

UNPASTEURIZED DAIRY - USA: INFECTION RISK, 2009-2014

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Consumer demand for organic and natural foods (i.e., minimally processed foods) has been on the rise (1). However, in contrast to some perceptions (2), natural food products are not necessarily safer than conventional ones, as evidenced by higher rates of foodborne illnesses associated with unpasteurized dairy products (3-6). Pasteurization has greatly reduced the number of foodborne illnesses attributed to dairy products, and continuous efforts to reduce milk contamination pre- and post-pasteurization are further decreasing the disease burden (3). Yet, despite a decrease in dairy consumption in the USA (7), recent studies (3,6) suggest that over the past 15 years the number of outbreaks associated with unpasteurized dairy products has increased. In parallel with this increase, an easing of regulations has facilitated greater access of consumers to unpasteurized milk (e.g., through farm sales or cow share programs). The number of states where the sale of unpasteurized milk is prohibited decreased to 20 in 2011 from 29 in 2004 (8-10). This trend toward increased availability of unpasteurized dairy products raises public health concerns, especially because raw milk consumers include children (2,4,6).

Our study aimed at estimating the outbreak-related disease burden associated with the consumption of fluid cow's milk and cheese made from cow's milk (herein also referred to as milk and cheese or dairy products) that are unpasteurized and contaminated with *Campylobacter* spp., *Salmonella* spp., Shiga toxin-producing *Escherichia coli* (STEC or EHEC), and *Listeria monocytogenes*. We also assessed how hypothetical increases in unpasteurized dairy consumption would affect this outbreak-related disease burden.

[The Methods Sections can be read at the original URL. - Mod.LL]

Results:

We used a total of 87 outbreaks causing 750 laboratory-confirmed illnesses and 215 hospitalizations in this analysis (Table 1 [for

Tables and Figures, see original URL. - Mod.LL]). The incidence rates of EHEC, *Salmonella* spp., and *Campylobacter* spp. illnesses and hospitalizations per 1 billion servings were higher for unpasteurized dairy product consumers than for pasteurized dairy product consumers. Illnesses and hospitalizations caused by *L. monocytogenes* infections were more often attributed to the consumption of pasteurized cheese than unpasteurized cheese (Table 2). Assuming no change in the consumption of unpasteurized dairy, dairy products contaminated with EHEC, *Salmonella* spp., *L. monocytogenes*, and *Campylobacter* spp. were predicted to cause 761 (95 percent PI 598-994) outbreak-related illnesses and 22 (PI 13-32) hospitalizations in 2015. Unpasteurized dairy products caused 96 percent (PI 94 percent-98 percent) of these illnesses.

We calculated the excess risk attributable to the consumption of unpasteurized milk and cheese (Table 2; Figure 3). Because no reported illnesses were caused by *Salmonella* spp. and EHEC during 2009-2014 and no hospitalizations were caused by *Campylobacter* spp., the corresponding incidence rates were extremely low (Table 2). Therefore, only RDs (and not IRRs) were reported for these pathogens. If all milk and cheese consumed were pasteurized, an average of 732 (95 percent PI 570-966) illnesses and 21 (95 percent PI 12-32) hospitalizations would be prevented per year in the USA. Of these prevented cases, 54 percent would be salmonellosis and 43 percent campylobacteriosis. The mean IRR of illnesses was 838.8 (95 percent CrI 611.0-1,158.0) overall from all 4 pathogens of interest (Figure 3), with 0.4 (95 percent CrI 0-1.2) from *L. monocytogenes* and 7601 (95 percent CrI 3711-15 346) from *Campylobacter* spp. The rate of hospitalization was higher for unpasteurized dairy consumers than for pasteurized dairy consumers (mean IRR 45.1, 95 percent CrI 33.7-59.2), with an IRR of 0.5 (95 percent CrI 0-1.7) for *L. monocytogenes*.

If the percentage of unpasteurized milk consumers in the USA were to increase to 3.8 percent and unpasteurized cheese consumers to 1.9 percent (i.e., an increase of 20 percent), the number of illnesses per year would increase by an average of 19 percent and the number of hospitalizations by 21 percent. If the percentages of unpasteurized milk and cheese consumers were to double, the number of illnesses would increase by an average of 96 percent, and the number of hospitalizations would increase by 104 percent, resulting in an additional 733 (95 percent PI 571-966) illnesses/year and 22 (95 percent PI 13-32) hospitalizations/year, which corresponds to a total of 1493 (95 percent PI 1180-1955) illnesses/year (Figure 4), most caused by *Salmonella* spp. and *Campylobacter* spp.

