



**DRAFT STATEMENT**

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**NATIONAL INSTITUTES OF HEALTH  
CONSENSUS DEVELOPMENT CONFERENCE STATEMENT**

NIH Consensus Development Conference:

Lactose Intolerance and Health

February 22–24, 2010

*National Institutes of Health (NIH) consensus and state-of-the-science statements are prepared by independent panels of health professionals and public representatives on the basis of (1) the results of a systematic evidence review prepared under contract with the Agency for Healthcare Research and Quality (AHRQ), (2) presentations by investigators working in areas relevant to the conference questions during a 2-day public session, (3) questions and statements from conference attendees during open discussion periods that are part of the public session, and (4) closed deliberations by the panel during the remainder of the second day and the morning of the third. This statement is an independent report of the panel and is not a policy statement of NIH or the Federal Government.*

*The statement reflects the panel’s assessment of medical knowledge available at the time the statement was written. Thus, it provides a “snapshot in time” of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.*

1 **Introduction**

2

3 Lactose intolerance is the syndrome of diarrhea, abdominal pain, flatulence, and/or bloating  
4 occurring after lactose ingestion. These symptoms—produced by malabsorption of lactose, a  
5 sugar found in milk and other dairy products—often result in afflicted individuals avoiding dairy  
6 products in their diets. Lactose malabsorption occurs because of a decreased ability to digest  
7 lactose, due to a deficiency in the levels of the enzyme lactase. Lactase breaks lactose down into  
8 two simpler sugars, glucose and galactose, which are readily absorbed into the bloodstream.  
9 This enzyme is produced by expression of the lactase-phlorizin hydrolase gene in the cells lining  
10 the small intestine.

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1 Infants of every racial and ethnic group worldwide produce lactase and successfully digest  
2 lactose provided by human milk or by infant formulas. However, sometime after weaning, in the  
3 majority of the world's children, there is a genetically programmed decrease in lactase (lactase  
4 nonpersisters). Many affected individuals in the United States belong to diverse populations,  
5 especially Asians, African Americans, Hispanics, Native Americans, Alaska Natives, and Pacific  
6 Islanders.

7

8 The symptoms of lactose intolerance result from bacterial fermentation of undigested lactose in  
9 the colon. Lactose malabsorption can be diagnosed by having individuals ingest a standard dose  
10 of lactose after fasting and finding elevated levels of breath hydrogen, which is produced by  
11 bacterial fermentation of undigested lactose in the colon. Other diagnostic tools include  
12 measuring the lactase activity in an intestinal biopsy sample or genetic testing for the common  
13 mutation that is linked to lactase nonpersistence. The demonstration of lactose malabsorption  
14 does not necessarily indicate that an individual will be symptomatic. Many variables determine  
15 whether a person who malabsorbs lactose develops symptoms, including the dose of lactose  
16 ingested, the residual intestinal lactase activity, the ingestion of food along with lactose, the  
17 ability of the colonic flora to ferment lactose, and individual sensitivity to the products of lactose  
18 fermentation.

19

20 Current management often relies on reducing lactose exposure by avoiding milk and milk-  
21 containing products or by drinking milk in which the lactose has been prehydrolyzed with  
22 lactase. Alternatively, lactase nonpersisters may tolerate moderate amounts of dairy products  
23 ingested with other foods. However, many individuals mistakenly ascribe symptoms of a variety

1 of intestinal disorders to lactose intolerance without undergoing testing. This becomes  
2 intergenerational when parents with self-diagnosed lactose intolerance place their children on  
3 lactose-restricted diets (even in the absence of symptoms) in the mistaken belief that they will  
4 develop symptoms if given lactose.

5

6 The public health burden from deficiencies attributable to lactose intolerance has not been  
7 established. However, many adults and children who avoid dairy products—which constitute a  
8 readily accessible source of calcium, vitamin D, and other nutrients—are not ingesting adequate  
9 amounts of these essential nutrients. For example, most African American adolescents consume  
10 inadequate amounts of calcium and vitamin D because they avoid dairy products. Deficient  
11 intakes of calcium and vitamin D are risk factors for decreased bone mineral density. This may  
12 increase the risk of fracture throughout the life cycle, especially in postmenopausal women.

