition and osteoporosis.

Ontario Association of Histotechnologists, The Michner Institute, Toronto, November 23, 2000. "Vitamin D: Its effects on health beyond just the bones."

The Hospital for Sick Children, Toronto, Seminar Series. October 2, 2000. Calcium and Bone Metabolism. R. Vieth.

Pathology and Laboratory Medicine, Mount Sinai Hospital, Continuing Education for Technical Staff. "Vitamin D Nutrition and Osteoporosis" September 6, 2000.

Evidence that current recommended vitamin D intakes are too low for adults. R. Vieth. Connective Tissue Research Group, Mount Sinai Hospital, Toronto. Monday April 12, 1999.

Bone markers relevant to osteoporosis.. Toronto Society for Clinical Chemistry. November 8, 1995.

Role of the vitamin D endocrine system in kidney-stone patients. R.Vieth and D.Cole. Grand Rounds Lecture, The Wellesley Hospital, Toronto, June 14, 1995.

Collagen crosslinking of the cartilagenous matrix: in vivo and in vitro. H Gahunia, R Vieth, KPH Pritzker. Inaugural Conference of Canadian Musculoskeletal Society, Montreal, June, 1995.

Responses in vitamin D-metabolizing enzymes to altered nutritional status. R Vieth. Department of Paediatrics, McMaster University, February 7, 1994.

New biochemical markers of bone resorption. City-Wide Rheumatology Rounds, Toronto. January5, 1993.

Why is the endocrine regulation of calcitriol so complicated? Departmental Seminars. Department of Clinical Biochemistry, University of Toronto. February 5, 1992.

Unique aspects of the hormonal control of vitamin D metabolism.. Departmental Seminars. Department of Clinical Biochemistry, University of Toronto. April 4, 1989.

National, Canadian presentations

Halifax: The Bone Club. Vitamin D and Bone Health. November 8, 2006.

Halifax: Endocrinology Rounds. Vitamin D and Endocrine Aspects of Bone Health. November 9, 2006.

Moncton NB, Pharmacy Refresher Course, Merck Satellite Symposium, Vitamin D. October 14th 5:00pm- 6:30pm. Crowne Plaza Hotel.

BC Dairy Foundation, 7th Annual Milk and Cookies Event, "Vitamin D – Are We Getting Enough?" June 26, 2006. Vancouver BC.

Canadian Cancer Society: North American Conference on UV, Vitamin D and Health. Metropolitan Hotel, March 8, 2006, Toronto.

Direct-MS, Calgary. Presentation to health professionals in Calgary, Alberta. October 12, 2005. Prospects For Vitamin D Nutrition For Disease Prevention And Treatment.

Direct-MS, Calgary. Health information presentation to the general public. An advertised lecture, in Calgary, Alberta. October 13, 2005. Health Prospects For Vitamin D Nutrition. Recorded and available as a Webcast <http://www.direct-ms.org/presentations.html>

Quebec Society of Medical Biochemists. Mont Saint Hiliard, Quebec. October 27, 2005

Merck Frosst Canada. Scientific/Medical Associates. Toronto. Vitamin D and Osteoporosis. January 26, 2005

University of Ottawa, Osteoporosis Rounds. Invited speaker, host Dr John Gay. Clinical applications of vitamin D. April 15, 2005

Wyeth Pharmaceuticals, R Vieth, Keynote Speaker, Nutrition and Osteoporosis. Re Canadian Product Launch of *Caltrate Select*, a new osteoporosis-prevention supplement. Mount Sinai Hospital, October 28 2004, Toronto.

Merck Frosst, Canada. Meeting of Medical Advisory Committee for Musculoskeletal Health. R. Vieth to speak on "Vitamin D and Osteoporosis". Toronto, October 22, 2004

Annual nutrition workshop, Nutritionists of the Ontario Public Health Association. Niagara on the Lake, May 27, 2004. Update on vitamin D and health.

Dietitians of Canada, Dairy Farmers of Canada, Montreal, Sept 23, 2003 Review of the role of vitamin D in the health of Canadians.

Annual meeting of Nutrition Associates, Dairy Farmers of Canada, Banf, Canada, May 15, 2002. Vitamin D and health.

Grand rounds, two different lectures: Jewish General Hospital Montreal, Quebec. May 15, 2002; Royal Victoria Hospital, Montreal Quebec. May 16, 2002

Plenary Lecture: Diagnosis and consequence of what may be, by objective means, our most common "nutritional" deficiency -- vitamin D. Upstate New York Section, American Academy of Clinical Chemistry. Royal Connaught Hotel, Hamilton, Ontario. May 5-6, 1998.

Biochemical markers relevant to osteoporosis. Telemedicine Canada Speaker- Broadcast Presentation. Faculty of Medicine, University of Toronto. February, 20, 1996.

Biochemistry of Vitamin D. Telemedicine Canada Speaker- Broadcast Presentation. Faculty of Medicine, University of Toronto. February, 27, 1996.

E2. PAPERS PRESENTED AT INTERNATIONAL MEETINGS.

Human colon and serum concentrations of 1,25-dihydroxyvitamin D are positively correlated
Wagner, D. Dias, A. van der Kwast, T. **Vieth, R.** American Society for Bone and Mineral Research, Toronto, Canada October, 2010.

R. Vieth, R. Choo, L. Klotz, G. Deboer, C. Danjoux, and G.C. Morton. Seasonal variation in the rate of rise in prostate-specific antigen in patients with untreated, clinically localized, low-to-intermediate grade, prostate carcinoma. Presented at: Cancer Chemoprevention & Cancer Treatment: Is there a role for vitamin D, 1,25(OH)₂-vitamin D₃, or new analogs (deltanoids)? NIH Campus, Bethesda, Maryland USA November 17-19, 2004

T.C.S. Woo, R. Choo, M. Jamieson, R. **Vieth**. Vitamin D (cholecalciferol) slows the rise in prostate specific antigen in men with relapsed prostate cancer T.C.S. Woo, R. Choo, M. Jamieson, R. Vieth. Presented at: Cancer Chemoprevention & Cancer Treatment: Is there a role for vitamin D, 1,25(OH)₂-vitamin D₃, or new analogs (deltanoids)? NIH Campus, Bethesda, Maryland USA November 17-19, 2004

T.C.S. Woo, R. Choo, M. Jamieson, R. **Vieth**. Vitamin D (cholecalciferol) slows the rise in prostate specific antigen in men with relapsed prostate cancer T.C.S. Woo, R. Choo, M. Jamieson, R. Vieth. Presented at: Cancer Chemoprevention & Cancer Treatment: Is there a role for vitamin D, 1,25(OH)₂-vitamin D₃, or new analogs (deltanoids)? NIH Campus, Bethesda, Maryland USA November 17-19, 2004

G. El-Hajj Fuleihan¹, A. Arabi¹, M. Choucair^{*2}, M. Nabulsi^{*3}, J. Maalouf^{*1}, **R. Vieth**,. Effect of vitamin D supplementation on bone gain of adolescent girls. American Society for Bone and Mineral Research Adolescents American Society for Bone and Mineral Research, Seattle WA USA Oct 2004 oral presentation.

A. Arabi¹, M. Choucair^{*2}, M. Nabulsi^{*3}, J. Maalouf^{*1}, **R. Vieth**, G. El-Hajj Fuleihan¹. Bone Mineral Density by Age, Gender and Pubertal Stages in Healthy Lebanese Children and Adolescents. American Society for Bone and Mineral Research Adolescents American Society for Bone and Mineral Research, Minneapolis, WI USA Sept 19-23, 2003

J. Maalouf^{*1}, L. Zahed^{*2}, **R. Vieth**, M. Nabulsi^{*4}, M. Choucair^{*5}, G. El-Hajj Fuleihan¹ VDR Polymorphisms and Musculo-Skeletal Parameters in Lebanese Adolescents American Society for Bone and Mineral Research, Minneapolis, WI USA Sept 19-23, 2003

Vieth R. Why it is important to stop the erroneous practice of referring to vitamin D as a hormone. 12th Workshop on Vitamin D. Maastricht, The Netherlands, July 6-10, 2003

Vieth, R., Dogan, M., Cole, D. E., Rubin, A., Bromberg, I. L., Josse, R., and Walfish, P. G. Vitamin D₃ at 90 or 7000 mcg weekly for 1 year: Responses of 25-hydroxyvitamin D, PTH, urine and plasma calcium. 30th European Symposium on Calcified Tissues, Rome, Italy. May 8-12, 2003

Vieth R, Walfish PG., How Much Vitamin D Supplementation do Adults Need to Ensure a Serum 25(OH)D Concentration Optimal for Suppression of PTH? American Society for Bone and Mineral Research, Toronto, Ontario, 2000. Cited for Plenary Award Session.

VIETH,R., CHAN,P.C. & MACFARLANE,G.D. (2000) Randomized, prospective evaluation of effectiveness and safety of vitamin D3 intake exceeding the lowest observed adverse effect level. The Journal of Bone and Mineral Research, 14, pp. S538.

David E. C. Cole, Hoang M. Trang, Reinhold Vieth, Vanya D. Peltekova, Andreas Pierratos, Betty Y.-L. Wong, Laurence A. Rubin, Geoffrey N. Hendy. Calcium Excretion is Independently Associated with the Vitamin D Receptor (VDR) and Calcium-sensing Receptor (CASR) Polymorphisms in a Nephrolithiasis Population. American Society for Bone and Mineral Research, San Francisco, December 1-6, 1998. Plenary Poster Sessions Award.

PATEL,M., COLE,D.E., SMITH JC, WONG B, TRANG,H., VIETH,R., MELZER P, HAWKER,G. & RUBIN,L.A. (1999) Alleles of the estrogen receptor alpha gene and an estrogen receptor cotranscriptional activator gene, amplified in breast cancer-1, associate with quantitative calcaneal ultrasound and femoral neck bone mineral density. Journal of Bone and Mineral Research, 14, pp. meeting presentation.

R. Vieth, L. A. Rubin, H. M. Trang*, G. A. Hawker, D. E. C. Cole. The Prevalence of Marginal Vitamin D Deficiency Increases Every Winter in Healthy Young Toronto Women. American Society for Bone and Mineral Research, San Francisco, December 1-6, 1998.

Trang H, Cole DEC, **Vieth R**. Relative effects of vitamin D2 and Vitamin D3 at increasing serum 25(OH)D, Tenth workshop on Vitamin D, Strasbourg, France, May 24-29, 1997. Abstract p.185.

Trang H, Rubin L, Cole DEC, Pierratos A, **Vieth R**. Comparison of vitamin D nutrition in normals and kidney stone formers. . American Society for Bone and Mineral Research, Cincinnati, September 10-14, 1997.

Cole DEC, Peltekova VD, Rubin LA, Hawker GN, **Vieth R**, Liew CC, Hwang D, Evrosvki J, Hendy G. Genetic determinants of serum calcium: Potential roles for A986S and R990G polymorphisms of the calcium-sensing receptor (CASR) gene. . American Society for Bone and Mineral Research, Cincinnati, September 10-14, 1997.

Cole DEC, Kooh SW, Binet A, **Vieth R**. Primary infantile hypomagnesemia in a 22-year old man: daily parenteral magnesium injections can be replaced by; nocturnal nasogastric infusions but not by high-dose calcitriol. Canadian College of Physicians and Surgeons, 1996

Cole DEC, Rubin LA, Hawker GA, Ragheb R, **Vieth R**, Brunet J-S. Effects of population structure on vitamin D receptor (VDR) polymorphism frequencies and their implications for genetic analysis of metabolic bone disease. American Society for Bone and Mineral Research, Seattle, September 6-11, 1996.

Gahunia HK, **Vieth R**, Pritzker, PH Pritzker. Collagen crosslinking of the cartilaginous matrix: in vivo and in vitro. Inaugural Canadian conference on the musculoskeletal system. Montreal, summer 1995.

Cheng PT, Aye LM, **Vieth R**, Muller K. Cyclical parathyroid hormone and estrogen treatment of osteopenic ovariectomized adult rats. American Society for Bone and Mineral Research, Baltimore MD, Sept 9-13, 1995.

Cheng PT, Aye LM, **Vieth R**, Muller K. Higher estrogen dose is required in cyclical parathyroid hormone and estrogen treatment of osteopenic ovariectomized rats than in preventive treatment with estrogen alone. International Conference on Animal Models in the Prevention and Treatment of Osteopenia. Cairns, Australia, February 11-13, 1995

E3. MEDIA COVERAGE/INTERVIEWS RELATED TO SCHOLARLY ACTIVITIES

October 22, 2015. CBC Television, Nature of Things Documentary: The Curious Case of Vitamins and Me.

December 17, 2014 CTV News. Interview regarding: Vitamin D supplement does little to reduce heart disease, stroke rates: study.

Mount Sinai Foundation 2011. Informational internet video:
Vitamin D - Q&A with Dr. Reinhold Vieth
<http://www.youtube.com/user/MountSinaiFoundation#p/a/u/0/H5HiBtY3ccw>

University of Toronto Magazine Spring 2010. The Vitamin D Crisis A full Interview with Reinhold Vieth. Posted By Scott Anderson On March 16, 2010

Financial Times Magazine, UK and International editions. Weekend magazine, and in its international edition, October 23, 2009. Cover story: profile story about vitamin D with a focus on researcher Reinhold Vieth.

SCHRÖDINGERS KATT - NRK TV, Science Dept. Norwegian Broadcasting Corporation Interview with Reinhold Vieth about artificial tanning and health. Broadcast, January 2010

CBC, CTV, and Global Television interviews, March 24, 2010 about Statistics Canada publication of Canada-wide results for serum 25(OH)D levels. On-camera news items on CBC National News, CTV National News, Global TV News, CBC Radio Toronto as well.

BBC Radio 4. The Food Programme Aug 2 2010. Vitamin D dietary guidelines, full episode available at <http://www.bbc.co.uk/programmes/b00t66nr>

American Association for Clinical Chemistry (AACC) Clinical Laboratory News, July 2009. Interviewed for cover-page article about analytical issues of vitamin D lab testing.

CBC Radio Quirks and Quarks June 7 2008. Vitamin D and human evolution.