The following conditional means sensitivity analysis reports the

change in the output mean if the input variable is set to its 5th and 95th percentiles while other inputs are sampled at random. The rates of illnesses (λ) caused by the consumption of unpasteurized milk and cheese were most sensitive to the underreporting factors (γ) for *Salmonella* spp. (mean range λ 34.9-72.5), *Campylobacter* spp. (mean range λ 33.1-45.3), and EHEC (mean range λ 3.1-4.1), and at a secondary level to the undertesting (ρ) and underdiagnosis (μ) factors (results not shown). The overall IRR of illnesses was most sensitive to the underreporting factor for *Salmonella* spp. (mean range IRR 710.1-1049.6). The number of illnesses per year caused by the consumption of milk or cheese was most sensitive to the rates of illnesses caused by *Salmonella* spp. and *Campylobacter* spp., as the main uncertainties apply to the incidence calculations for all pathogens (results not shown). Including the 9 outbreaks with a suspected-etiology status or the outbreak of unspecified pasteurization status (Figure 1) into the main analysis did not change the IRRs or the predicted number of illnesses or hospitalizations per year (results not shown).

Discussion:

Unpasteurized dairy products are responsible for almost all of the 761 illnesses and 22 hospitalizations in the USA that occur annually because of dairy-related outbreaks caused by EHEC, *Salmonella* spp., *L. monocytogenes*, and *Campylobacter* spp. More than 95 percent of these illnesses are salmonellosis and campylobacteriosis. Consumers of unpasteurized milk and cheese are a small proportion of the USA population (3.2 percent and 1.6 percent, respectively), but compared with consumers of pasteurized dairy products, they are 838.8 times more likely to experience an illness and 45.1 times more likely to be hospitalized. Illnesses caused by *L. monocytogenes*, however, were found to be more often associated with the consumption of pasteurized cheese, albeit only causing 1 additional outbreak-related illness per year on average.

An easing of regulations has allowed greater access to unpasteurized milk in recent years (8-10), and this study shows that illnesses and hospitalizations will rise as consumption of unpasteurized dairy products increases. If such consumption were to double, the mean number of outbreak-related illnesses that occur every year would increase by 96 percent. Most unpasteurized dairy-related outbreaks are caused by pathogen contamination at the dairy farm (versus postpasteurization contamination for pasteurized products) (3); thus, one could assume that decreasing pathogen prevalence in bulk milk tanks on raw milk farms would help reduce illnesses. EHEC has been found in 2.5 percent (95 percent CrI 0.1 percent-9.1 percent), *Salmonella* spp. in 4.6 percent (3.7%-5.6 percent), *L. monocytogenes*

in 2.5 percent (0.1percent-9.0 percent), and *Campylobacter spp.* in 4.7 percent (2.8 percent-7.0 percent) of bulk milk tanks on US raw milk farms (25-29). Given these low prevalences, strategies for further reduction are limited and involve multiple aspects of unpasteurized milk production (30). Boiling of milk before consumption seems to be a more realistic mitigation strategy, but this practice is unlikely to be implemented by unpasteurized dairy product advocates because it would affect the perceived benefits.

This study focused on the outbreak-related illnesses, which is only a fraction of all dairy-related illnesses in the USA. Two studies have documented the fraction of outbreak-related cases among FoodNet laboratory-confirmed cases (15,31); the fraction ranges from 0.5 percent for *Campylobacter spp.* to 19.0 percent for EHEC according to Ebel et al. (31). These data suggest that the number of sporadic illnesses caused by contaminated dairy products in the USA might be much larger than that for outbreak-related illnesses. However, because of the lack of information on the characteristics of sporadic illnesses (such as food source attribution), we restricted the scope of this analysis to outbreak-related disease burden.

