Unpasteurized Milk: A Continued Public Health Threat

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Although milk and dairy products are important components of a healthy diet, if consumed unpasteurized, they also can present a health hazard due to possible contamination with pathogenic bacteria. These bacteria can originate even from clinically healthy animals from which milk is derived or from environmental contamination occurring during collection and storage of milk. The decreased frequency of bovine carriage of certain zoonotic pathogens and improved milking hygiene have contributed considerably to decreased contamination of milk but have not, and cannot, fully eliminate the risk of milkborne disease. Pasteurization is the most effective method of enhancing the microbiological safety of milk. The consumption of milk that is not pasteurized increases the risk of contracting disease from a foodstuff that is otherwise very nutritious and healthy. Despite concerns to the contrary, pasteurization does not change the nutritional value of milk. Understanding the science behind this controversial and highly debated topic will provide public health care workers the information needed to discern fact from fiction and will provide a tool to enhance communication with clients in an effort to reduce the incidence of infections associated with the consumption of unpasteurized milk and dairy products.

Food available in the United States is plentiful, inexpensive, and, for the most part, safe. Advances in animal production, food processing and hygiene, and refrigeration have eliminated several foodborne diseases that plagued Americans in the past century. However, in the past 30 years, several previously unrecognized foodborne bacterial infections, including infection with Campylobacter jejuni, Listeria monocytogenes, and Escherichia coli strain O157, have emerged as significant causes of human morbidity and mortality. Other infectious diseases once believed to be controlled have started to reappear. It is estimated that, each year, 76 million Americans become ill from eating contaminated food [1].

Milk and other dairy products, primarily from cows but also less frequently from goats and sheep, are important components of the American diet. The US Department of Agriculture recommends that people consume 2–3 servings of dairy products daily. Inclusion of these products in the diet aids in the prevention of certain diseases, such as obesity, hypertension, and diabetes, and they are a source of calcium—important for growing bones and the prevention of osteoporosis [2]. In addition, dairy products also provide dietary sources of protein, vitamins, and other minerals [3]. Notwithstanding the benefits, there are some individuals who believe that milk is inappropriate for inclusion in the human diet [4]. Moreover, it has long been recognized that milk is a vehicle for the transmission of numerous bacteria of both human and animal origin. Milk can be contaminated at any stage in the production-to-consumption continuum.

THE ORIGIN OF MILK CONTamination

Commensal microflora. Typically, unless there is an intramammary infection or an animal has a systemic disease, milk in the mammary gland at the site of its production does not contain bacteria. However, as milk is excreted, it can become contaminated with bacteria that live as commensal microflora on the teat skin or on the epithelial lining of the teat canal, the duct that conveys the milk from the mammary gland to the teat orifice. In cattle, bacteria of the genera Staphylococcus, Streptococcus, Bacillus, Micrococcus, and Corynebacterium and, occasionally, coliforms colonize this location [5]. Thus, even in a healthy animal, by the time the milk leaves the animal, it may contain numerous bacterial contaminants.

Mastitis. The single disease that has the most significant impact on milk quality is mastitis, the inflammation of the
mammary gland. On the basis of bovine milk samples submitted to diagnostic laboratories during a period of several years in New York and Pennsylvania (1991–1995) and Wisconsin (1994–2001), the prevalence of intramammary infections was ∼50% [6, 7]. Staphylococcus and Streptococcus species were the most commonly isolated bacteria from bovine milk in these studies; ∼20% of the samples contained organisms of either group. The milk produced by animals with subclinical mastitis is not noticeably different from the milk produced by uninfected animals and frequently is added to the collection or storage tank on a farm. Milk from cows with clinical mastitis, however, typically has a changed appearance (i.e., it may contain flakes, clots, or blood or may have changed color) and is withheld from human consumption.

Other diseases and environmental contamination. Systemic disease can also result in localization of pathogens in the mammary gland or associated lymph nodes and consequent excretion of pathogens in milk. Bovine tuberculosis and brucellosis are classic examples of zoonotic milkborne diseases. The contribution of cattle to the epidemiology of these 2 diseases in humans was so important that enormous efforts were made to eradicate these infections among cattle in the United States. The programs have largely been successful, and Mycobacterium bovis and Brucella abortus are seldom found in domestic US cattle [8].