Business News Network (BNN). June 2007. Cancer and vitamin D interview

CBC Radio One, June 7 2007. Fourteen separately scheduled live interviews from CBC affiliates across Canada Regarding the new Canadian Cancer Society advice that all adult Canadians should “consider” supplementing with 1000 IU vitamin D daily.

Canada AM, CTV Network. January 2007. Interview about Vitamin D and cancer. R Vieth.

MORE Magazine. Who’s afraid of vitamin D? Jacqueline Hennessey. Summer issue 2007.

Homemaker’s Magazine, May 2006. in article, “How to build better bones.”

Good Housekeeping, March 2006. in article, “Vitamins that you really need”.

Readers Digest, Canada, March 2006, pg 83; Building Better Bones

Toronto Star, Vitamin D feature article, Feb 24, 2006

Ottawa Citizen, Vitamin D feature article, Jan 2006

Newsweek Magazine. Interviewed for feature story, for early January, 2006

Discovery Health Channel. Medical Hotseat, First broadcast Aug 21, 2005: Sun Safety – a panel debate. One of 4 panelists.

CTV News. January 15/16 2005. Story about Vitamin D and cancer. R Vieth.

Newsweek Magazine. Interviewed for feature story Jan or Feb 2005.

Hamilton Spectator. Feature story on vitamin D (different from below). December 6, 2004

Winnipeg Free Press. Feature story, Vitamin D. November 8, 2004

London Free Press (and Canoe website). November 6, 2004.

CITY TV/Pulse24. Vitamin D, sunshine story. October 20, 2004. Laura DiBaptista.

Readers Digest, October 2004 cover story. The Healing Vitamin: Even with a healthy diet, you may be D-ficient. By Diane Peters

Science News. The weekly newsmagazine of science. October 16, 2004. Vitamin D: What's enough? Feature story by Janet Raloff – one of several experts interviewed.

Journal of American Medical Association. September 22/29, 2004—Vol 292:1416. Scientists Probe Role of Vitamin D: Deficiency a Significant Problem, Experts Say Catherine Meyer, MD

WebMD. Vitamin D may ease depression. Sid Kirchheimer. August 2, 2004

Medical Post, Canada. Skin wars: Dermatologists warn about cancer while nutrition experts bemoan vitamin D deficiencies. Who's right in the battle under the sun? Celia Milne. July 28 2004

CMAJ, May 2004. Interviewed for opinion regarding academic freedom.

The Scientist, April 19, 2004. Interviewed for opinion regarding academic freedom.

Kansas City Star. April 6, 2004. Vitamin D-ficiency Recent studies suggest we aren't getting enough of a good thing. By Karen Uhlenhuth, Syndicated throughout the US.

AMED News (weekly newspaper of the American Medical Association) April 5, 2004. Vitamin D found to boost health, if people get enough: Recommendations for increasing intake of the nutrient are under consideration and sometimes trigger controversy. <http://www.ama-assn.org/amednews/2004/04/05/hlsb0405.htm>

Canadian Living Magazine for issue of April 2004: New advice on vitamin D intakes. By Fran Berkoff

CBC Television, The National. Vitamin D and multiple sclerosis. January 12, 2004

Canadian Press. Vitamin D and multiple sclerosis. January 12, 2004

National Post Newspaper Vitamin D and multiple sclerosis. January 12, 2004

Canadian Press, and the Toronto Star. Jan 20 2003 More vitamin D may help seniors fight osteoporosis, researchers say.

Good Times Magazine, November, 2002. Interview and article, vitamin D and osteoporosis/ the POWDER Study

Canadian Living Magazine, November, 2002. Interview and article, vitamin D and osteoporosis/ the POWDER Study

Medical Post of Canada. January 15, 2002 Women need more vitamin D: Official recommended levels offer no benefit. David Hodges.

Reuter's Health News Service. December 11, 2001

The Globe and Mail. November 20, 2001 The ABC's of Vitamin D. Its other health effects, and potential role in multiple sclerosis. Avis Favaro.

CTV National News, November 18, 2001. Vitamin D intake is not enough to have much effect on adults.

Full, 1-hr Radio interview: Your Own Health and Fitness, KPFA 94.1 FM, San Francisco. Layla Barman: How much vitamin D do we need? November 28, 2000; repeat broadcast, Jan 2003

Your Baby Magazine, Interview and article, May 2000.

Clinical Pearls News Interview, 1999, and feature article.

Canadian Living Magazine, June, 2000. Vitamin D nutrition

Talk 640 Radio, Healthy Maturity – 30-min on air interview, June 20, 1999

CHFI Radio, Chronicle, Toronto, January 18, 1999

CBC Radio, Whitehorse, Yukon, January 12, 1999

CBC Radio, Fredericton, New Brunswick, January 7, 1999

The Weather Channel, Chris McDermott. Vitamin D deficiency is common in many Canadians in winter. Telecast at several times daily in their cycle of weather related stories, over 2 week span, January 1999

Toronto Sun, and across the Sun Newspaper chain – a separate story from the above, Marlene Habib, Winter and vitamin D, January 18, 1999

Canadian Press, Marlene Habib, Vitamin D deficiency is common in many Canadians in winter. Ran in many Canadian daily newspapers, including London Free Press, and Canoe.com Sun newspaper chain website, December 23, 1998

CITY TV News (Laura DiBatista), vitamin D deficiency in Canadians. April 14, 1998

CTV NewsOne, April 14, 1998

CTV National News (Avis Favro), April 13, 1998

The Toronto Star, and other Canadian papers, Vitamin D for winter in Canada. Front page of Life section feature article, January 2, 1998

F. TEACHING AND DESIGN

Courses for which I was or am Co-ordinator (responsible for design and operation of course):

LMP1407, 1991 to present (initially coded as course JCL). School of Graduate Studies. This winter-term course was initiated in 1991 by Dr Baines and myself to provide clinical research skills for our graduate students and residents. I have been the primary coordinator for this course since 1993; and sole lecturer since 2002, teaching 26 hrs of teaching biostatistics.

INNOVATION: These classes are held in the Computer Lab of Medical Sciences Building; the “text” is SPSS statistical software, and the teaching focuses on the principles of statistics needed to use that. Current enrollment, 120 postgraduates.

Consistently, retake rate >90%, see student comments; current enrollment 61 post-graduate students, most students in the course are from departments outside LMP. This course is a requirement for postdoctoral clinical chemistry diploma residents.

LMP404. Started Sept 2002, ongoing. Bone and skeletal disorders. INNOVATION: This was a completely new Faculty of Arts and Science course to support LMP's undergraduate specialist's program. In the first year of this course I designed every aspect of the course, and provided 10 hrs of lectures. Further, for guest lecturers who did not provide study notes suitable the students, I reworked the material so there would be handouts. In addition, there was a web page with all notes and discussion group for the students. 35% of the mark was based on presentation and handout done by the students themselves. Overall, this was a very successful premiere for a course. This year, Dr W Vogel will be sharing these responsibilities.

LMP 405. 1995 to 2002-3 (formerly CLB405). Faculty of Arts and Science. I have been co-ordinator of undergraduate independent research courses for department of Laboratory Medicine and Pathobiology or Clinical Biochemistry for 8 yrs; in recent years. This involved 1 initial hour to introduce the course and its objectives, ongoing communication with students, and arranging the process of examination and marking of laboratory reports.

G. GRADUATE STUDENT THESIS SUPERVISION

Current PhD Students: One:

Dennis Wagner (Dept Nutritional Sciences)

Current MSc Students: Two

Banaz Al-Khalidi (Dept Nutritional Sciences)

Nadeen Taha (Dept Nutritional Sciences)

During career, have been supervisor of the following:

(Successfully Completed)

A. DOCTORAL

Samantha Kimball (PhD, 2011, Dept of Nutritional Sciences)

Heather Hanwell (PhD 2011, Dept of Nutritional Sciences)

Student

Harpal Gahunia. (cosupervision with Dr Pritzker)

B. MASTER'S Student

cosupervisor)

Hoang Trang (Primary supervisor, Dr Cole was

C. POST-DOCTORAL FELLOWS

Dr Lindsay King, and Dr Irina Piatkov

Member of Supervisory Committees

Doctor of Philosophy:

Current:

Andrea Glenn, NFS

Graduate (MSc)

Committee

Raha Jahani, NFS

Graduate (MSc)

Committee

Christina Fielding, NFS

Graduate (MSc) Committee

Holly Pang Pharmacy

Graduate (MSc)

Committee

Edwin Chow Pharmacy

Graduate (PhD)

Committee

Doris Li, LMP	Summer Student	Project Supervisor
Margot Latanzi, NFS	Undergraduate	Project Supervisor

Previous

Wei Deng, Dr J Heersche
 Rachel Zand, supervisor, Dr EP Diamandis
 Wei Li, 1998-2000, supervisor, Dr J Heersche
 Nostrad Zarmagi., 1997, Dr. EP Diamandis
 He Yu, 1996. supervisor, Dr. EP Diamandis
 Gail Anderson, 1996 (internal referee). supervisor, Dr. J. Heersche
 Xiauyen Wu, 1996 (internal referee) supervisor, Dr. H. Sonnenberg
 Lola Bartoszewicz, 1995. supervisor, Dr. F. Keeley
 Amin Wang, 1995. supervisor, Dr. D. Templeton

Master of Science:

Sujatha Chakravarthi (ongoing), Dr Venket Rao
 Michael Lee, 2002, supervisor, Dr. CC Liew
 Wei Ding, 1999, supervisor, Dr. D. Templeton

DOCUMENTATION OF TEACHING

COURSES TAUGHT

a) UNDERGRADUATE

MEDICINE

classroom hours	PBL tutor	seminar leader	
1996-97		4	2
1997-98		2	
1998-99		2	
1999-present			4 hours (annually)

I was a PBL (problem-based learning) tutor for 3 yrs, and have been a seminar leader in the Meds Nutrition and Metabolism course for most years since 1982

ARTS AND SCIENCE

1996.2002 Lectures, 2 hrs each year for course NFS488H, Food Safety and Toxicology, Department of Nutrition, Dr Vinket Rao, course coordinator
 1996-2003 LMP405 Undergraduate project course. Coordinator of the course, and each year supervised at least one student.
 2002-2005 LMP404 LMP404h Skeletal Disorders. Coordinator of the course. Teach 6h/term, and oversee student presentations
 2003-2004 Anthropology guest lecturer, nutrition and evolution.
 2002-ONGOING NFS487H Nutrigenomics 2hrs

FACULTY OF PHARMACY

1996-present 2 hours each year, statistics and the interperetation of clinical laboratory Pathobiology Course PHM143, Lectures given annually
 Lecture 1. **Calcium, and Bone Disease**
 Lecture 2. **Vitamin D: Fortification vs Supplement vs Prescription Drug**

b) GRADUATE COURSES

	CLB1404	CLB1405	CLB1401	CLB1603
LMP1407*				
classroom hours				
1995-96	3		4	3
10				
1996-97	3-		4	3
12				
1997-98	3		2	3
12				
1998-99				
			15	
1999-2000				
			15	
2000-2003				
			15	
2004-2008				
			26h Annually	

* Course co-ordinator, and co-lecturer, Introductory statistical analysis for postgraduate biomedical researchers. Sole instructor for course from 2004 onward.

Other Professional Activities,

Organizing Committee: 15th Workshop on Vitamin D – Houston Texas, June 19-20, 2012

Member of **Expert Advisory Panel for Canadian Academy of Health Sciences**, to advise Health Canada on the implementation of the 2011 Institutes of Medicine dietary guidelines for vitamin D and calcium.

Member of **Clinical Trial Steering Committee**. The SOLAR Trial of vitamin D in MS. Merck Serono. Golden Tulip Apollo Hotel, Amsterdam Apollolaan 2, 1077BA, Amsterdam, The Netherlands 6 March 2010, and January 2011.

Member **Data Safety and Monitoring Committee for Clinical Trial**: Establishment of the Vitamin D Requirements During Lactation. Medical University of South Carolina. Ongoing through 2009

Member Data Safety and Monitoring Committee for Clinical Trial: Evaluation of Vitamin D Status Through Maternal (Pregnancy) Supplementation. . Medical University of South Carolina. Ongoing through 2009

Consensus Group Member. American Geriatrics Society. Consensus Conference on Vitamin D for the Prevention of Falls and Their Consequences. Center for Disease Control, Atlanta GA. March 18-19 2009-2011

Organizing Committee: 14th Workshop on Vitamin D - Brugge, Belgium, 4 - 8 October 2009.

U of Toronto Faculty, Course coordinator, CME day on vitamin D. Faculty Club, Nov 2 2009

The Cholecalciferol Council, one of 7 experts for media consultation in the field of vitamin D http://www.cholecalciferol-council.com/vitamin_D_experts.htm

Osteoporosis Society of Canada, Scientific Advisory Panel Consultant, 2001- 2008.