13 Very low intake of vitamin D can lead to the development of rickets, especially in children of  
14 African descent and other highly pigmented individuals. Although milk alternative products are  
15 typically fortified with vitamin D and other nutrients, they may be more expensive and less  
16 widely available than conventional products. The bioequivalence of these and other calcium  
17 supplements is uncertain.

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19 To examine this important topic more closely, the *Eunice Kennedy Shriver* National Institute of  
20 Child Health and Human Development and the Office of Medical Applications of Research of  
21 the National Institutes of Health convened a Consensus Development Conference to assess the  
22 available scientific evidence related to the following questions:

23

- 1           • What is the prevalence of lactose intolerance, and how does this prevalence differ by  
2           race, ethnicity, and age?
- 3
- 4           • What are the health outcomes of dairy exclusion diets?
- 5
- 6           • What amount of daily lactose intake is tolerable in subjects with diagnosed lactose  
7           intolerance?
- 8
- 9           • What strategies are effective in managing individuals with diagnosed lactose  
10          intolerance?
- 11
- 12          • What are the future research needs for understanding and managing lactose  
13          intolerance?

14

15   At the conference, invited experts presented information relevant to these questions. A  
16   systematic evidence review, prepared under contract with the Agency for Healthcare Research  
17   and Quality, was summarized; the systematic evidence review (available at  
18   <http://www.ahrq.gov/clinic/tp/lactinttp.htm>) emphasizes randomized controlled trials with health  
19   outcomes as their endpoints. Conference participants also provided oral and written comments  
20   in response to the conference questions, and the panel considered all of this evidence when  
21   preparing the consensus statement.

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1 **1. What is the prevalence of lactose intolerance, and how does this prevalence differ by**  
2 **race, ethnicity, and age?**

3  
4 The prevalence of lactose intolerance is difficult to discern because studies have varied in their  
5 interpretation of what constitutes this condition. To estimate reliably the prevalence of lactose  
6 intolerance, one first must define lactose intolerance to permit the identification of those  
7 individuals with the condition and the exclusion of those without the condition. By applying this  
8 case definition to a representative population sample, one can then estimate the prevalence in the  
9 general population and assess how this prevalence differs by age and ethnicity. We define  
10 lactose intolerance as the onset of gastrointestinal symptoms following a blinded, single-dose  
11 challenge of ingested lactose by an individual with lactose malabsorption, which are not  
12 observed when the person ingests an indistinguishable placebo. Although lactose malabsorption  
13 and lactase nonpersistence can be easily identified, they are not equivalent to lactose intolerance.

14  
15 The prevalence of lactose intolerance in the United States cannot be estimated, despite a  
16 systematic evidence review that identified 57 articles, including 15 studies in the United States  
17 with a total of 4,817 participants. None of the studies used this definition or evaluated a  
18 representative sample of the U.S. population. Seven studies that assessed self-reported lactose  
19 intolerance provide limited insight because the self-diagnoses were not confirmed by testing for  
20 lactose malabsorption, and the symptoms seen in true lactose intolerance may result from several  
21 other conditions such as irritable bowel syndrome. Nine studies evaluated only the genetic  
22 predisposition to lower than expected levels of lactase in adults (lactase nonpersistence) without

1 assessing lactose malabsorption or intolerance directly. Five studies reported decreased  
2 intestinal tissue lactase activity, and 31 studies addressed lactose malabsorption directly (as  
3 evidenced by a positive hydrogen breath test after ingestion of lactose).

4  
5 Although these studies shed some light on the epidemiology of lactose intolerance (discussed  
6 below), they cannot be used to estimate the prevalence of lactose intolerance. Many individuals  
7 who have the biologic underpinnings for lactose malabsorption (low lactase levels or a genetic  
8 profile associated with low lactase) or who have demonstrated lactose malabsorption do not  
9 experience the onset or the increase in severity of gastrointestinal symptoms following a blinded  
10 lactose challenge. Complicating this further, evidence demonstrates that many who self-report  
11 lactose intolerance show no evidence of lactose malabsorption. Thus, the cause of their  
12 gastrointestinal symptoms is unlikely to be related to lactose.