In contrast to M. bovis and B. abortus, several other organisms are commonly found today in the milk of asymptomatic US cattle and goats or contaminate milk from environmental sources. These include Coxiella burnetii; Listeria species; Mycobacterium avium subspecies paratuberculosis; Campylobacter species; coliforms, including E. coli; and Salmonella enterica [9–14]. Cattle can be a major reservoir of these organisms and still remain clinically healthy and maintain near-optimal milk production. For example, C. burnetii, the causal agent of Q fever, is not an important cause of clinical disease in cattle; however, its prevalence in pooled milk collected on farms in the United States was reported to be 94%, on the basis of PCR assays [15]. Similarly, a US Department of Agriculture 2007 dairy study estimated that at least 68% of all US dairy herds are infected with M. avium subspecies paratuberculosis, the causal agent of Johne disease, a chronic, progressive gastrointestinal disease of ruminants [16]. Although the association between M. avium subspecies paratuberculosis and Crohn disease, a similar condition of humans, is debated, the zoonotic potential exists [17–19].

The dairy farm environment is an important reservoir for many foodborne pathogens [20]. The frequency of contamination in pooled farm milk has been reported to be <1% to 8.9% for Salmonella species, 2.7% to 6.5% for L. monocytogenes, <1% to 3.8% for Shiga toxin–producing E. coli, <1% to 12.3% for C. jejuni, and 1.2% to 6.1% for Yersinia enterocolitica [21–24].

Moreover, the rich nutrient composition and neutral pH make milk a good vehicle for the survival and growth of bacteria. Generally speaking, if milk is maintained properly chilled, bacterial proliferation, with the exception of that of psychrotrophic organisms such as Listeria species, can be suppressed. Unfortunately, prevention of proliferation is not sufficient to ensure milk safety—even low numbers of contaminating pathogens may be adequate to result in human illness. Thus, simple survival of pathogens in milk is of major concern. Ultimately, the nature and complex interaction among microflora initially present in milk dictate how well pathogens will survive in milk [25–28].

In summary, there are 2 primary factors that contribute to the microbiological quality of milk: the inclusion of organisms in excreted milk (preharvest) and the contamination of milk at the time of collection, processing, distribution, and storage (postharvest). If pathogenic bacteria are among the contaminants, the product will pose a food safety threat. Several approaches have been used to minimize the possibility that milk contaminated with pathogenic organisms will reach the consumer. These include enhanced animal health, improved milking hygiene, and pasteurization.

CONTAMINATION CONTROL STRATEGIES
An overwhelming majority of dairy producers feel responsible for the safety and wholesomeness of the food products that leave their farms [29]. Good animal health and hygienic conditions on the farm are important for the welfare of the animals and the profitability of the producers, as well as for the quality and wholesomeness of the raw food products leaving the farms for human consumption. Nevertheless, many dairy producers are unaware of the zoonotic potential of the most common bacterial contaminants in milk. In a recent mail-based survey of 461 Ohio dairy farm respondents, 36% did not think Salmonella species caused disease in humans. Likewise, 81%, 88%, and 91% of farmers indicated that Listeria, Cryptosporidium, and Campylobacter species, respectively, were not associated with disease in humans (J.T.L., unpublished data).

Enhanced animal health. Over the past 100 years, veterinary care and diagnostic tests have improved, and many zoonotic diseases have been eliminated from the population of food-producing animals in industrialized nations. On the other hand, as mentioned above, there are a number of infections that may be present in animals and remain completely asymptomatic yet have serious public health implications.

Improved milking hygiene. Complete control of microbiological hazards (i.e., zoonotic pathogens) is challenging, if not impossible, in the dairy farm environment, because these organisms may have multiple reservoirs; they do not always
produce identifiable disease; their transmission pathways are incompletely known; and cost-efficient, sensitive diagnostic tests are not available. Dairy product food safety, however, can be enhanced by implementing excellent hygienic standards for housing and milking centers and cow cleanliness and through uniform adoption of milking practices that reduce contamination of milk [30].

**Pasteurization.** Because of the above-mentioned challenges related to preharvest eradication of pathogens and the ineffectiveness of environmental hygiene screening to adequately control microbial risks in milk, pasteurization has become the cornerstone of milk safety. Pasteurization is the process of heating milk for a predetermined time at a predetermined temperature to destroy pathogens (table 1). The current guidelines for temperature and time combinations for pasteurization are based on the ability of the process to destroy *C. burnetii*. The thermal destruction process is logarithmic, and bacteria are killed at a rate that is proportional to the number of bacteria present. Pasteurization improves the safety and lengthens the shelf life of a product by destroying pathogenic and spoilage organisms; however, it is not the same as sterilization.