Member, Policy Development Group: EVIDENCE-BASED NUTRITION WORKSHOP. Creighton University, Omaha NB. September 3, 2008

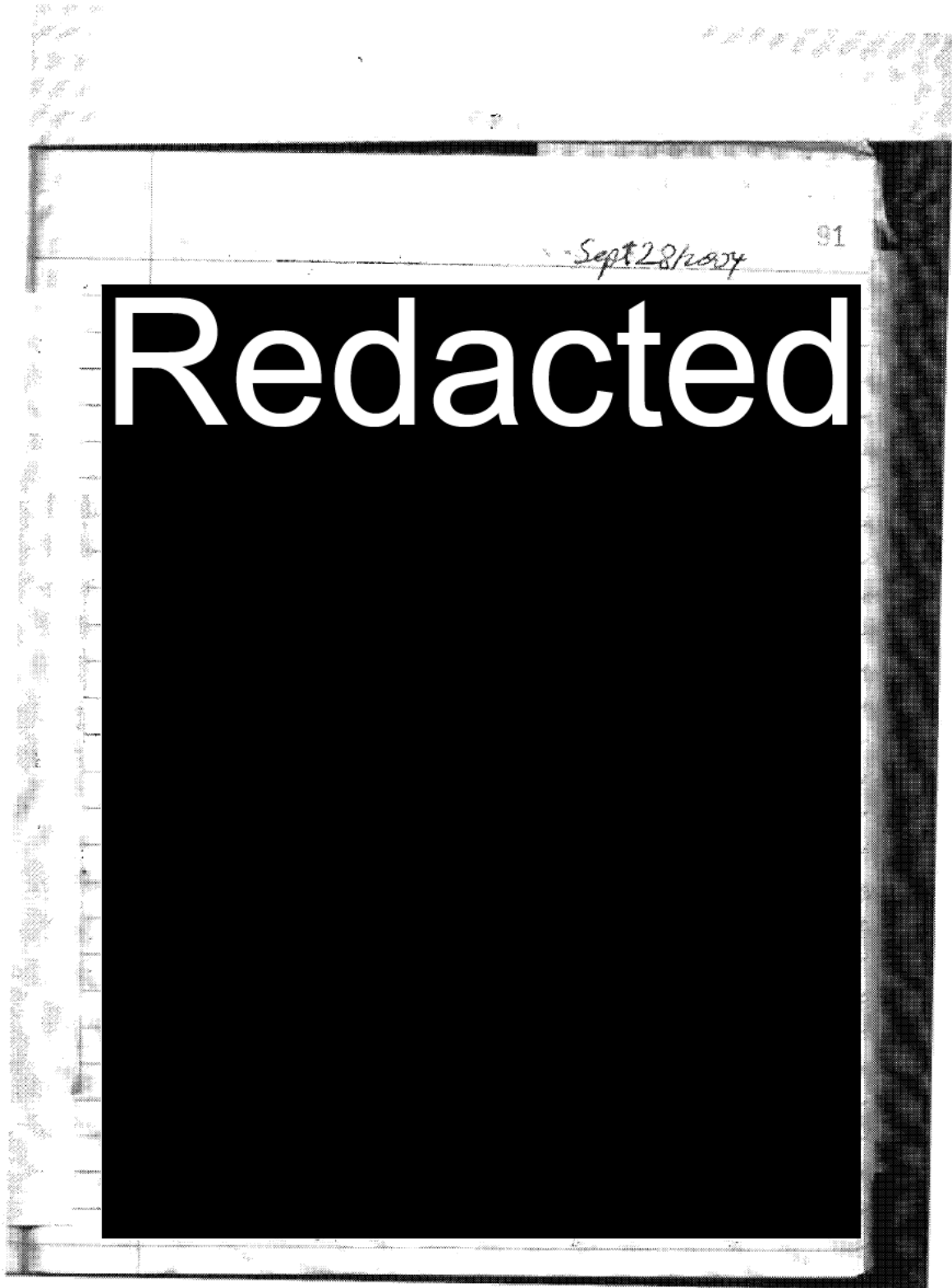
Exhibit B

List of Documents Reviewed

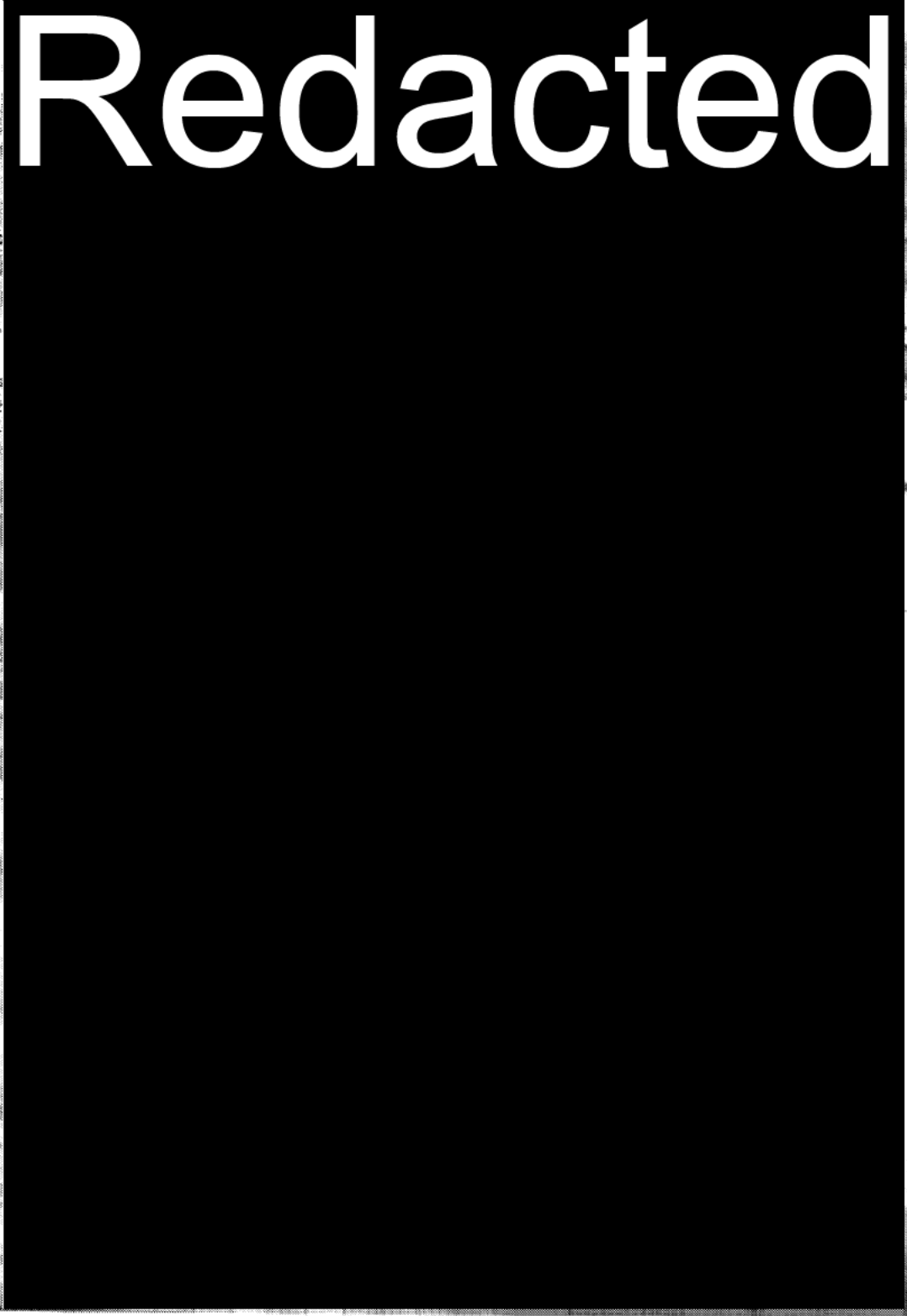
1. A.M. Widström, G. Lilja, P. Aaltomaa-Michalias, A. Dahllöf, M. Lintula, E. Nissen, “Newborn behaviour to locate the breast when skin-to-skin: a possible method for enabling early self-regulation,” 100 *Acta Pædiatrica* (2011) 100, 79–85.
2. A.M. Widström and J. Thingström-Paulsson, “The position of the tongue during rooting reflexes elicited in newborn infants before the first suckle,” 82 *Acta Pædiatrica* (1993), 281-3.
3. Carlo Dani, Alesandra Cecchi, Arianna Commare, Gherardo Rapisardi, Rita Breschi and Simone Pratesi, “Behavior of the Newborn during Skin-to-Skin,” *Journal of Human Lactation* (2015), 1-6.
4. United States Patent No. 9,066,958.
5. Lab Notebook pages, R.Vieth000-0000394-414.
6. Deposition transcript of David J. Sherman and exhibits, dated December 5, 2023.
7. Deposition transcript and exhibits of Stephen Benyunes, dated December 5, 2023.
8. Deposition transcript and exhibits of Robert O. Williams, III, dated December 7, 2023.

9. Petition for Inter Partes Review of U.S. Patent 9,066,958, dated March 16, 2023.
10. Patent Owners' Preliminary Response, dated June 29, 2023.
11. Order Granting Institution of Inter Partes Review, dated September 15, 2023.
12. Declaration and exhibits of Dr. Robert Williams, dated March 16, 2023.
13. Harder reference.
14. Translations of Harder by Tinworth, Sherman and Benyunes.
15. Wolf reference.
16. Translation of Wolf.
17. European Pharmacopoeia.
18. Blass reference.
19. Gartner reference.
20. Declaration and exhibits of Reinhold Vieth, dated May 26, 2017.
21. Declaration and exhibits of Reinhold Vieth, dated June 29, 2023.