13  
14 Despite the limitations in the available studies discussed above, several trends are noteworthy  
15 across the studies regarding lactose intolerance, lactose malabsorption, lactase nonpersistence,  
16 age, and ethnicity. First, lactose intolerance determined by self-report or nonblinded lactose  
17 challenge is less frequent across all ethnic groups than is lactose malabsorption determined by  
18 breath hydrogen tests or lactase nonpersistence determined by biopsy or genetic testing. Second,  
19 lactose intolerance, lactose malabsorption, and lactase nonpersistence vary across racial and  
20 ethnic groups with the lowest reported occurrence in European Americans and the higher  
21 although variable occurrence in African Americans, Hispanic Americans, Asian Americans, and  
22 Native Americans. The systematic evidence review notes that the racial and ethnic variability in  
23 lactose intolerance following nonblinded lactose challenge was not as extreme as that reported in

1 lactose malabsorption and lactase nonpersistence. Third, lactose intolerance with nonblinded  
2 lactose challenge and lactose malabsorption was low in young children, but increased with age.  
3 In children younger than 6 years, lactose malabsorption was low in all the studies and peaked  
4 between ages 10 and 16 years. Little evidence suggests that lactose intolerance increases in  
5 older persons. These trends need to be verified in representative population studies using the  
6 case definition of lactose intolerance.

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## 8 **2. What are the health outcomes of dairy exclusion diets?**

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10 The health outcomes of dairy exclusion diets depend on whether other sources of nutrients, such  
11 as calcium and vitamin D, occur in the diet in sufficient quantities to replace dairy products as a  
12 source of these nutrients, and to what extent other components of milk are beneficial.

13

14 Calcium is necessary for normal growth and bone development as well as subsequent  
15 maintenance of bone density. The strongest argument for promotion of dairy ingestion is the  
16 beneficial effect of calcium (and fortified vitamin D in milk) on growth and development of the  
17 skeleton. Calcium is necessary for adequate bone accretion and optimal peak bone mass, which  
18 is a major determinant of risk for osteoporosis and fragility fractures later in adult life. Evidence  
19 suggests that certain age groups, such as children and teenagers, may be at increased risk for  
20 deficient bone acquisition if their diets are deficient in calcium or vitamin D. There is weak  
21 evidence that children with diets deficient in calcium have increased fracture rates. The maximal  
22 accumulation of bone mineral, and therefore the maximal calcium requirement, occurs during

1 puberty. Although studies indicate that young children who drink milk are likely to meet or  
2 exceed the adequate intake for calcium, teenagers, as a group, tend not to take in enough calcium  
3 to meet recommended needs. This is exacerbated by dairy avoidance in individuals who  
4 consider themselves to be lactose intolerant, regardless of whether they have undergone  
5 objective testing for lactose intolerance.

6

7 Studies have demonstrated that the presence of lactose does not affect the efficiency of calcium  
8 absorption across the intestine, and that lactase nonpersisters do not have significant impairment  
9 in calcium absorption. Thus, the limiting factor in achieving optimal peak bone mass in young  
10 individuals is the intake of calcium. Similarly, in older individuals, low calcium intake rather  
11 than absorption efficiency appears to be a major factor contributing to loss of bone mass.

12 Replacement of calcium using supplements or dairy products slows the rate of bone loss in older  
13 people, possibly as a result of an overall decrease in bone turnover. Across the age spectrum, the  
14 factor limiting adequate calcium accrual in many individuals appears to be dairy avoidance.

15

16 Dairy exclusion diets may exacerbate the risk for osteoporosis for those already at greatest risk.

17 These include women throughout the life cycle and certain racial/ethnic groups. Despite low

18 calcium intake, the majority of studies including African Americans indicate that osteoporosis is

19 less prevalent in this group. However, low intake of dairy foods may place African Americans at

20 risk for deficiencies of other necessary nutrients for bone health such as vitamin D, in addition to

21 low calcium intake. Individuals with diseases that result in decreased calcium absorption due to

22 intestinal inflammation (inflammatory bowel disease) or that require the use of corticosteroids

23 (which in themselves directly reduce bone mass) have increased risk of osteoporosis.