**GUIDELINES, REGULATIONS, AND LAWS RELATED TO MILK SAFETY AND PASTEURIZATION**

In the United States, the US Food and Drug Administration (FDA), under the Department of Health and Human Services, is responsible for providing oversight of quality standards for dairy products and dairy processing. The milk sanitation program of the US Public Health Service is one of its oldest activities. In 1924, the US Public Health Service developed a model regulation known as the “Standard Milk Ordinance” for voluntary adoption by state and local milk-control agencies [31]. This regulation, known today as the “Grade ‘A’ Pasteurized Milk Ordinance” (PMO) was developed and is periodically reviewed and modified in cooperation with state and local governments, the dairy industry, and educational and research institutions. All 50 states have voluntarily adopted the PMO guidelines. These guidelines provide guidance pertaining to all aspects of production, handling, transportation, processing, testing, and sale of milk. The guidelines are expected to minimize microbial contamination of milk and relate to areas such as cow housing, milking barn hygiene, water supply, and sanitation methods. In addition, the PMO establishes maximum allowable bacterial limits in raw milk destined for pasteurization, as well as in pasteurized milk. The federal government and FDA, however, have no jurisdiction in the enforcement of milk sanitation standards within state borders, and individual states can establish regulations concerning adoption of specific PMO recommendations and can decide on the rules regarding the sale of unpasteurized milk within state borders. In 1987, the FDA prohibited the interstate shipment of raw milk for human consumption.

In 2006, the sale of raw milk was illegal in 26 states [32]. In states where raw milk sales are not allowed, various schemes have been developed to make raw milk available to the consumer. The marketing strategies designed to circumvent current laws include selling raw milk labeled as “animal or pet food” across state lines, publishing list of states where the sale of raw milk is allowed, and selling “shares” in cows or “leasing” cows. In buying shares of cows or leasing cows, consumers pay for the upkeep, care, and milking of their cows (or portion thereof) and, in return, receive raw milk from “their” animals, avoiding the buying and selling of raw milk per se. In the states where raw milk sales are legal, regulations vary—in some states, the sale of raw milk is allowed in retail outlets, whereas, in others, it is restricted to on-farm sales directly to consumers, and the volume of salable milk may be limited.

**TRENDS IN CONSUMPTION OF RAW MILK AND IN MILKBORNE DISEASES IN THE UNITED STATES**

Consumption of raw milk has always been common among farm families, currently varying from 35% to 60% [21, 22, 24]. Most farm families report taste and convenience as the main reasons for raw milk consumption [24]. A small portion of the general US population also consumes raw milk. According to the US Centers for Disease Control and Prevention’s FoodNet Population Survey in 2002, 3.5% of respondents reported to have consumed unpasteurized milk in the past 7 days before the survey [33]. Demand for raw milk has considerably increased in recent years, despite the fact that public health officials consider the benefits of milk pasteurization to be undisputable. With the advent of mandatory pasteurization, the incidence of milkborne diseases dropped dramatically. In the United States in 1938, milkborne outbreaks constituted ~25% of all disease outbreaks due to contaminated food and water.

**Table 1. Time and temperatures for pasteurization of fluid milk approved by the US Food and Drug Administration.**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Time, s</th>
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<tbody>
<tr>
<td>63°C (145°F)</td>
<td>1800</td>
</tr>
<tr>
<td>72°C (161°F)</td>
<td>15.0</td>
</tr>
<tr>
<td>89°C (191°F)</td>
<td>1.0</td>
</tr>
<tr>
<td>90°C (194°F)</td>
<td>0.5</td>
</tr>
<tr>
<td>94°C (201°F)</td>
<td>0.1</td>
</tr>
<tr>
<td>96°C (204°F)</td>
<td>0.05</td>
</tr>
<tr>
<td>100°C (212°F)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

**NOTE.** Data are from [31].
At the beginning of the 21st century, milk and milk products were associated with <1% of all such outbreaks [31]. Between 1880 and 1907, an average of 29 outbreaks of milkborne diseases were reported each year in the United States [34]. Headrick et al. [35] reported 46 outbreaks of milkborne disease in the 19-year period from 1973–1992; an average of 2.4 per year. A review of foodborne diseases reported to the CDC [36] that were suspected or confirmed to be associated with unpasteurized milk or milk products between 1993–2006 identified 68 outbreaks, an average of 5.2 per year (figure 1). Although some of this increase may be a result of increased detection and reporting, it is clear that disease associated with the consumption of raw milk is still an important public health concern in the United States. Very young, aged, infirm, or immunocompromised persons are the most susceptible to the pathogens that may be present in raw milk. However, anyone can be affected, including healthy young adults, as described by Blaser et al. [37] in an outbreak of C. jejuni infection among 19 of 31 college students who consumed unpasteurized milk on a visit to a farm.