Exhibit C



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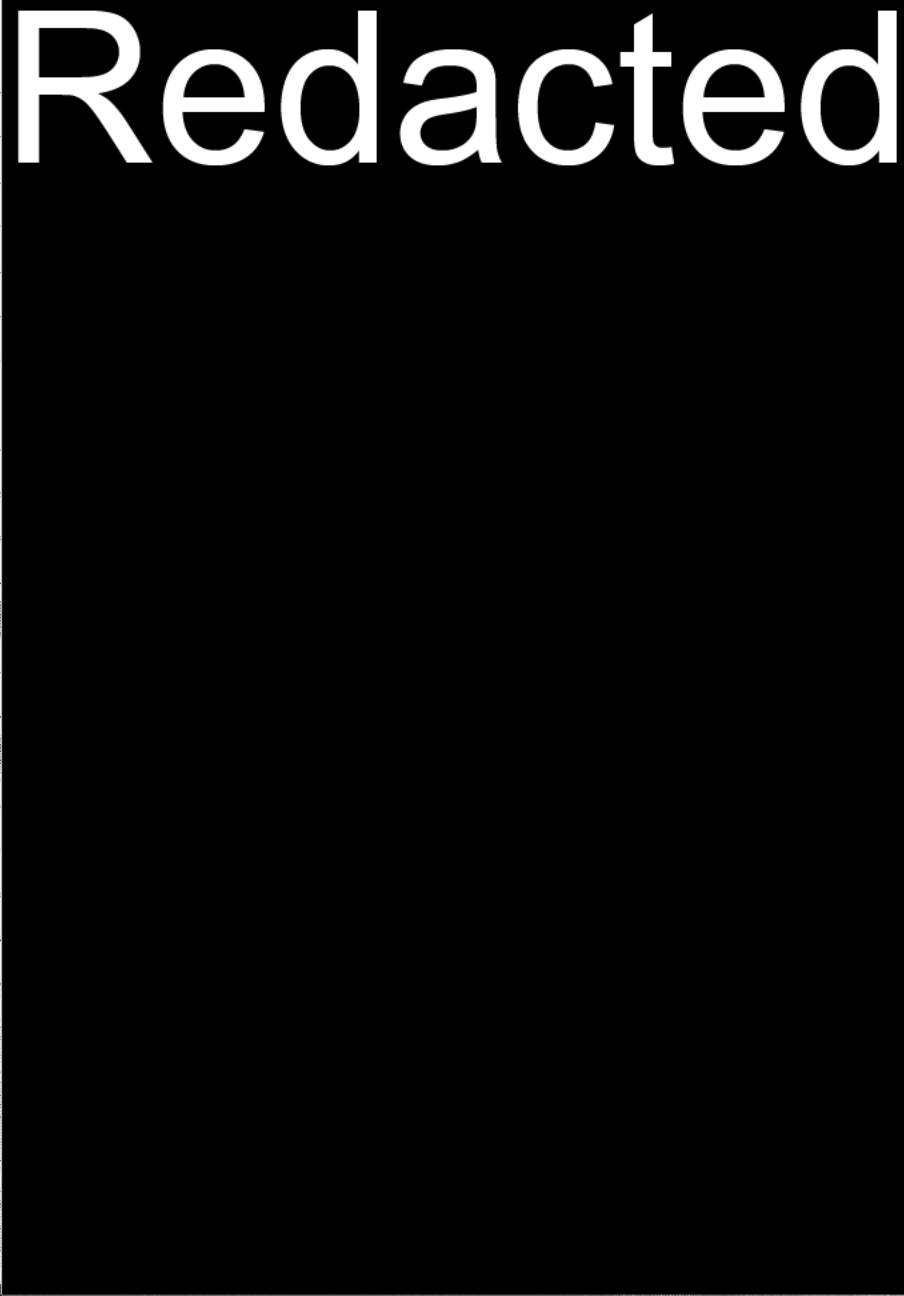
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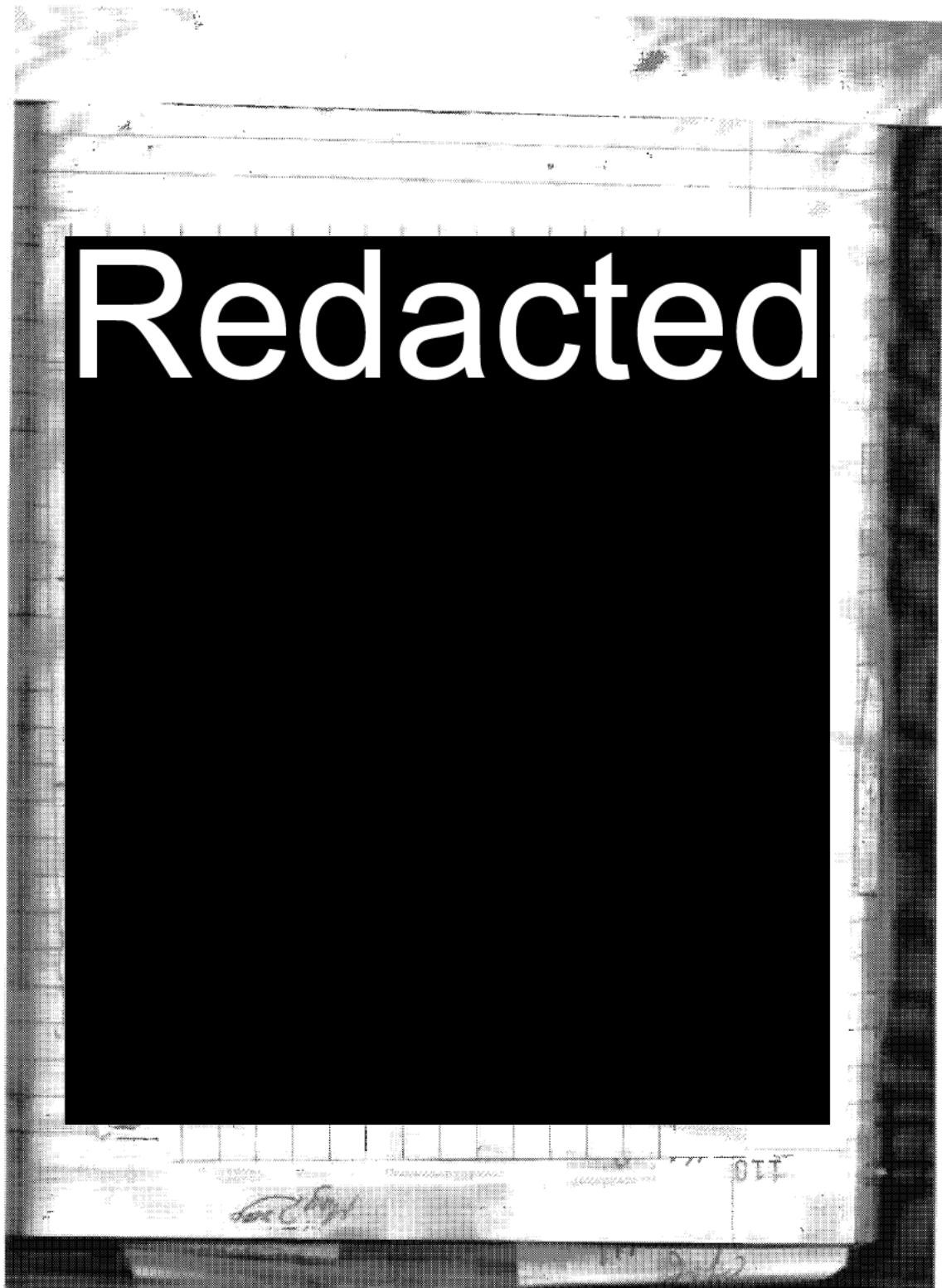
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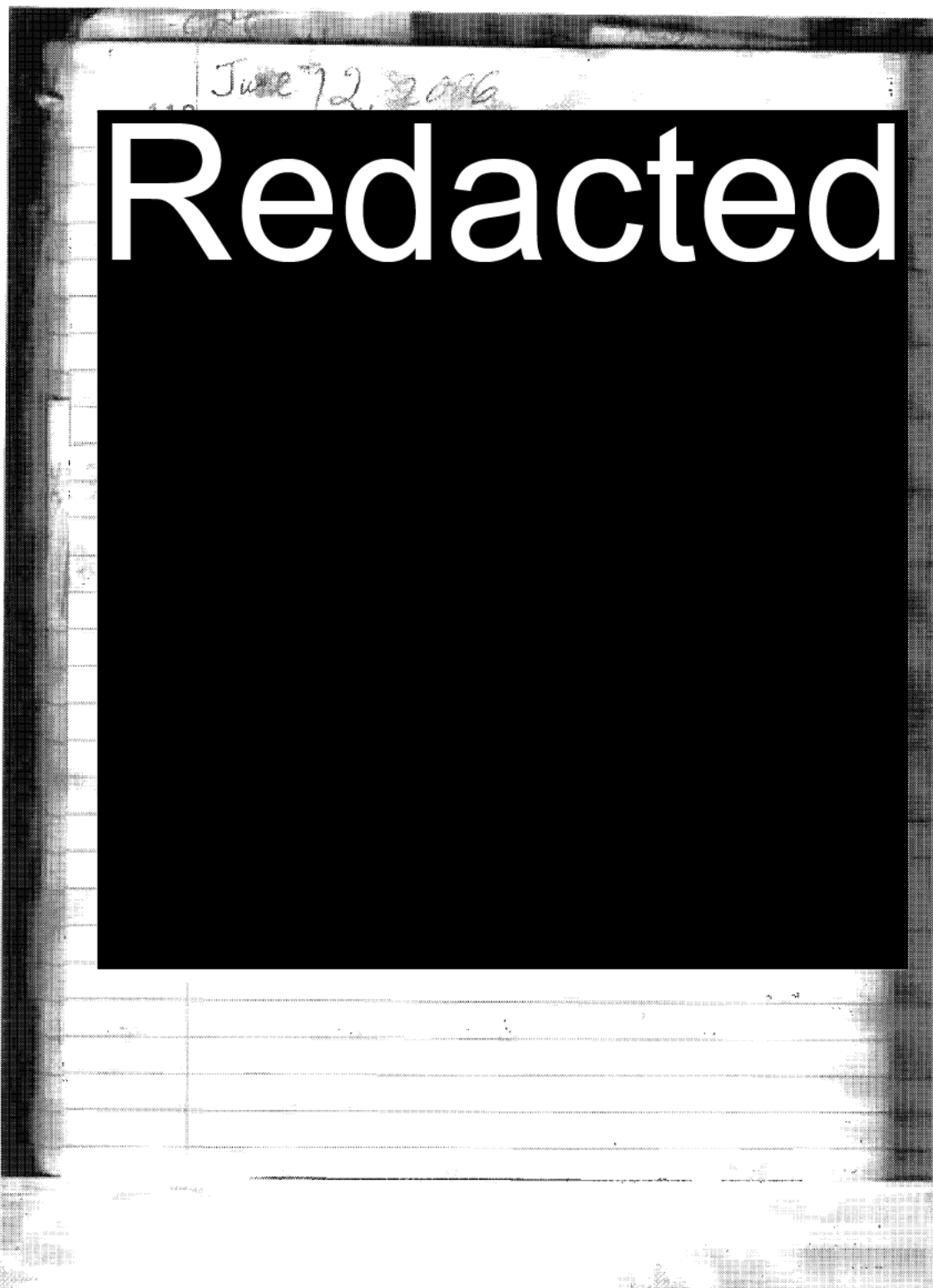
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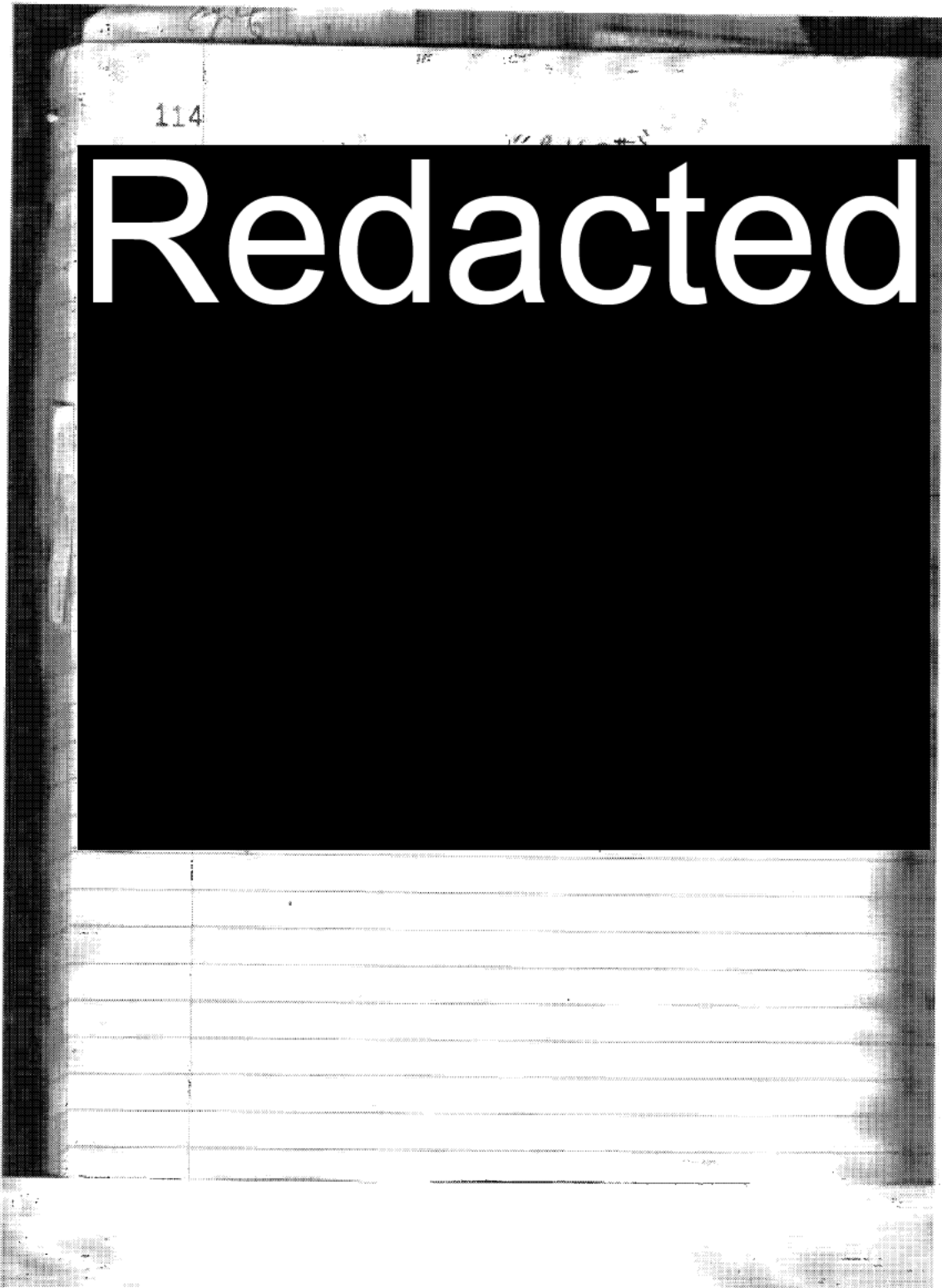
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Nutrition Facts
Valeur nutritive

Per 1 cup (250 mL) / pour 1 tasse (250 mL)

Amount	% Daily Value
Teneur	% valeur quotidienne
Calories / Calories 140	
Fat / Lipides 3 g	6 %
Saturated / saturés 0.5 g	1 %
Trans / trans 0 g	0 %
Cholesterol / Cholestérol 0 mg	0 %
Sodium / Sodium 480 mg	20 %
Carbohydrate / Glucides 23 g	8 %
Fibre / Fibre 4 g	16 %
Soluble Fibre / Fibre soluble 1 g	
Insoluble Fibre / Fibre insoluble 3 g	
Sugars / Sucres 3 g	
Protein / Protéines 8 g	
Vitamin A / Vitamine A	2 %
Vitamin C / Vitamine C	5 %
Calcium / Calcium	6 %
Iron / Fer	15 %