1  
2 Dairy exclusion diets may decrease gastrointestinal symptoms (bloating, cramps, and diarrhea)  
3 in symptomatic individuals who have lactose malabsorption or lactose intolerance. The degree  
4 of relief is likely related to the level of expression of lactase, and the quantity of lactose ingested.  
5 People who remain symptomatic on a dairy exclusion diet may have other causes for their  
6 gastrointestinal symptoms, such as irritable bowel syndrome, celiac disease, inflammatory bowel  
7 disease, or small bowel bacterial overgrowth as an underlying cause.

8  
9 Dairy exclusion diets may affect other health outcomes. In several studies, individuals taking  
10 calcium supplements or increased dairy intake have decreased blood pressure in several studies.  
11 Calcium supplementation has been suggested to improve cardiac and vascular smooth muscle  
12 contractility; however, additional research is needed to clarify whether this has a significant  
13 impact on cardiovascular risk. Calcium ingestion has been associated with decreased risk of  
14 development of adenomatous colon polyps. It is not known whether this translates into  
15 decreased rates of colon cancer. One area of recent interest is the effect of lactose ingestion on  
16 colonic bacterial populations, as this may increase production of fatty acids such as butyrate,  
17 which may promote mucosal growth and reduce inflammation.

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19 **3. What amount of daily lactose intake is tolerable in subjects with diagnosed**  
20 **lactose intolerance?**

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1 Among individuals appropriately diagnosed with lactose intolerance, differences in a variety of  
2 factors—including lactase activity, gastric emptying rates, fecal bacterial metabolites, colonic  
3 mucosal absorptive capacity, and intestinal transit time—can greatly influence their  
4 susceptibility to develop intolerance symptoms following the ingestion of foods and beverages  
5 containing lactose. Individuals differ in the intensity of symptoms of lactose intolerance due to  
6 differences in abdominal pain perception and psychological impact of pain and social  
7 discomfort. Determining the amounts of lactose that can be tolerated is an important step in  
8 developing evidenced-based dietary recommendations that meet the needs of the individual.

9  
10 High-quality evidence to address the question is limited as documented by the 28 studies  
11 summarized in the systematic evidence review. Studies were variable in terms of the definitions  
12 of lactose intolerance, study population selection criteria, how lactose was administered, and the  
13 type of assessment methods. The lack of validated measures made quantifying the severity of  
14 symptoms difficult to interpret. The majority of studies used a single dose of lactose without  
15 food and evaluated short-term responses. Efforts often were not made to mask the taste  
16 difference between lactose-free milk and milk lactose containing lactose.

17  
18 To assess tolerability, only a handful of studies tested the subjects in a double-blinded fashion  
19 with increasing amounts of lactose administered throughout the day to determine the daily  
20 tolerable load of lactose. Furthermore, the majority of studies consisted of small numbers of  
21 subjects, and no data were reported on the relationships of age, sex, or race/ethnicity. No studies  
22 focused exclusively on children; two studies examined adolescents exclusively; and two others

1 included both children and adolescents. Only two studies were conducted on pregnant women;  
2 none focused on lactating women.

3  
4 In the majority of available studies, subjects were classified as malabsorbers or absorbers based  
5 on breath hydrogen measurements or a blood glucose test, and symptoms of lactose intolerance  
6 were not always required for study entry. A blinded control was rarely employed to define  
7 lactose intolerance at study entry, thus it is probable that some subjects would have reported  
8 symptoms following ingestion of lactose-free solutions. Thus, the majority of studies  
9 investigated subjects with proven lactose malabsorption, not diagnosed lactose intolerance. As a  
10 result, only recommendations for individuals with proven lactose malabsorption and perceived  
11 lactose intolerance can be made with reasonable assurance.

12  
13 The available evidence suggests that adults and adolescents who have been diagnosed with  
14 lactose malabsorption could ingest at least 12 grams of lactose (equivalent to the lactose content  
15 found in 1 cup of milk or 1 cup of yogurt) with no or minor symptoms. Individuals with lactose  
16 malabsorption can tolerate larger amounts of lactose if ingested with meals and distributed  
17 throughout the day. However, 50 grams of lactose (equivalent to the lactose content found in 1  
18 quart of milk) usually induces symptoms in those adults with lactose malabsorption when  
19 administered as a single dose without meals. For women with lactose malabsorption, tolerance  
20 to dietary lactose may improve during pregnancy but then worsen after delivery. Some data  
21 support that the routine ingestion of lactose increases the amount of lactose that is tolerable in  
22 both adults and adolescents. There is no scientific evidence to identify the tolerable dose of  
23 lactose for children with lactose malabsorption.