**Recent disease outbreaks related to consumption of raw milk.** Since 2005, several outbreaks of disease, including salmonellosis, campylobacteriosis, and E. coli O157:H7 infection, that were related to consumption of unpasteurized milk or dairy products have been reported. During the end of 2005, 18 cases of infection with E. coli O157:H7, mostly among children aged <14 years, occurred in Oregon and Washington states. Five patients, aged 1–13 years, were hospitalized, 4 with hemolytic uremic syndrome. Laboratory and risk factor analyses linked the cases to raw milk from a dairy participating in a cow-share program in Washington [38]. In 2007, 29 cases of S. enterica serotype Typhimurium infection were associated with consumption of raw milk or raw-milk products in Pennsylvania. A S. typhimurium strain isolated from a dairy selling raw milk to consumers at the farm matched the outbreak strain isolated from the case patients by PFGE. Sixteen of the 29 case patients were aged <7 years [39]. At least 87 people became ill in Kansas in 2 separate outbreaks of campylobacteriosis during the end of 2007. In both outbreaks, illness was associated with consumption of raw milk or raw-milk products [40]. In 2008, an outbreak of campylobacteriosis in California was associated with consumption of unpasteurized milk supplied from a farm operating a cow-share program. One of the patients con- sequently developed Guillain-Barre syndrome [41]. Intrastate sale of raw milk is legal in Washington, Pennsylvania, Kansas, and California.