Our analysis relied on outbreak data from NORS (11), which is a passive reporting system affected by underreporting. We used dairy-related outbreak cases from FoodNet (14-16) as a comparison to estimate underreporting; therefore, any potential bias of this comparison was carried over to our estimation of outbreak-related illnesses. By extrapolating incidence rates of cases from the FoodNet catchment areas to the overall USA, we assumed that the FoodNet surveillance population and reporting practices were representative of the entire USA. However, the FoodNet catchment population represents only 15 percent of the US population from 10 nonrandom sites. Also, a recent study (31) suggested state-to-state variations in reporting practices; these variations might be even greater between FoodNet and non-FoodNet states. This difference might influence state-specific incidence rates or underreporting ratios, as well as other characteristics of the reported cases. For example, if a state reported the incriminated food source as the food item (e.g., homemade yogurt), it would not have been selected for inclusion in this analysis, but if they reported the ingredient used for preparation (e.g., in the case of homemade yogurt, fluid milk), it would have been included in our analysis. However, the size and direction of such biases and uncertainties associated with these complex surveillance systems (NORS and FoodNet) are difficult to quantify because of the paucity of data.

The rates of illnesses were most sensitive to the estimated

underreporting factors, which were assumed to be associated with the severity of symptoms (23,24) and other factors, such as state health department resources, and thus independent of the pasteurization status. Also, because this analysis only considered outbreaks involving milk and cheese (and no other dairy products), we are probably underestimating the incidence of illnesses and hospitalizations. However, milk and cheese are the most commonly consumed dairy sources and cause the most outbreaks (milk and cheese caused 99 percent of dairy-related outbreaks reported to NORS during the study period), so the underestimation is likely limited. Nonetheless, the overall comparison of risk between consumers of pasteurized and unpasteurized products should remain valid.

Estimates of the proportion of the population consuming dairy products were derived from the FoodNet population survey (12). We assumed that respondents who reported consumption of unpasteurized milk or cheese were not consuming pasteurized dairy. However, if unpasteurized milk or cheese only represented a fraction of their dairy consumption, the number of servings of unpasteurized dairy products could have been overestimated, and thus the risk for consumers of unpasteurized dairy products might have been underestimated. Also, the FoodNet population survey is based on a relatively small convenience sample and might therefore not be accurate. For example, the self-reported estimates of consumption of unpasteurized milk and cheese (3.2 percent and 1.6 percent, respectively) (12) might be underestimates or overestimates, potentially caused by consumers confusing the terms raw, organic, and natural (or other reasons). In addition, consumption might have changed since the 2007 FoodNet population survey (12), which might have resulted in an under- or overestimation of the risk from unpasteurized milk products. However, because the proportion of dairy consumers using unpasteurized products remains small, and the IRRs are very large, this overestimation is likely limited, and the trend for additional illnesses as unpasteurized dairy consumption grows remains valid. Similarly, estimates of the consumption of pasteurized cheese are underestimates: data available only provide estimates of the highest exposure to a single type of cheese, rather than to any type of cheese (12), potentially resulting in a risk overestimation for consumers of pasteurized dairy products. This is a limitation, notably for outbreaks linked to queso fresco and other Mexican-style soft cheeses. Despite these limitations, to the authors' knowledge, this study is based on the best available data and builds upon other well-accepted risk attribution methods (15,16,32).

In conclusion, outbreaks linked to the consumption of cow's milk and cheese were estimated to cause on average 761 illnesses and 22 hospitalizations per year in the USA. Unpasteurized products are

consumed by a small percentage of the US dairy consumers but cause 95 percent of illnesses; the risk for illness was found to be >800 times higher for consumers of unpasteurized milk or cheese than for consumers of pasteurized dairy products. Therefore, outbreak-related illnesses will increase steadily as unpasteurized dairy consumption grows, likely driven largely by salmonellosis and campylobacteriosis.

For References, see original URL - Mod. LL

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[The statement that "no reported illnesses were caused by *Salmonella* spp. and EHEC during 2009-2014" appears to be disputed by the ProMED posting about EHEC from unpasteurized milk in Tennessee in 2013 and in Minnesota in 2010 and *Salmonella* Newport from unpasteurized milk in Utah also in 2010. This may alter the numbers but not the conclusions.

The statement that "unpasteurized products are consumed by a small percentage of the US dairy consumers but cause 95 percent of illnesses; the risk for illness was found to be >800 times higher for consumers of unpasteurized milk or cheese than for consumers of pasteurized dairy products" underscores the need to be critical about attempts by state legislatures to liberalize laws regarding the sale or availability of unpasteurized dairy products as reported, for example, in:

Montana-

<<http://www.greatfallstribune.com/story/news/local/2017/03/30/bill-label-raw-milk-related-products/99845984/>>;