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The panel stresses the importance of additional scientific investigations to provide evidence-based and culturally sensitive recommendations about the amount of daily lactose intake that can be tolerated by lactose intolerant individuals, with special emphasis on pediatric and adolescent populations and pregnant and lactating women.

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**4. What strategies are effective in managing individuals with diagnosed lactose intolerance?**

The available studies on interventions in individuals with lactose intolerance—such as reduced lactose dairy products, probiotics, and colonic adaptation—appear to have significant limitations that preclude a definitive recommendation as to their effectiveness. There is a need for well-designed, controlled studies on potential therapeutic interventions with well-defined populations, blinding of observers and subjects, adequate control populations, an adequate period of symptom observation, and sufficient power for outcomes of interest.

It is important to distinguish lactose intolerance from other etiologies of gastrointestinal symptoms. Outcomes will be optimized by targeting the specific underlying condition. In addition, making this distinction will help avoid unnecessary food group restriction. It is unknown whether individuals who have self-diagnosed lactose intolerance will accept interventions that ask them to consume a food they believe leads to side effects. Education

1 regarding lactose intolerance and appropriate evaluation of gastrointestinal symptoms may be the  
2 most productive therapeutic approach in these individuals.

3  
4 Even in persons diagnosed with lactose intolerance, small amounts of milk, yogurt, aged cheeses,  
5 and lactase-treated foods may be effective approaches. The limited data available suggest that  
6 individuals with lactose intolerance can ingest 12 grams of lactose (the equivalent of one glass of  
7 milk) without significant symptoms, particularly if ingested with other foods. Lactase-treated  
8 products also have a fair amount of evidence suggesting they are tolerated better than  
9 nontreated products.

10  
11 It remains to be determined whether individuals with lactose intolerance have any nutritional  
12 deficiencies or long-term clinical sequelae, although skeletal health remains a concern.

13 Although dairy foods are an excellent source of calcium, vitamin D, protein, magnesium,  
14 potassium, riboflavin, and other nutrients, these individual nutrients are available in other foods,  
15 fortified foods, and supplements. However, data also are lacking on the effects of interventions  
16 designed to increase dairy intake versus counseling affected individuals on ways to meet nutrient  
17 requirements from other sources. An overall nutritional eating plan should be emphasized,  
18 focusing on nutrients potentially reduced by a dairy-free diet while maintaining appropriate  
19 caloric intake. An excellent source of overall nutritional guidance as well as nondairy dietary  
20 sources of calcium—such as calcium-fortified soy or rice drinks, fruit juices, soy products, dried  
21 beans, and leafy greens—can be found at [www.mypyramid.gov](http://www.mypyramid.gov). The following table could be  
22 used as a reference for individuals who wish to meet the daily requirements of calcium.

23

1 **Table 1: Daily requirements of calcium by age and comparative serving equivalents of**  
 2 **common dairy sources.**  
 3

		<b>Low-fat milk</b>	<b>Low-fat plain yogurt</b>	<b>Low-fat hard cheeses (cheddar, provolone, mozzarella, etc.)</b>
		<b>Per cup</b>	<b>Per cup</b>	<b>Per 1.5 oz</b>
<b>Energy (kcal)</b>		102	148	93
<b>Lactose (g)</b>		11-13	11-17 <sup>1</sup>	0.3-1
<b>Calcium (mg)</b>		305	332	301
<b>Calcium/lactose ratio (mg/g)</b>		23-28	20-30	301-1003
<b>Age (yr)</b>	<b>Calcium Needed (AI;<sup>2</sup> mg/d)</b>	<b>Amount Needed to Provide AI<sup>2</sup> for Calcium</b>		
1-3	500	1.6 cups	1.5 cups	2.5 oz
4-8	800	2.5 cups	2.4 cups	4.0 oz
9-18	1,300	4.3 cups	3.9 cups	6.5 oz
19-50	1,000	3.3 cups	3.0 cups	5.0 oz
51+	1,200	3.9 cups	3.5 cups	6.0 oz