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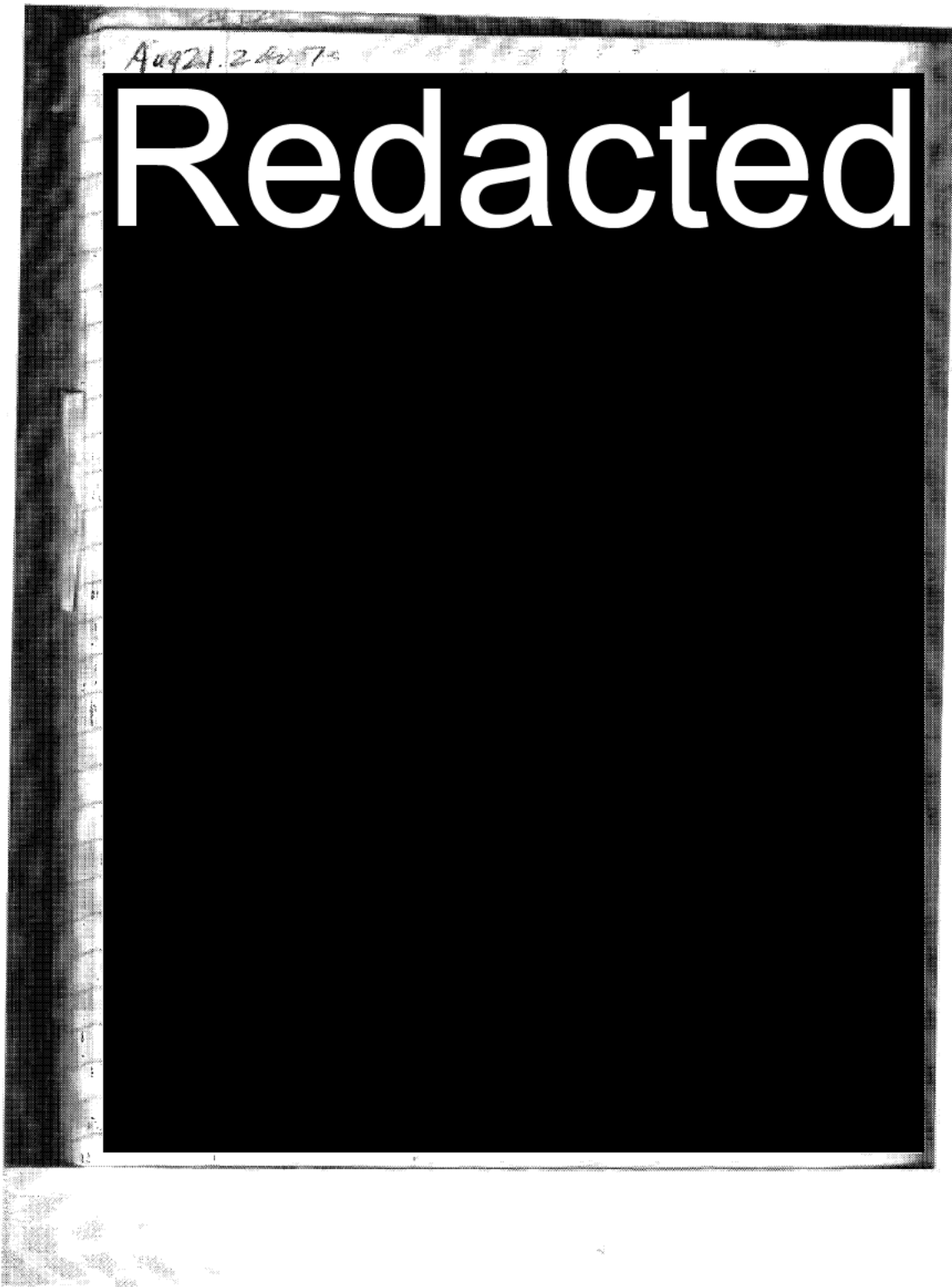
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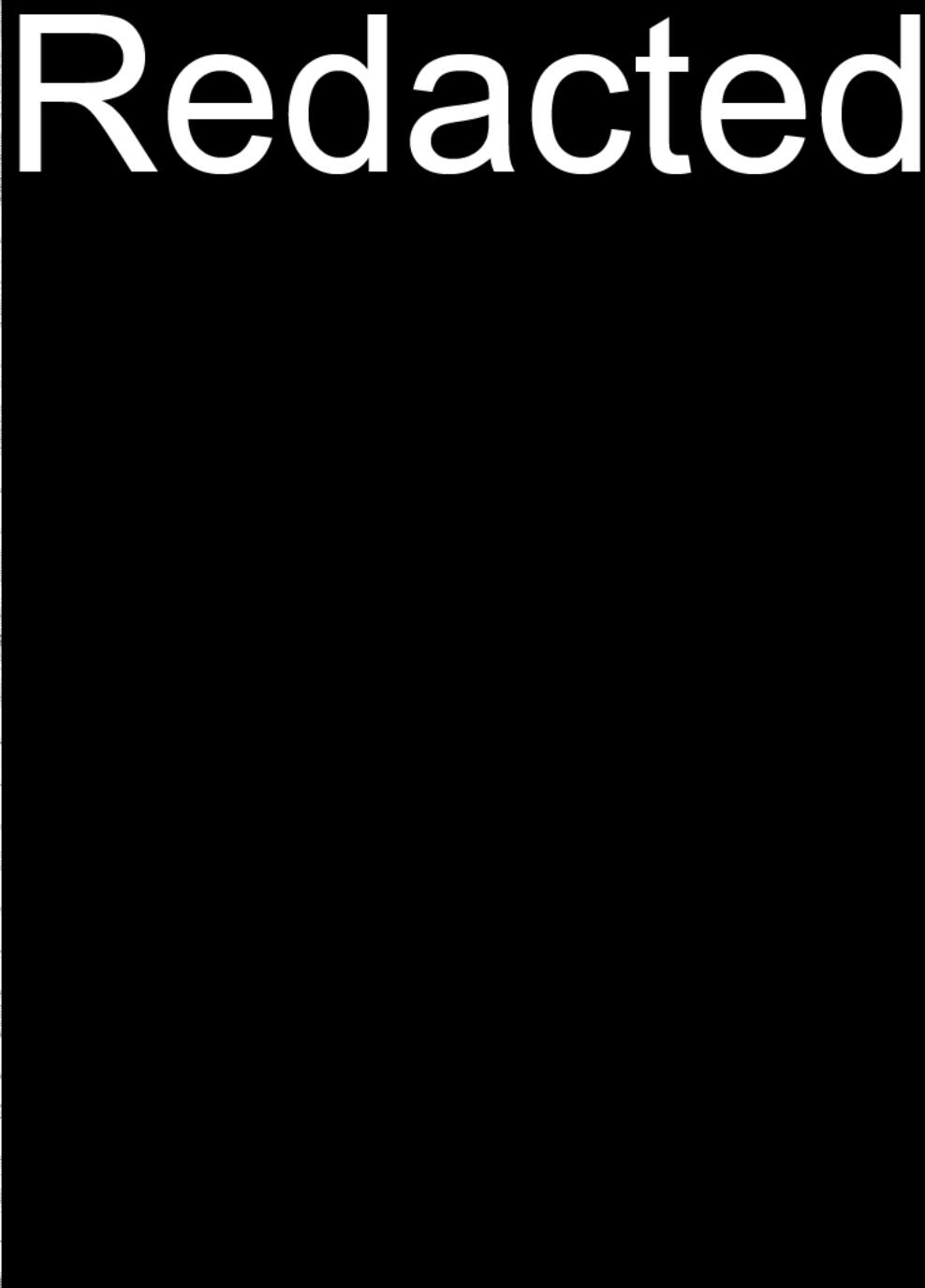
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Exhibit D

The position of the tongue during rooting reflexes elicited in newborn infants before the first suckle

A-M Widström and J Thingström-Paulsson

Nursing Research Unit, Department of Pediatrics, Karolinska Hospital, Karolinska Institute, Stockholm, Sweden

Widström A-M, Thingström-Paulsson J. The position of the tongue during rooting reflexes elicited in newborn infants before the first suckle. *Acta Paediatr* 1993;82:281–3. Stockholm. ISSN 0803–5253

A common breast-feeding problem is when the infant “places its tongue in its palate” and has difficulties in attaching to its mother’s nipple. The aim of this study was to document the position of the tongue in the mouth cavity during rooting reflexes elicited in newborn infants before the first suckle. Eleven healthy, full-term infants were videotaped 101 ± 31 min after birth during an evoked distinct rooting reflex before the first suckle. The videotaped rooting reflex was analyzed in detail concerning the degree of turning of the head, mouth opening and position of the tongue, in pictures that were “frozen” at specific intervals. “Licking movements” preceded and followed the rooting reflex in the alert infants. In 10 of the 11 infants the tongue was placed in the bottom of the mouth cavity during a distinct rooting reflex ($p = < 0.05$). It is suggested that forcing the infant to the breast might abolish the rooting reflex and disturb placement of the tongue. A healthy infant should have the opportunity of showing hunger and optimal reflexes, and attach to its mother’s nipple by itself. □ *Breast-feeding, newborn infants, rooting reflex, tongue reflex*

A-M Widström, Nursing Research Unit, Eugeniahemmet, T2, Karolinska Hospital, Box 60500, S-104 01 Stockholm, Sweden

Previous studies have shown that the newborn infant, if placed skin-to-skin on its mother’s chest immediately after birth, reveals a predictable behavioural sequence, which culminates when the infant, by itself, finds the mother’s nipple and starts to suckle (1). Thus the newborn infant has a competence which we believe is not fully utilized in many breast-feeding situations. The infant is often “helped” to the breast by the nurse who grips the infant firmly over the neck and presses the infant’s mouth against the nipple which is held by the other hand. By helping the infant to attach to the breast, the infant’s reflexes are probably not optimally elicited and might even be disturbed.

One breast-feeding problem described by the staff on our maternity wards involves infants who “place their tongue in their palate” and thus have problems in attaching to the breast since the tongue has to be put under the nipple when the infant suckles.

Our hypothesis is that an alert, non-crying infant, during a distinct and undisturbed rooting reflex places its tongue low in its mouth to be able to attach to the nipple and suckle.

The aim of this study was to document the position of the tongue in the mouth cavity during rooting reflexes elicited in newborn infants before the first suckle.

Materials and methods

Eleven mothers, four primiparae and seven multiparae, with normal pregnancies and normal deliveries partici-

pated in the study with their newborn healthy, full-term infants. The infants were born during the day and were consecutively taken into the study during the research period of two weeks in February, 1990. One couple did not want to participate in the study. The mean birth weight and gestational age of the infants were 3492 ± 406 g and 39.4 ± 1.4 weeks, respectively. Apgar score was 9 at 1 min and 10 at 5 min postpartum. The parents gave their informed consent. The study was approved by the local Ethics Committee.

When the infant had shown interest in feeding, i.e. revealed sucking movements and hand-to-mouth activity, the infant was taken into the study. The mother was asked to sit up and hold her infant in her arms and elicit rooting reflexes by touching the infant’s cheek with a finger. The mother and infant were videotaped until a distinct rooting reflex was seen. The mean age of the infants at the time of the experiment was 101 ± 31 min.

The videotaped rooting reflex was analyzed in detail in pictures that were “frozen” at specific intervals. The starting point for the reflex analyzed was when the infant’s face was centered. The degree of the turning of the head, the opening of the mouth and the position of the tongue in the mouth cavity were assessed according to three-graded scales (head: centered = 0, half-way turned = 1, maximally turned = 2; mouth: closed = 0, half open = 1, wide open = 2; tongue: in the bottom of the cavity = 0, in the middle = 1, high up towards the palate = 2). These assessments were made every 1 s for the first 6 s and then every 2 s up to 18 s after the start of

the reflex. The infants' "licking movements", defined as the tongue being frequently stretched out through the loosely closed lips, were also noted. To analyze the relation between head, mouth and tongue movements in each infant, line graphs were constructed.

The infants' awake states were assessed according to the Brazelton Neonatal Behaviour Assessment Scale (BNBAS); deep sleep, light sleep, drowsy, alert, considerable motor activity, crying (2).

The transcription of all the videotapes was made by the same person. To test the reliability, three randomly selected tapes were transcribed by a second researcher. The same reflex pattern was observed.

Statistical analysis was performed using the Sign test.

Results

At the time of the experiment, nine of the infants were in an alert state (BNBAS, awake state=4). Two were drowsy (BNBAS, awake state=3). The infants' awake state and age are shown in Table 1. Licking movements preceded and also followed the rooting reflex in all the infants except the two who were drowsy (see Table 1). In 10 of 11 infants, the maximal opening of the mouth occurred when the head was turned maximally to the side. In 10 of 11 infants the tongue was placed in the bottom of the mouth cavity during a rooting reflex. Thus to exhibit this behavior is more common than not to exhibit it ($p < 0.05$). An example of an infant performing a rooting reflex during which the tongue is kept low is seen in Fig. 1. In the infant in our study who lifted the tongue, the mother had problems evoking a distinct reflex. Although this infant was alert it did not show spontaneous rooting movements or hand-to-



Fig. 1. A baby with a distinct rooting reflex; the mouth is wide open (score=2), the head is turning towards the shoulder (score=0-1) and the tongue is kept low in the mouth cavity (score=0).

mouth activity during the experiment. After a few minutes the father took the infant and evoked a reflex. The reflex was weak; the head was turned less than half-way, and the mouth was not maximally opened and the tongue was lifted.

The two infants exposed to pethidine (see Table 1) performed rooting reflexes and tongue movements which did not differ from those of the other infants for the variables measured. The mothers were given pethidine 100 mg im during labor. The dose-delivery interval (DDI) is shown in Table 1.

Discussion

Our results indicate that the newborn infant, without being fed, can respond to a rooting stimulus by turning the head towards the stimulus, opening its mouth wide and keeping its tongue at the bottom of the mouth. The head-turning and the mouth-opening components of the rooting reflex are well known (3-5). The control of the tongue position makes rooting an important reflex system which enables the infant to catch the mother's nipple and attach adequately to the breast without help.

To facilitate focusing the camera on the infant's mouth, the rooting reflex was artificially evoked by the mother's finger. In a natural situation at the breast, the infant, besides sensory stimulation and the sight of the nipple, is exposed to smell and taste from the nipple and areola which might elicit a different behavior than when the reflex is artificially evoked. For instance, the maximal opening of the mouth might not necessarily occur when the head is maximally turned towards the shoulder. We also found that licking movements pre-

Table 1. Number of infants, dose-delivery interval (DDI) for injection of maternal pethidine, infant's age and awake state at experiment, and licking in relation to rooting reflex.

Infant no.	Maternal pethidine (DDI min)	Age at experiment (min)	Awake state	Licking in relation to rooting	
				Before	After
1	—	137	Drowsy	No	No
2	—	130	Alert	Yes	Yes
3	—	48	Drowsy	No	No
4	—	77	Alert	Yes	Yes
5	—	93	Alert	Yes	Yes
6	—	74	Alert	Yes	Yes
7	—	86	Alert	Yes	Yes
8	58	119	Alert	Yes	Yes
9	135	121	Alert	Yes	Yes
10	—	83	Alert	Yes	Yes
11	—	148	Alert	Yes	Yes

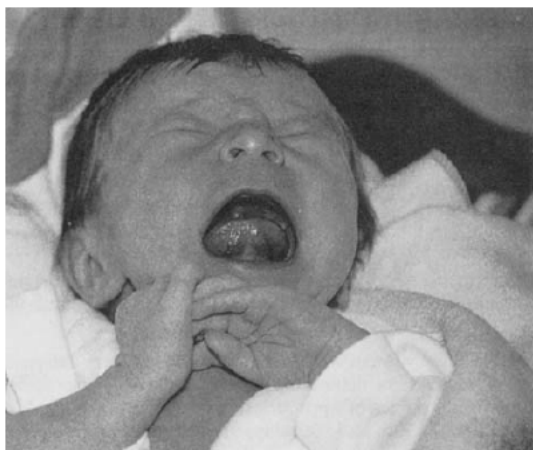


Fig. 2. A crying infant with the tongue lifted high towards the palate.

ceded the rooting reflex if the infant was in an alert state. This might indicate another biological function; the infant has to get the nipple erect by licking in order to attach to it. Preliminary observations indicate that this is common behavior at the breast.

Other preliminary observations indicate that healthy infants place their tongue in the palate when crying (Fig. 2). This might be a security reflex, to prevent obstruction of the trachea during the inspiration phase.

One way the problem of infants placing their tongue in their palate might come about is in the process of forcing a crying baby to the breast, even if the force is gentle. At the next feed the infant might remember the

forced situation and defend itself by placing its tongue in its palate. The problem might also originate from a situation where an infant who is not hungry is forced to the breast, i.e. an infant with low reflexes. The infant in our study who showed low interest in feeding, as well as an indistinct rooting reflex and lifting of the tongue, might be an example of an infant who would be forced to the breast by the staff. This might in turn result in a disturbed rooting-tongue reflex system.

Instead, a healthy infant should be left in peace until it shows hunger and optimal reflexes and is capable of attaching to the nipple by itself. It should be remembered that this licking and rooting procedure can take some time.

Acknowledgements.—This study was supported by the Swedish Medical Research Council (K90-27p-08897-02B), Centrum för Vårdvetenskap at the Karolinska Institute and Förening Mjölkdroppen.

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3. Kussmaul A. Untersuchungen über das seelenleben des neugeborenen menschen. Tübingen, 1859.
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Received Jan. 31, 1992. Accepted Sept. 18, 1992.