**Opposition to pasteurization.** Despite the overwhelming scientific understanding of pathogens in milk and the public health benefits of pasteurization, there is considerable disagreement between the medical community and raw-milk advocates concerning the alleged benefits of consumption of raw milk and the purported disadvantages of pasteurization. Raw-milk advocates suggest that unpasteurized milk products are completely safe and that they can prevent and treat a wide spectrum of diseases, including heart disease, kidney disease, cancer, and lactose intolerance [42–45]. In addition to the contaminating microflora, milk contains substances that have bacteriostatic and antimicrobial properties. The presumed role of these substances and their heat stability after exposure to pasteurization temperatures are outlined in table 2. Scientific evidence to substantiate the assertions of the health benefits of unpasteurized milk is generally lacking [57]. Nevertheless, when the public is presented with a large body of conflicting information, their decision-making process does not always yield the same results as that of experts [58]. This problem is particularly complicated by the fact that individuals with established attitudes not only seek information that is supportive of their views [59, 60] but also unconsciously process information in a biased fashion [61].
Table 2. Effects of pasteurization on proteins and other milk components.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Role in milk</th>
<th>Effects of pasteurization</th>
<th>Reference(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactoferrin</td>
<td>An iron-binding protein; scavenger of iron, thereby providing antibacterial effects by limiting the availability of free iron required for bacterial proliferation</td>
<td>Unheated and pasteurized bovine lactoferrin have similar antibacterial properties; ultrahigh-temperature treatment denatures the protein</td>
<td>[46]</td>
</tr>
<tr>
<td>Lactoperoxidase</td>
<td>A milk enzyme, which, in conjunction with other enzymes, contributes to the bacteriostatic properties of milk. To be effective, both hydrogen peroxide and thiocyanate ions must be present; both of these chemicals are not endogenous to milk but are by-products of other bacterial metabolic activity.</td>
<td>Retains 70% activity when heated to 72°C for 15 s, with further decreases in activity as the temperature is increased</td>
<td>[47]</td>
</tr>
<tr>
<td>Lysozyme</td>
<td>In conjunction with lactoferrin, has bactericidal effects</td>
<td>In excess of 75% of bovine milk, lysozyme will survive at 80°C for 15 s</td>
<td>[48]</td>
</tr>
<tr>
<td>Bovine immunoglobulin</td>
<td>Transfers immunity to bovine pathogens to calves; may provide some lactogenic immunity in the gut</td>
<td>No loss in activity when held for 30 min at 62.7°C; retains 59%–76% of activity after high-temperature, short-time pasteurization</td>
<td>[49]</td>
</tr>
<tr>
<td>Lactose</td>
<td>A primary sugar present in milk</td>
<td>Pasteurization does not change the concentration of lactose but will destroy lactase-producing bacteria that might be present and that might aid in the tolerance to dairy products among lactase-deficient persons. With heating, lactose in milk is degraded initially into lactulose and epilactose and subsequently into galactose and tagatose. Large doses of indigestible carbohydrates, including lactulose, may cause digestive upset in lactose malabsorbers. However, pasteurization does not typically lead to detectable levels of lactulose present in milk.</td>
<td>[50, 51]</td>
</tr>
<tr>
<td>Other milk proteins (caseins, whey, and others)</td>
<td>Render milk more allergenic; studies show that the sensitizing capacity of cow’s milk is retained or, usually, reduced after heat treatment, whereas pasteurization minimizes the heat destruction of nutrients</td>
<td>The nutritive value of these proteins is largely unaffected by pasteurization</td>
<td>[52]</td>
</tr>
<tr>
<td>Vitamins</td>
<td>Milk is a good source of the B-complex vitamins thiamine, folate, and riboflavin</td>
<td>Pasteurization does not cause appreciable losses of the fat-soluble vitamins A, D, E, and K</td>
<td>[48]</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>Milk contains a small amount of vitamin C, but it is not considered to be a good dietary source of it</td>
<td>Pasteurization will result in a loss of 0%–10% of the vitamin C present</td>
<td>[48]</td>
</tr>
<tr>
<td>Bacteriocins</td>
<td>Have narrow-spectrum antimicrobial activity; often produced by other bacteria contaminating milk</td>
<td>Heat-stable; retain activity after pasteurization</td>
<td>[53, 54]</td>
</tr>
<tr>
<td>Oligosaccharides</td>
<td>Competitively bind to pathogens to prevent adherence of pathogens to target mucosal receptors</td>
<td>Heat stable</td>
<td>[55]</td>
</tr>
<tr>
<td>Xanthine oxidase</td>
<td>An enzyme linked with flavor; changes in milk during storage</td>
<td>Retains enzymatic activity after 7 min at 73°C, or −50 s at 80°C</td>
<td>[56]</td>
</tr>
</tbody>
</table>
This results in a population that is not easily persuaded by informational messages alone. Clinicians, therefore, are faced with the challenge of communicating health risks and promoting behavioral changes among individuals who hold strong opinions about their dietary selections. One possible strategy to overcome this obstacle is to better understand the values underlying their patients’ decision-making processes and target these areas, rather than the disease-risk data, to influence healthier food choices among patients [62]. Other factors that motivate objective information processing include message clarity, message repetition, and source credibility [63, 64]. The last point is an area where clinicians have an enormous advantage and influence in communication of risks.

Testing as an alternative to pasteurization. One method that has been proposed to ensure the safety of raw milk relies on product testing. The underlying premise is that if pathogens are not detectable in raw milk or the animals from which it is derived, then it should be safe for human consumption. It must be noted, however, that product testing cannot ensure safety. Testing schemes are limited by assay sensitivity—both of the sampling-collection strategy and the microbiological analysis. Microbiological assays have improved over time, and several rapid and sensitive methods are available to test for pathogens [65, 66]. Nevertheless, the problem of testing to ensure safety is complicated by several factors: (1) milk contamination occurs sporadically, (2) contamination may not be evenly distributed in a product, (3) extremely small amounts are infectious, and (4) extremely small numbers (below the detectable limit) of organisms present in the product may proliferate to levels that reach unacceptable risks after testing.

SUMMARY AND CONCLUSIONS

Despite the enormous advances in animal health, milking hygiene, and processing technology that have occurred during the past century, milkborne disease outbreaks continue to occur in the United States. Given that milk is derived from animals, it inherently carries the risk of being contaminated with pathogens from its source (cattle, goats, sheep, and the farm environment). The key factor in the prevention of milkborne disease is consumer avoidance of raw milk consumption. In an effort to protect human health, a number of organizations have published guidelines and statements concerning milk pasteurization. The American Medical Association (policy H-150.980) [67] clearly asserts that milk sold for human consumption should be pasteurized. Likewise, the American Veterinary Medical Association asserts that only pasteurized milk and milk products should be sold for human consumption [68]. Thus, physicians, veterinarians, and dairy farmers who promote, or even condone, the human consumption of unpasteurized milk and dairy products may be at risk for subsequent legal action [32, 69].

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