4  
 5 <sup>1</sup> Despite the high lactose content, low-fat plain yogurt is generally much better tolerated than  
 6 low-fat milk by individuals with lactose malabsorption.  
 7

8 <sup>2</sup> The adequate intake (AI) for calcium is based on 1997 Institute of Medicine Daily  
 9 Recommended Intakes.  
 10

11 Note: AI for pregnancy and lactation remains the same.  
 12

13 Data are lacking on other proposed interventions, but some strategies—such as colonic  
 14 adaptation where lactose intake is gradually increased over time—do have intriguing preliminary  
 15 data and may be helpful in some individuals. Although researchers continue to investigate the  
 16 various treatment strategies, individual treatment approaches can be developed both for lactose  
 17 intolerant individuals and for those who avoid dairy foods for other reasons. Individualized  
 18 strategies could combine inclusion of small amounts of dairy foods and lactase-treated products  
 19 and could provide suggestions for alternate nutrient sources, emphasizing the approaches and  
 20 food items that are acceptable to each individual. The goals of treatment should be to ensure  
 21 adequate intake of nutrients important for skeletal health and other clinical outcomes. There are

1 likely stages of the life cycle when meeting these goals is particularly critical for bone accrual  
2 and maintenance, such as during adolescence, pregnancy and lactation, and older age.

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4 **5. What are the future needs for understanding and managing lactose intolerance?**

5

6 Reliable estimates of the U.S. prevalence of lactose intolerance and lactose malabsorption are  
7 not available in a representative population of diverse ages and ethnicity. Most of the available  
8 research assessed subjective symptoms in an unblinded fashion from selective groups of subjects  
9 or from individuals unable to fully absorb lactose irrespective of symptoms of lactase  
10 nonpersistence. Therefore, we recommend that a study be conducted to determine the  
11 prevalence of lactose intolerance in the U.S. population and the differences across age and  
12 ethnicity groups. Such a study needs to examine a representative sample of the U.S. population  
13 and determine:

14

15 • The prevalence of self-reported baseline symptoms

16

17 • The prevalence of lactose malabsorption with or without symptoms following a blinded  
18 lactose challenge

19

20 • The relationship between self-reported symptoms and the presence of lactose  
21 malabsorption

22

- 1 • The prevalence of lactose intolerance in those individuals with lactose malabsorption  
2 based on the blinded challenge.

3  
4 The best approach to minimize placebo effects would be to conduct blinded challenges using a  
5 standardized, taste-masked dose with and without lactose and to define symptoms using a well-  
6 validated scoring system. Additional studies on what constitutes an optimal challenge dose of  
7 lactose should also be conducted. Dietary history regarding lactose consumption and symptoms  
8 associated with mutations in the lactase gene potentially could obviate the need for taste-masked,  
9 blinded oral challenges with lactose and placebo. An opportunity exists to use the infrastructure  
10 of the ongoing National Health and Nutrition Examination Survey (NHANES) or other ongoing  
11 nationally representative studies, which already are collecting dietary intake data and would  
12 allow additional and potentially informative evaluation of the intake of lactose-containing foods  
13 in those with rigorously determined lactose malabsorption with or without symptoms.

14  
15 Despite the widespread belief that decreased vitamin D and calcium intake associated with  
16 restricted intake of dairy products will lead to poor health outcomes, particularly related to bone  
17 mineral density and risk for fractures, few data are available on bone health in individuals with  
18 lactose intolerance and dairy avoidance. Future studies should investigate the association  
19 between dietary calcium intake and outcomes in people with lactose intolerance on low-lactose  
20 diets. A diverse population should be evaluated, including children, the elderly, males and  
21 females, members of ethnic/racial subgroups, and those with susceptible genetic polymorphisms.  
22 The latter genetic alterations should include not only alterations in the gene encoding lactase but  
23 also potential modifying genes.