Exhibit E

REGULAR ARTICLE

Newborn behaviour to locate the breast when skin-to-skin: a possible method for enabling early self-regulation

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1.Division of Reproductive and Perinatal Health Care, Department of Woman's and Children's Health, Karolinska Institutet, Stockholm, Sweden

2.Division Nursing, Department of Neurobiology, Care science and Society, Karolinska Institutet, Stockholm, Sweden

3.South Hospital, Stockholm, Sweden

4.Karolinska University Hospital, Stockholm, Sweden

5.School of Life Sciences, University of Skövde, Sweden

Keywords

Breastfeeding behaviour skin-to-skin, Newborn, Pain threshold, Psychological bonds, Self-regulation

Correspondence

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Received

29 March 2010; revised 8 August 2010;
accepted 10 August 2010.

DOI:10.1111/j.1651-2227.2010.01983.x

ABSTRACT

Aim: The aim of this study was to provide a more detailed analysis of the infant's behavioural sequence that begins immediately after birth and terminates with grasping the nipple, suckling and then falling asleep.

Method: Twenty-eight full-term infants were videotaped immediately after birth. A video protocol was developed to examine infant behaviours identified from five random videotapes.

Results: When birth crying had stopped, the babies showed a short period of relaxation and then successively became alert. They went through an 'awakening phase', an 'active phase' with movements of limbs, rooting activity and looking at the mother's face, a 'crawling phase' with soliciting sounds, a 'familiarization phase' with licking of the areola, and a 'suckling phase' and last a 'sleeping phase'. Five factors related to the time spent to locate the breast: more number of looks at the breast 10–20 min after birth ($p < 0.0001$); and exposure to meperidine ($p = 0.0006$) related to increased time. Early start of crawling ($p = 0.0040$); increased number of 'soliciting sounds' ($p = 0.0022$); and performing hand–breast–mouth movements ($p = 0.0105$) related to shorter time.

Conclusion: Inborn breastfeeding reflexes were depressed at birth, possibly because of a depressed sensory system. It is hypothesized that when the infant is given the option to peacefully go through the nine behavioural phases birth cry, relaxation, awakening, activity, crawling, resting, familiarization, suckling and sleeping when skin-to-skin with its mother this results in early optimal self-regulation.

INTRODUCTION

We now know that the healthy newborn infant has an inborn sequential behavioural pattern during the first hours following birth if placed skin-to-skin on the mother's chest. Gradually, the reflexes come to life: the infant successively acquires sucking and rooting reflexes, fists the hand, brings the hand to its mouth at about half an hour after birth, and within 1 h postpartum, finds the mother's breast and begins suckling (1,2). It has recently been shown that the newly born infant massages the mother's breasts in preparation for the first feed. The massage-like movements are followed by increased maternal oxytocin levels and are, among other things, suggested to be significant for mother–infant interaction (3).

Apart from eliciting the infant's sequential behaviour, skin-to-skin contact has been found to be the best natural way to keep the infant warm after birth (4). To be born by the vaginal route brings about a surge of catecholamine, which facilitates the newborn's adaptation to extra uterine

life (5). Aeration of the lungs, liquid absorption and cardiac performance are improved. When the more acute effects of this surge of catecholamine are over, negative consequences related to stress may follow, such as extensive crying and sustained peripheral vasoconstriction. Recent research has suggested that these consequences are counteracted by skin-to-skin contact (6).

Even though much is known about the infant's inborn behavioural sequence, we wanted to look more close into how the infant located the mother's breast and for example if it could be understood what senses the infant may use. With more understanding of the infant's biological program while skin-to-skin, the less we as health care providers may disturb the healthy infant and the parents during their first hours together.

The goal of this study was thus to provide a more detailed analysis of the infant's behavioural sequence that begins immediately after birth and terminates with grasping the nipple, suckling and falling asleep.

MATERIAL AND METHODS

Selection

To meet the selection criteria, participants had to be a healthy woman with a normal, single-child pregnancy; a spontaneous, normal labour; and a full-term, healthy infant (38–42 weeks of gestational age).

At 08:00 h, women in labour at a maternity hospital in Stockholm, Sweden who met the inclusion criteria were asked if they were willing to participate in the study. The first infant to be born on the observation day was videotaped. Twenty-eight mothers and infants were videotaped directly after delivery. The local Ethics Committee approved the study.

Videotaping

Immediately after birth, the infant was placed naked, skin-to-skin on the mother's chest, with its eyes level to the mother's nipples. The mother was asked to allow the infant to move naturally on her chest. Thus, she did not shift the infant's position, but stroked and talked to the infant without restriction. The video camera was directed at the upper part of the infant's body, including the face. The videotaping ended when the infants started suckling. For those who did not suckle, the videotaping was discontinued when the infants entered their first sleeping period.

Video examination

Five random videotapes were studied by the research group to identify and define infant behaviours. The researchers looked at the videotaped infants with 'open minds' and without any preset hypotheses. The observers agreed upon a standardized description of the behaviours and activities of the infant from birth to first suckle or first sleeping period (see Results section Tables 1 and 2).

Transcription

A data sheet for transcription was developed where the phases and behaviours identified were listed in the vertical

Table 1 Definition of phases/behaviours identified

Phases	Behaviours
Birth cry	Intense crying just after birth
Relaxation phase	Infant resting/recovering. No activity of mouth, head, arms, legs or body
Awakening phase	Infant begins to show signs of activity. Small thrusts of head: up, down, from side-to-side. Small movements of limbs and shoulders
Active phase	Infant moves limbs and head, is more determined in movements. Rooting activity, 'pushing' with limbs without shifting body
Crawling phase	'Pushing' which results in shifting body
Resting phase	Infant rests, with some activity, such as mouth activity, sucks on hand
Familiarization	Infant has reached areola/nipple with mouth positioned to brush and lick areola/nipple
Suckling phase	Infant has taken nipple in mouth and commences suckling
Sleeping phase	The baby has closed its eyes

Table 2 Definitions of behaviours not restricted to a specific phase

Behaviours	Definition
Eyes	Closed or opened Looks mainly at mother's breast Looks mainly in the direction of the mother's face
Soliciting sounds	An affirmative, short, ringing so sound
Hand-to-mouth	Hand in/or touching the mouth
Hand-breast-mouth	Infant moves hand across mother's breast and brushes the nipple/areola and brings hand to mouth
Rooting	Twisting movement where face is brought across or lifted above mother's chest and turned to side or hand
Rocking/pushing	Rocking activity without shifting position

plane and the time, minute by minute, in the horizontal plane. A single demarcated behaviour was marked by a dot, and a behaviour that lasted for some time was noted with a line corresponding to the time the behaviour was seen. No behaviours were assessed according to graded scales. With this type of observation sheet, it was easy to obtain an overview of an infant's behaviour. This type of videotape transcription has been described by Erickson (7).

Tests for inter-observer reliability

Before the systematic coding took place, three random tapes were tested for inter-observer reliability. For congruence, 10-min observations of each video were compared. Between observer 1 and 2, the coding was congruent in 95% of the observed behaviours; between observer 1 and 3, 75% were congruent; and for observer 2 and 3, the corresponding figure was 80%.

Coding procedure

The videos were simultaneously studied minute by minute by all three observers. A 'conference score' was noted. The tape was stopped while the notes were made. If something was unclear within the minute studied, the tape was rewound and the sequence restudied until the observers agreed. The observers did not have access to any background data concerning the mother or baby.

Statistics

Values are given as medians and ranges unless otherwise specified. The Wilcoxon signed-rank test, the Mann-Whitney *U*-test, chi-square test and multiple regression analysis were used.

RESULTS

Information regarding maternal age, weeks of pregnancy and infant birth weight can be seen in Table 3.

Infant phases of activity during the first hour of life are described in Table 1. After the baby was dried, had stopped birth crying after a median time of 2 (2–4) min, and was left in peace on the mother's chest, a short period of 'relaxation' was apparent. In the relaxation phase, the baby did not

Table 3 Background data (medians and range or frequencies)

Parity	
Primiparae	12
Multiparae	16
Age (years)	29.5 (21–37)
Weeks of pregnancy	40 (38–42)
Analgesia	
Epidural anaesthesia	4
Pudendal block	14
Meperidine	10
Other	11
Birth weight, grams	3475 (2500–4650)

move any parts of the body, not even the mouth. Soon thereafter, the infant entered an awakening phase and started to make small thrusts with its head and small movements with its shoulders and arms. The awakening phase was followed by an active phase, when the infant showed more distinct activity. Most of the behaviours described in Table 2 (e.g. looking at the breast, looking at the mother's face, rooting movements, hand-to-mouth activity, soliciting sounds) occurred during the active phase. Between different activities, resting phases were identified. During the crawling phase, the infant approached the areola, and during the familiarization phase, the baby became acquainted with the areola by licking and touching the nipple before eventually entering the suckling phase, in which the baby started suckling the breast without help. Recorded median time points after birth at which a phase or behaviour first appeared are shown in Table 4.

Eighteen of the 28 infants reached the areola (primary outcome variable in this study) by themselves and started touching and licking, and 15 of them began suckling spontaneously.

Eyes of infants

The infants opened their eyes for the first time at a median age of 2.5 (0–16) min. A period of frequent opening and closing of the eyes followed. At 7.5 (0–124) min of age, the infants started to keep their eyes opened for periods longer than 5 min, and at 64 (10–153) min, they started to feel sleepy, (i.e. frequently closing their eyes for periods longer than 5 min). During the period in which infants had opened eyes, there were significantly more looks at the breast than at the mother's face during the first 10-min period after birth ($p = 0.04$) (Fig. 1A). Most looks at the mother's breast occurred during the second 10-min period after birth ($p = 0.055$) (Fig. 1B). Most looks at the mother's face occurred 10 min later ($p = 0.039$) (Fig. 2).

Infants' soliciting

During the total observation period (i.e. from birth to 10 min after the first suckle or up to 120 min, if the infant did not suckle), a median of five (0–90) soliciting sounds were registered. The number of soliciting sounds increased significantly from 15 min before the infants first brushed the areola with their mouths to the nearest 15 min after

Table 4 Median minutes (25th–75th quartile) after birth at which a phase or a spontaneous behaviour first appeared in 28 newborn infants. Medians and quartiles are calculated only on infants showing a behaviour

Variable	Infants showing the behaviour	Median (25th–75th quartile)	Infants not showing the behaviour
Birth cry	28	0 (0–0)	0
Relaxation phase	24 ^a	2 (2–4)	0
Awakening phase			
Head movements/small thrusts	28	2.5 (1–5)	0
Opening of the eyes	28	3.5 (1–7)	0
Mouth activity	28	3 (2–16)	0
Active phase	28	8 (4–12)	0
Eyes stay open for 5 min or more	26	9.5 (6–16)	2
Looks at breast	25	15 (0–53)	3
Looks at mother	24	15.5 (11.5–21.5)	4
Rooting	25	17 (12.8–23.5)	3
Hand-to-mouth movement	28	18 (9–31)	0
Soliciting	25	23 (17.5–32.5)	3
Resting phase	25	18 (13–26.5)	3
Crawling phase	21	36 (18–54)	7
Familiarization phase	18	43 (29–62)	10 ^b
Hand–breast–mouth movement	9	46 (32.8–70.5)	19
Suckling phase	15	62 (43.5–90.3)	13
Sleeping phase	28	70 (52.5–79)	0

^aFour videos could for technical reasons not be visually evaluated the first minutes. Delivery room routines as drying the baby and cutting the cord may have disturbed the length of this phase.

^bOf these ten infants, five had been exposed to meperidine (Pethidine hydrochloride, ACO Pharmacia) during labour.

($p = 0.05$). At 15 min before brushing the areola, there was a significant difference in the median number of soliciting sounds between boys and girls [i.e. 2.5 (0–6) vs. 0 (0–1) ($p = 0.02$), respectively]. At 15 min after the first brushing, the difference was not significant [i.e. 4 (0–10) vs. 1 (1–8) (ns)].

Movement of hand from areola/nipple to mouth

All of the nine infants who displayed hand–nipple–mouth movements (9/9) found the areola. In contrast, the areola was found by only nine of the 19 infants who did not show hand–nipple–mouth movements ($p = 0.01$).

Factors related to infants' success or failure in finding the areola

To determine which factors or specific skills might play a part in an infant's ability to locate the breast, a multiple regression analysis was performed. The dependent variable was the time taken to reach the areola. The regression analysis included the following independent variables: (i) number of looks at the mother's breast 10–20 min following birth, (ii) hand–breast–mouth movements (0/1), (iii) number of soliciting sounds 15 min before brushing the areola with

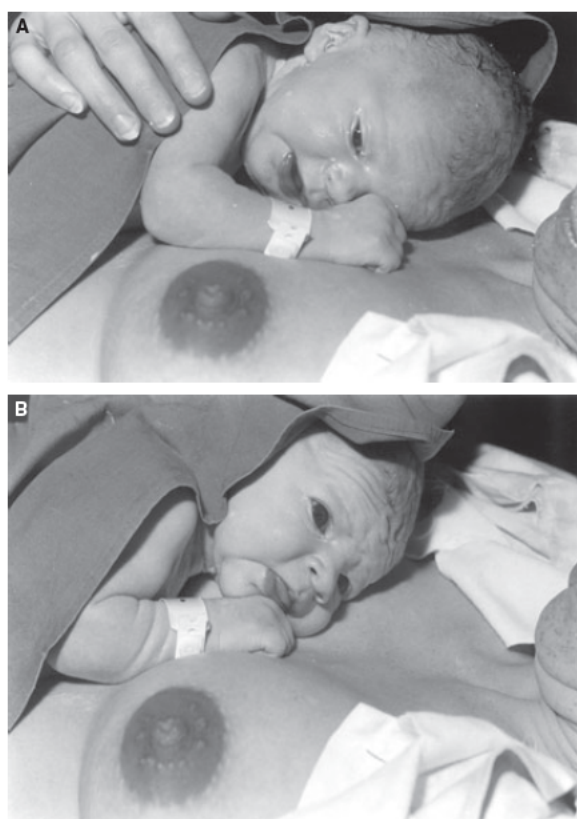


Figure 1 (A) The baby looks at the breast 15 min old. (B) The baby looks at the mother 21 min old. Photo: Thomas Annersten.

the mouth, (iv) exposure to meperidine and (v) use of pudendal block.