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The efficacy of dietary calcium intake from nondairy products and from nutritional supplements should be examined in relation to bone health and as to whether other foods influence calcium absorption from these sources. Studies should be done to determine if there is an optimal period during childhood and adolescence when adequate intake of calcium is crucial to ensure lifetime bone health. Other health outcomes including obesity, diabetes, cardiovascular disease, and cancer also should be assessed in individuals with treated and untreated lactose intolerance and in other subjects avoiding milk products because of perceived lactose intolerance in comparison with the general population. Additional issues of importance need to be addressed in children with lactose intolerance through long-term observational studies and randomized controlled clinical trials of various treatment strategies. These issues include the incidence of infection, allergic disease, and standard measures of growth and development.

Data are lacking as to whether individuals of different race/ethnicity, age, and gender who have lactose malabsorption have differing tolerance to lactose. Blinded, randomized controlled trials are needed to determine if the quantity of lactose that can be tolerated by lactose intolerant individuals varies by these characteristics. Symptoms should be reported in a standardized, validated format so that clinically significant as well as statistically significant differences can be appreciated.

The lack of uniformity in study design and methodology hampers a rational, evidence-based approach to management of lactose intolerance. Defining the tolerable dose of lactose in those with lactose malabsorption is critical to determining the clinical importance of lactose

1 malabsorption and the prevalence of lactose intolerance, and it may provide critical information  
2 for management. A stepwise approach should be developed to define the specific amount of  
3 dairy foods to introduce to the individual with lactose intolerance (i.e., the least amount of  
4 lactose that is associated with symptoms). Studies also should be conducted to confirm whether  
5 lactose is better tolerated if distributed throughout the day or given with meals. The use of  
6 lactase or lactose-hydrolyzed milk may be of moderate value in reducing symptoms; however,  
7 sample sizes and the reporting of symptoms were so variable in reported studies that making firm  
8 recommendations is difficult. The use of prebiotics and probiotics including yogurt is a popular  
9 intervention for individuals with lactose intolerance, but further studies are needed to document  
10 the efficacy of such products in reducing symptoms and providing adequate amounts of calcium  
11 and vitamin D. Dietary calcium intake from low-lactose dairy products, nondairy products, and  
12 nutritional supplements are an alternative management strategy in individuals with lactose  
13 intolerance, but few data are available on the effect of such interventions on patient outcomes,  
14 including bone mineral content and fractures.

15  
16 It will be important to determine whether testing for lactose malabsorption will change the  
17 behavior of individuals who are avoiding dairy products, many of whom may not have lactose  
18 intolerance. Future research should employ standardized interventions, blinded controls, and  
19 reporting of improvement of symptoms in a consistent, validated fashion to compare the efficacy  
20 of these dietary management strategies in obtaining good health outcomes.

21  
22 Once effective interventions have been identified, behavioral and culturally sensitive approaches  
23 to convince people to adopt recommended dietary changes should be developed and tested.

1 Clearly, the perception of symptoms in individuals with lactose intolerance may be highly  
2 subjective and very susceptible to a number of psychological factors. Thus, various strategies  
3 may result in very different behavioral change, and their effectiveness should be compared  
4 rigorously.

5  
6 Additional work needs to be done to improve the management of patients with irritable bowel  
7 syndrome and a hypersensitive colon who also may have lactose intolerance.

## 8 9 **Conclusions**

10

- 11 • Lactose intolerance is a real and important clinical syndrome, but its true prevalence  
12 is not known.
- 13
- 14 • The majority of people with lactose malabsorption do not have clinical lactose  
15 intolerance. Many individuals who think they are lactose intolerant are not lactose  
16 malabsorbers.
- 17
- 18 • Many individuals with real or perceived lactose intolerance avoid dairy and ingest  
19 inadequate amounts of calcium and vitamin D, which may predispose them to  
20 decreased bone accrual, osteoporosis, and other adverse health outcomes. In most  
21 cases, individuals do not need to eliminate dairy consumption completely.

22

- 1           • Evidence-based dietary and supplementation approaches are needed to ensure  
2           appropriate consumption of calcium and other nutrients in lactose intolerant  
3           individuals.
- 4
- 5           • Educational programs and behavioral approaches for individuals and their health care  
6           providers should be developed and validated to improve the nutrition and symptoms  
7           of individuals with lactose intolerance and dairy avoidance.

## **Consensus Development Panel**

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