The independent variables related to the infant's reaching the areola are listed in order of significance: (i) an increased number of looks at the breast 10–20 min increased the time spent to reach the areola ($p < 0.0001$); (ii) exposure to meperidine increased the time spent locating the areola (0.0006); (iii) an increased number of soliciting sounds 15 min before touching the areola shortened the time spent reaching the areola ($p = 0.0022$) and (iv) presence of hand-breast-mouth movements decreased the time spent locating the areola ($p = 0.0105$). The time point for first crawling correlated positively to the time point when the areola was located ($p = 0.004$). Together, these variables explained 88% (adj. R^2) of the variation of the dependent variable (Table 5). The use of a pudendal block did not significantly influence the point in time when the baby reached the areola.

Time licking the areola before suckling

Fifteen of the infants started to suckle after they had reached the areola. They spent a mean time of 14 min (Range 1–45) licking and touching the areola and breast before suckling.

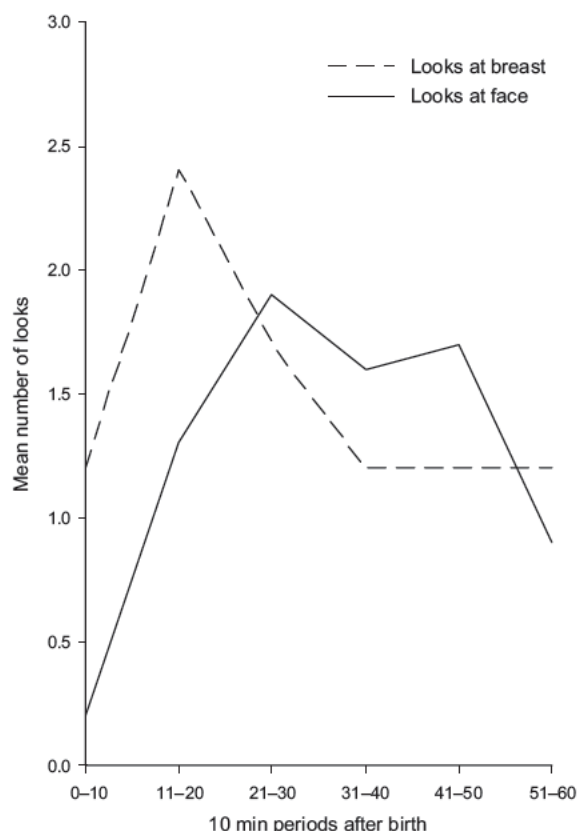


Figure 2 The infant's mean number of looks at either mother's breast or face is shown for 10-min periods during the first hour after birth.

Table 5 Multiple regression analysis to establish the influence of behavioural variables and analgesic routines on the point-in-time when the infant locates the areola. Adjusted R^2 0.878

Variable	Coefficient	SE	t-value	p-value
Intercept	24.158	12.956	1.865	0.891
Looks at breast 10–20 min after birth	11.540	1.718	6.716	<0.0001
Meperidine	78.143	16.497	4.737	0.0006
Soliciting before familiarization phase	−18.573	4.689	−3.961	0.0022
Time point for first crawl	0.935	0.259	3.618	0.0040
Hand–breast–mouth movement	−35.398	11.493	−3.080	0.0105

DISCUSSION

The main findings in this study were that the newborn infant, after the birth cry, when immediately put skin-to-skin on the mother's chest, showed a short period of relaxation without any body movements. It successively increased body movements and exhibited a number of activities, such

as looking at the mother's areola/nipple and making specific soliciting sounds and hand-breast-mouth movements. These activities played a role in the infant's locating of the mother's breast.

Relaxation and awakening phases

The relaxation phase (no movements at all) lasted less than a minute as the infant was left undisturbed, and successively and slowly, the infant's reflex system was engaged. It seems as if the infant had a limited ability to regulate its body, as if the sensory system was depressed. It has been suggested that the surge of catecholamine and β -endorphin during birth brings about an increased pain threshold in the infant the first hour after vaginal birth (8–10). Bergqvist et al. have in a recent study found that infants have a high pain threshold after birth. They found that infants exposed to injections of vitamin K within >30 to $\leq$ 90 min of delivery express less pain than those administered injections >90 to <260 min after birth (11).

An alternative explanation could be that the human foetus produces oxytocin (12), which may be a response to the stressful experience of being born (5). Oxytocin has been shown to increase the pain threshold in rats (13,14). The production of this substance in the human foetus may be enhanced during its stressful journey through the birth canal. The oxytocin released may increase the pain threshold or cause sedation, which is mirrored by the relaxation phase observed in the first minutes after birth. Because of these effects, the infant is not likely to spontaneously show a high rooting reflex immediately following birth.

Suctioning of the airways was not performed in these healthy full-term infants. It is a clinical observation that healthy crying newborn infants being suctioned are able to make defensive movements trying to get rid of the catheter, although not able to grab the catheter because the hands are flaccid, but using pushing movements. This is probably a survival mechanism to keep the airways free from foreign objects. It could be speculated from an evolutionary perspective that the short relaxation phase (after the lifesaving birth cry had stopped) may be a mechanism hindering detection by predators. But soon thereafter another surviving mechanism slowly comes into play; the search for food.

It should be taken into consideration that the procedure of drying the infant might have affected the length of birth cry as well as the time point the relaxation phase first could be seen.

Eyes

A number of animal species that are born with their eyes open are not as dependent on olfactory cues as are rat pups, whose eyes are closed at birth (15). We found that the infant seemed to look more often at the mother's nipple than at her face during the first 10–20 min after birth. In addition to olfactory cues, it is tempting to further speculate whether it is the shape and colour of the areola and the nipple, which has become darker during pregnancy that is drawing the attention of the infant.

It is interesting that half the infants who found the areola brushed their hand across the mother's areola/nipple and then brought their hand to their mouth. Of the infants who did not find the nipple, none made this kind of movement. Von Hofsten (16) found that at 5 days of age, infants have the ability to make a directed movement towards a moving ball at a distance of a couple of decimetres from their face. It is likely that the newborn babies in this study were able already during the first hour after birth to intentionally reach for the nipple. This movement of the hand from the breast to the mouth could thus be intentional and would be of importance for communicating taste–smell sensations that stimulate the infant to continue searching for the breast.

Olfaction

Olfaction seems to affect an infant's ability to locate the nipple, as was reflected by an increased number of soliciting sounds when the infants approached the areola with their mouth. This could be interpreted as the infant getting increasingly excited by the smell and taste from the areola and intuitively sending out signals to the mother to attract her attention and help.

Rat studies have indicated that washing of the mother's nipples just after birth essentially eliminates the first attachment of the newborn pups to a nipple (15). However, when extracts from the wash are then placed on the washed rat nipple, the pups' ability to attach to the nipple is restored, though not always completely. It has recently been observed in the same type of experiment that the newborn baby also crawls for the unwashed nipple (17). Even natural breast odours unsupported by other maternal stimuli appear to be sufficient to attract and guide the infant to the odour source (18). The newborn is most sensitive to remember odours soon after birth (19). This early sensitivity to odours may not only guide the infant to the breast but also serve the infant's recognition of the mother and thus facilitate the bonding process between them.

Active phase – crawling phases and resting phases

In this study, we found that infants starting crawling movements early found the areola in a shorter time than those infants starting crawling later. It is likely that those babies who were less active spent more time trying to identify the areola by looking at the mother's breast. This inactive behaviour is likely to be related to the exposure to meperidine. It is well known that sedation and analgesia causes depressed pre-feeding behaviour (2,20).

It is interesting to note that the infants during the active phase took periods of resting. According to our experience, the infants should not be pushed to go on searching while they are resting but be left in peace and start searching on their own initiative. They seemed to work hard and to need rests.

At about 40–50 min after birth, the infant seemed to be more interested in searching the mother's face than her breast. Possibly, the mother's voice is drawing the infant's attention at that time. It is well known that the newborn

infant is capable of turning its head towards a human voice (21). We also know from the work of de Casper and Fifer (22) that the newborn infant already *in utero* learns to recognize the voice of the mother. In our experimental setting, the importance of looking into the mother's face became obvious, as the infant had to shift position to be able to see the face. When the infant turns its head early and looks at the face of the mother, the infant may associate the already known voice of the mother with her face. The mother's voice might thus be the 'attachment link' between intrauterine and extra uterine life. It should be remembered that during our study, the infant was placed between the mother's breasts with the eyes level to the areola. The position of the infant may be the factor deciding the order of the events 'looking at the breast' and 'looking at the mother's face'.

Familiarization

When the infants had reached the areola, they started licking and touching the areola with the lips. The 15 infants starting to suckle spent a mean time of 14 min to touch and shape the nipple before attachment. It could take up to 45 min after reaching the areola before they attached. It is wise to refrain from 'helping' the infant to attach because unfortunately the help can sometimes be too forcing and the infant may experience suffocation, fight the breast and establish aversive behaviours when later coming close to the breast (23).

Effect of skin-to-skin contact on infant self-regulation

When in contact with the mother's body, the baby becomes calm and relaxed (6), which may facilitate the baby's ability to make use of all its senses and reach the areola and find the breast. During this process, the baby coordinates its body movements with its senses of sight, hearing, smell and taste as shown in this study.

The effect of skin-to-skin contact on self-regulation in preterm infants has been evaluated in several studies. In these studies, the preterm infant has repetitively been put skin-to-skin with its mother during the neonatal period and found to improve self-regulation measured with different methods at different time points after birth (24–26). Byströva et al. (27) found that full-term infants after 90 min of skin-to-skin contact soon after birth showed optimized self-regulation and dyadic mutuality 1 year later as measured by a standardized tool (Parent-Child Early Relational Assessment PCERA) (28).

The effects of skin-to-skin seen on self-regulation in studies on preterm infants may partly be an effect of that the infant has an optimal chance to successively re-organize/organize body movements with its senses and repeatedly become calm during skin-to-skin sessions. This process to improve self-regulation may take weeks or months in the preterm infant. We hypothesize that the full-term healthy infant when skin-to-skin with its mother immediately after birth optimizes its ability to reach self-regulation within the first period of wakefulness when going through the inborn biological program to find the mothers breast.

The finding of Lundqvist-Persson (29) that 3-day-old infants with low self-regulation levels are at risk for poorer social and cognitive development as well as regulatory disorders strengthens the importance of establishing early self-regulation even in the full-term infants.

Based upon our findings and conclusions, the baby should stay skin-to-skin with its mother the first hours after birth, and it is clear that delivery ward routines should be designed so as to not disturb the infant's self-regulation process, first suckling and maternal-infant attachment behaviours. As the infant seems to be depending on olfactory cues, the staff must avoid washing the mother's breasts and also postpone the baby's bathing and weighing. The administration of meperidine is an example of another disturbing factor and should not be given to the mother as a standard clinical routine. That meperidine delayed infant behaviour indicates that infants can be compromised by drugs during labour and may become vulnerable. Care must be taken to ensure that airways remain free.

All healthy infants should remain with their mothers from birth throughout the maternity stay to further facilitate breastfeeding and attachment.

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Exhibit F

Behavior of the Newborn during Skin-to-Skin

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Abstract

Background: Early skin-to-skin contact (SSC) significantly increases the breastfeeding rate in healthy term infants.

Objective: This study aimed to confirm previously described behavioral sequences during SSC.

Methods: We recorded live and videotaped infant behavioral sequences during SSC in a cohort of healthy term infants, whose outcome was then evaluated.

Results: We studied 17 mother-infants dyads. While the majority of infants (59%) had behavioral phases that have been previously reported, some of them had alternative sequences. We observed the infant's massage of the mother's breast with its hand during SSC, which had not been previously reported. We found no correlations between behavioral sequence during SSC, breastfeeding, and neonatal outcome. Moreover, maternal pain stimuli did not affect the neonatal SSC behavioral sequence.

Conclusion: Our study confirms that immediate and undisturbed postpartum SSC is characterized by specific behavioral phases whose sequence may vary without affecting the suckling rate at the end of SSC, breastfeeding success, or the short-term neonatal outcome.

Keywords

breastfeeding, infant, maternal pain, skin-to-skin

Well Established

Early skin-to-skin contact (SSC) is characterized by specific behavioral phases whose sequence has not been extensively investigated, although it seems that its variation does not affect the suckling rate and breastfeeding success.

Newly Expressed

We documented a new behavior during SSC and confirmed that behavior sequence does not affect breastfeeding. The successful suckling rate at the end of SSC does not appear to be affected by maternal pain stimuli and does not affect the short-term neonatal outcome.

Background

Early skin-to-skin contact (SSC) is a practice that begins as soon as possible after birth and refers to placing the naked baby prone on the mother's bare chest.¹ A recent meta-analysis has demonstrated that early SSC significantly increases the breastfeeding rate in healthy term infants at 1 to 4 months postbirth, improves cardiorespiratory stability in late preterm infants, and increases the blood glucose level 75

to 90 minutes following birth.¹ It has also been demonstrated that SSC decreases a newborn's stress level, which is associated with separation from his or her mother,² and positively affects the transition from the womb to the extrauterine environment.³

Although the beneficial effects of SSC are well known,^{1,2} the infant's behavioral sequence during SSC has been poorly investigated. Widström et al⁴ have recently reported that the infant goes through 9 behavioral phases (birth cry, relaxation, awakening, activity, crawling, resting, familiarization, suckling, and sleeping) during SSC with its mother, which

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Table 1. Behavioral Phases, Adapted from Widström et al⁴.

Phases	Behaviors
Birth cry	Intense crying just after birth
Relaxation phase	Infant resting/recovering; no activity of mouth, head, arms, legs, or body
Awakening phase	Infant begins to show signs of activity; small thrusts of head: up, down, from side-to-side; small movements of limbs and shoulders
Active phase	Infant moves limbs and head, is more determined in movements; rooting activity; "pushing" with limbs without shifting body
Crawling phase	Pushing that results in shifting body
Resting phase	Infant rests, with some activity, such as mouth activity, sucks on hand
Familiarization	Infant has reached areola/nipple with mouth positioned to brush and lick areola/nipple
Suckling phase	Infant has taken nipple in mouth and commences suckling
Sleeping phase	The baby has closed its eyes

may facilitate its ability to make use of all its senses, find the breast, reach the areola, and start suckling the nipple.

Thus, the primary research objective of this study was to evaluate the infant's behavioral sequence during SSC to confirm what has been previously described⁴; secondary research objectives were the evaluation of possible correlation between SSC behavioral sequence and breastfeeding success.

Methods

This prospective observational controlled study was conducted at the Margherita Birth Center of the Careggi University Hospital, Florence, Italy, from October 2012 to May 2013. After approval by the Ethics Committee of the Careggi University Hospital and informed parental consent had been obtained, we studied healthy infants with a gestational age of ≥ 37 weeks and birth weight appropriate for gestational age, born after uncomplicated pregnancy in Italian women by vaginal delivery without any kind of labor analgesia. Exclusion criteria were the occurrence of any event that could interfere with the newborn's spontaneous behavior during SSC, such as the need for mild resuscitation, biochemical blood measurements (ie, glycemia), or transient separation from the mother (ie, for manual removal of placenta).

Study Design

In the Margherita Birth Center, labor and delivery occur in the same room where mother-infant dyads stay until their discharge from the hospital. This study initiated immediately after birth: the infant was dried, avoiding hands and wrists (although there are not specific evidences, we believe that to leave amniotic fluid and mother's smell/flavor on newborn's hands and wrists may contribute to a more "natural" search of nipples), its head was covered with a dry cap and a warm blanket across the back, and it was placed naked and prone, skin-to-skin on the mother's chest, with its eyes level to the mother's nipples. The mother was asked to allow the infant to move naturally on her chest, but she could stroke and talk

to the infant without restriction. Similarly, midwives were asked to not interfere with the newborn's movements, to not help the newborn reach the areola/nipple, and to limit ambient noise.

Mothers and infants were observed during SSC by real-time reporting of the time, duration, and sequence of neonatal behaviors on data sheets designed for this study. In particular, we reported the behaviors described by Widström et al,⁴ as shown in Tables 1 and 2.

Contemporarily, mothers and infants were videotaped to allow subsequent reevaluation of neonatal behaviors by 2 other observers (A.C. and R.B.) so as to confute, confirm, or implement the initial examination. The video camera was directed at the upper part of the infant's body, including the face. The interobserver variability was preliminarily evaluated, and the observation congruity was found to be $>85\%$. Each observation and videotaping was discontinued when infants entered their first suckling phase or sleeping period.

We recorded the age, number of pregnancies, parity, labor duration, and need for perineal laceration repair for each mother. We recorded the following data for each infant: gestational age, birth weight, length, head circumference, Apgar score at the first and fifth minutes, arterial cord blood pH, weight loss at 24 hours of life and at discharge, need of phototherapy, and breastfeeding rate at discharge and at 1 month of life (phone interview).

For the purpose of our study, breastfeeding was defined according to the World Health Organization⁵ as "an unequalled way of providing ideal food for the healthy growth and development of infants"; exclusive breastfeeding is defined "as no other food or drink, not even water, except breast milk (including milk expressed or from a wet nurse) for 6 months of life" but allows the infant to receive vitamins, minerals, and medicines.

Statistical Analysis

Data were described by mean values and standard deviation, or rate and percentage, or median value and interquartile

Table 2. Behaviors Not Restricted to a Specific Phase, Adapted from Widström et al⁴.

Behaviors	Definition
Eyes	Closed or opened Looks mainly at mother's breast Looks mainly in the direction of the mother's face
Soliciting sounds	An affirmative, short, ringing sound
Hand-to-mouth	Hand in/or touching the mouth
Hand-breast-mouth	Infant moves hand across mother's breast and brushes the nipple/areola and brings hand to mouth
Hand-breast-massage	Infant massages the breast with the fist or open hand
Rooting	Twisting movement where face is brought across or lifted above mother's chest and turned to side or hand
Rocking/pushing	Rocking activity without shifting position

range. Although the comparison of data from different studies is not completely appropriate, we compared the behavior rate observed in our population to that of Widström et al⁴ for allowing the immediate evaluation of possible differences. We could not make a similar comparison of the timing of the appearance of each behavior phase because the previous study³ reported median values and interquartile ranges of this variable that do not permit a statistical comparison.

To assess the possible correlation between the occurrence of some behavioral phases during SSC and the suckling success rate, we compared the frequency of these phases in infants who were able to suckle at the end of SSC to that of infants who were not. The possible effects of maternal pain stimuli on the SSC behavior sequence was evaluated by comparing the frequency of each phase in infants whose mother had perineal laceration repair to that of infants whose mother had not.

Comparisons were made using Fisher's exact test for categorical variables. A $P < .05$ was considered statistically significant.

Results

We enrolled 17 mother-infant dyads whose clinical characteristics are reported in Table 3. The frequency of behavioral phases was similar to what has been previously reported,⁴ except for mouth activity in the awakening and sleeping phases after suckling, which were less frequent in our population (59% vs 100%, $P = .001$). The SSC ended with suckling in 41% of our infants.

The sequence of behavioral phases disagreed with Widstrom et al's⁴ sequence in 41% (7/17) of our newborns (Table 4). We observed that the order of cry, relaxation, and awakening phases was different. In detail, in 2 infants (12%) cry followed the relaxation phase, in 1 infant (6%) the relaxation phase followed the awakening phase. Moreover, the resting phase occurred not only after the active phase (6/17; 35%) but also after crawling (6/17; 35%) and familiarization (5/17; 29%) phases.

Although we could not make an exact statistical comparison of time of appearance of behavioral phases, we observed

Table 3. Clinical Characteristics of Mother-Infant Dyads (n = 17).

Demographic and Clinical Data	Mean ($\pm$ SD) or Proportions (%)
Mothers	
Age, y	33 $\pm$ 3
No. of pregnancies	2 $\pm$ 1
Parity	1 $\pm$ 1
Primiparae	10 (59)
Labor duration, h	3 $\pm$ 2
Infants	
Birth weight, g	3348 $\pm$ 385
Gestational age, w	39 $\pm$ 1
Head circumferences, cm	34 $\pm$ 1
Total length, cm	50 $\pm$ 1
Apgar score	
1 min	10 $\pm$ 1
5 min	10 $\pm$ 0
Arterial cord blood pH	7.29 $\pm$ 0.07

that they seem to appear at a similar time (minutes) in ours and Widstrom et al's⁴ populations, although active and sleeping phases were slightly delayed and hand-breast-mouth movement and suckling phases were slightly anticipated (Table 5). It is interesting that 76% (13/17) of our infants showed hand-breast-massage movements that Widström et al⁴ did not mention. This behavior was more common during the active and resting phases, but we observed it also during the awakening, crawling, and familiarization phases (unreported data).

The SSC ended with effective suckling in 41% (7/17) of infants at the median age of 45 minutes (interquartile range [IQR] = 39-56 minutes). The remaining infants started suckling the breast within the first 24 hours of age.

The sequence of behavioral phases was similar in infants who began suckling at the end of SSC or did not, except for the infant's hand massage of the breast, which was less frequent in the former (43% vs 100%, $P = .014$). Moreover, maternal pain stimuli did not affect the neonatal SSC behavioral sequence.

Table 4. Behavior Phase Frequency during Skin-to-Skin Contact in Our Population (n = 17) Compared to Widström et al's⁴ study (n = 28).

Behavioral Phases	Our Population Proportions (%)	Widstrom et al ⁴ Proportions (%)	P
Birth cry	17 (100)	28 (100)	N/A
Relaxation phase	13 (76)	24 (86)	.402
Awakening phase			
Head movements	17 (100)	28 (100)	N/A
Opening of the eyes	17 (100)	28 (100)	N/A
Mouth activity	10 (59)	28 (100)	<.001
Active phase	17 (100)	28 (100)	N/A
Eyes stay open ≥5 min	17 (100)	26 (93)	.519
Looks at breast	16 (94)	25 (89)	1.000
Looks at mother	14 (59)	24 (86)	1.000
Rooting	17 (100)	25 (89)	.279
Hand-to-mouth movements	17 (100)	28 (100)	N/A
Hand-breast massage	13 (76)	N/A	N/A
Soliciting	17 (100)	25 (89)	.279
Resting phase	17 (100)	25 (89)	.279
Crawling phase	16 (94)	21 (75)	.132
Familiarization phase	11 (65)	18 (64)	.618
Hand-breast-mouth movements	11 (65)	9 (32)	.062
Suckling phase	7 (41)	15 (54)	.542
Sleeping phase	10 (59)	28 (100)	<.001

Abbreviation: N/A, not applicable.

Table 5. Time of Appearance (Minutes) of Behavioral Phases during Skin-to-Skin Contact in Our Population (n = 17) Compared to Widström et al's⁴ Study (n = 28)⁴.

Behavioral Phases	Our Population Median (IQR)	Widstrom et al ⁴ Median (IQR)
Birth cry	0 (0-0)	0 (0-0)
Relaxation phase	3 (1-6)	2 (2-4)
Awakening phase		
Head movements	5 (2-7)	2.5 (1-5)
Opening of the eyes	5 (0-8.5)	3.5 (1-7)
Mouth activity	6 (2-18)	3 (2-16)
Active phase	13 (10-25)	8 (4-12)
Eyes stay open ≥5 min	7.5 (4-11)	9.5 (6-16)
Looks at breast	9.5 (6-18)	15 (0-53)
Looks at mother	13.5 (5-20)	15.5 (11.5-21.5)
Rooting	31 (18-38)	17 (12.8-23.5)
Hand-to-mouth movements	12 (5-23)	18 (9-31)
Hand-breast massage	28 (12-52)	N/A
Soliciting	8 (6-17)	23 (17.5-32.5)
Resting phase	20 (15-38)	18 (13-26.5)
Crawling phase	28.5 (21-48)	36 (18-54)
Familiarization phase	46 (24-52)	43 (29-62)
Hand-breast-mouth movements	31 (12-47)	46 (32.8-70.5)
Suckling phase	45 (39-56)	62 (43.5-90.3)
Sleeping phase	94 (78-108)	70 (52.5-79)

Abbreviation: IQR, interquartile range; N/A, not applicable.

Weight loss, need of phototherapy for jaundice, and exclusive breastfeeding were similar in infants who began suckling at the end of SSC and in those who did not. It is noteworthy that all studied infants were exclusively breastfed not only at 24 hours of life and at discharge from the hospital but also at 1 month of age.

Discussion

In this study we aimed to evaluate the infant's behavioral sequence during SSC immediately after birth to confirm what has been previously described by Widström et al⁴ and to document the possible occurrence of other behavioral phases.

Fewer of our infants were able to start suckling at the end of SSC than in the Widström et al⁴ study (41% vs 54%). This might be explained by the higher number of primiparous mothers in our population (59% vs 43%), since multiparity favors the development of maternal holding capacity,^{6,7} and a multiparous mother might spontaneously and more effectively induce her newborn to the nipple.

While the majority of our infants (59%) had the same phase sequence reported by Widström et al,⁴ a relevant percentage (41%) had a different one. We observed that some phases, such as resting, can be inserted between other phases, such as the active phase, crawling, and familiarization. This might be due to the infant's need to rest following phases of great energy expenditure. Therefore, our findings suggest that the sequence of neonatal behaviors during SSC is flexible and changes among different mother-baby dyads. It may be speculated that some infants need to repeat 1 or more phases to confirm a learned behavior or to test what is the most appropriate response to environmental and sensorial stimuli.⁸⁻¹²

The sleeping phase was less frequent in our infants than in the Swedish population,⁴ but they studied infants "from birth to first suckle or first sleeping period," and it is unclear how the sleeping phase could be observed in infants who suckled before sleeping and had their examination interrupted. However, it is interesting that, as for the resting phase, the sleeping phase was more frequent in infants who did not suckle at the end of SSC, as if they had a huge energy expenditure requiring a resting phase.

We observed a behavior never described before during SSC, namely, the infant's massage of the breast performed with the fist or open hand mainly during the active and resting phase. This massage may be very useful for breastfeeding, being a powerful stimulus for maternal oxytocin release.¹³ This behavior was more frequent in infants who did not suckle at the end of SSC, suggesting again that infants who expend more energy have less probability of ending SSC with effective breast suckling.

In our population, maternal pain (ie, secondary to perineal laceration repair) did not affect neonatal behavioral phases

during SSC. We speculated that mothers divert their attention so briefly from the infant that the mother-infant interaction is not negatively influenced.

Our findings indicate that effective suckling at the end of SSC is not related to the neonatal short-term outcome, namely, weight loss and jaundice rate of infants. On the other hand, all our infants had successful exclusive breastfeeding at discharge and at 1 month of life. This confirms that the actual importance of an immediate postpartum SSC is the SSC itself and not the infant finally achieving suckling, as underlined in step 4 of the of the revised Baby-Friendly Hospital Initiative.¹⁴ In fact, the achievement of mother-infant SSC is an accurate predictive factor of subsequent exclusive breastfeeding and a well-structured mother-infant bonding,^{1,15-20} probably because, as previously demonstrated in a randomized controlled study,³ SSC beneficially influences state organization and motor system modulation of the newborn infant shortly after delivery, increasing his or her independent self-regulation in face of the inevitable increase of extrauterine environmental stimulus. However, we believe that our results in obtaining exclusive breastfeeding data were also favored by the great attention and involvement of midwives and mothers in supporting breastfeeding that is typical of midwife-led units, such as the Margherita Birth Center.

The limitations of our study include the small size of our population, mainly due to the denied informed parental consent by those wishing to preserve the privacy of the first postpartum hours, but given the homogeneity of our population, it is unlikely that a population substructure could affect our observations; the lack of using a score for measuring maternal pain; and the need to explain many observations through rational speculation, due to lack of knowledge in this field.

Conclusion

Our study confirms that immediate and undisturbed postpartum SSC is characterized by specific behavioral phases whose sequence may vary without affecting the suckling rate and breastfeeding success. We documented a new behavior observed during SSC, namely, the infant's massage of the mother's breast. We observed that the successful suckling rate at the end of SSC is not affected by maternal pain stimuli and does not affect the neonatal short-term outcome. Our findings are consistent with the concept that the effect of SSC is not only the quick start of breastfeeding but also the widespread beneficial role in the development of adequate mother-infant bonding of which exclusive breastfeeding is one of the more evident and important expressions.

Declaration of Conflicting Interests

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