Outbreak-Related Disease Burden Associated with Consumption of Unpasteurized Cow's Milk and Cheese, United States, 2009–2014

Solenne Costard, Luis Espejo, Huybert Groenendaal, Francisco J. Zagmutt

The growing popularity of unpasteurized milk in the United States raises public health concerns. We estimated outbreak-related illnesses and hospitalizations caused by the consumption of cow's milk and cheese contaminated with Shiga toxin–producing *Escherichia coli*, *Salmonella* spp., *Listeria monocytogenes*, and *Campylobacter* spp. using a model relying on publicly available outbreak data. In the United States, outbreaks associated with dairy consumption cause, on average, 760 illnesses/year and 22 hospitalizations/year, mostly from *Salmonella* spp. and *Campylobacter* spp. Unpasteurized milk, consumed by only 3.2% of the population, and cheese, consumed by only 1.6% of the population, caused 96% of illnesses caused by contaminated dairy products. Unpasteurized dairy products thus cause 840 (95% CrI 611–1,158) times more illnesses and 45 (95% CrI 34–59) times more hospitalizations than pasteurized products. As consumption of unpasteurized dairy products grows, illnesses will increase steadily; a doubling in the consumption of unpasteurized milk or cheese could increase outbreak-related illnesses by 96%.

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 United States (*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), and *Listeria monocytogenes*. We also assessed how hypothetical increases in unpasteurized dairy consumption would affect this outbreak-related disease burden.

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DOI: https://dx.doi.org/10.3201/eid2306.151603

Methods

Data Sources

We used outbreak data from the National Outbreak Reporting System (NORS) (*11*) to estimate the incidence rates of illnesses and hospitalizations. NORS is a web-based platform that stores data on all foodborne disease outbreaks reported by local, state, and territorial health departments in the United States that have occurred since 2009. We included all outbreaks that occurred during 2009–2014 in which the confirmed etiologic agents were any of the 4 pathogens of interest (*Campylobacter* spp., *Salmonella* spp., STEC, and *L. monocytogenes*) and the implicated food vehicle or contaminated ingredient was milk or cheese (Figure 1). Outbreaks associated with multiple products; processed dairy products other than milk and cheese (e.g., cream, butter, yogurt, and kefir); milk produced by species other than cows; and cheese originating from species other than cows were excluded from the analysis (online Technical Appendix 1, https://wwwnc.cdc.gov/EID/article/23/6/15-1603-Techapp1.xlsx).

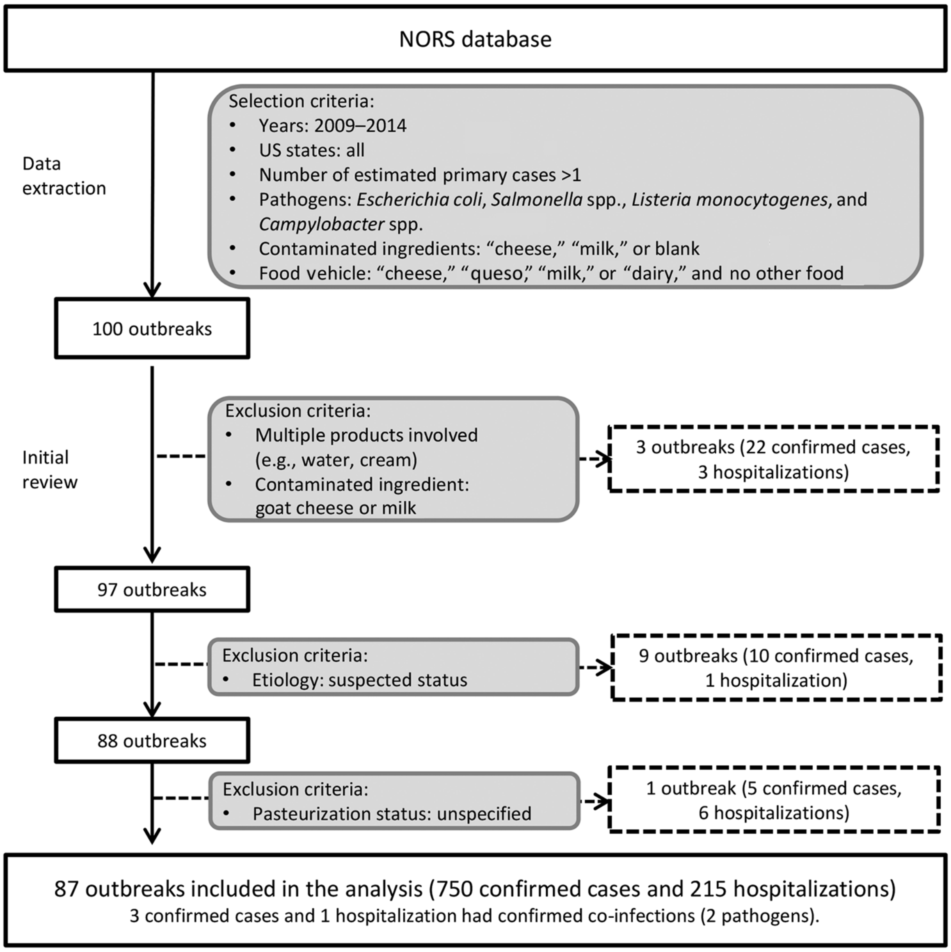

Figure 1. Process for selecting US outbreaks associated with cow's milk and cheese, 2009–2014. Laboratory-confirmed cases are cases with illness in which a specimen was collected and a laboratory was able to confirm the pathogen(s) or agent(s) causing illness. Hospitalizations are cases in which the patient was hospitalized as a result of becoming ill during the outbreak. NORS, National Outbreak Reporting System.

In addition, outbreaks with a suspected etiology status or associated with a dairy product with an unknown pasteurization status were excluded.

The stochastic model (Figure 2) was developed to estimate the following: the incidence rates of illness and hospitalization for pasteurized and unpasteurized dairy products, the excess risk associated with unpasteurized milk and cheese consumption, and the effect potential increases in consumption of unpasteurized dairy products would have on the outbreak-related disease burden (online Technical Appendix 2 Tables 1–5, https://wwwnc.cdc.gov/EID/article/23/6/15-1603-Techapp2.pdf). Inputs (other than the outbreak data) used in the stochastic model were derived from readily available sources of information (online Technical Appendix 2). Dairy consumption estimates were derived from the Foodborne Active Surveillance Network (FoodNet) Population Survey (*12*).

Estimation of the Incidence of Outbreak-Related Illnesses and Hospitalizations

We modeled the uncertainty of the pathogen-specific and pasteurization status–specific incidence rates of illness and hospitalization (λ) in the United States per serving of dairy product using a conjugate gamma distribution (*13*). The number of hospitalizations and laboratory-confirmed cases occurring during the study period (2009–2014) that were caused by a given pathogen after consumption of milk or cheese of a certain pasteurization status was obtained from the NORS database. For laboratory-confirmed cases, this number was adjusted for underreporting, under testing (only a proportion of suspected cases were sampled and tested), and underdiagnosis (based on diagnostic test sensitivity), in order to estimate illnesses for 2009–2014. These pathogen-specific factors were assumed to be independent of the product consumed and its pasteurization status, and constant for the years considered. The analysis did not include adjustment factors for potential misclassification in terms of etiology or pasteurization status. These 2 outbreak characteristics were carefully reviewed, and any outbreak for which the information could not be verified was excluded. It was thus assumed that etiology and pasteurization status misclassifications were negligible in this analysis.

Because NORS is a passive surveillance system, the inherent underreporting associated with it needed to be accounted for. We estimated an underreporting factor by

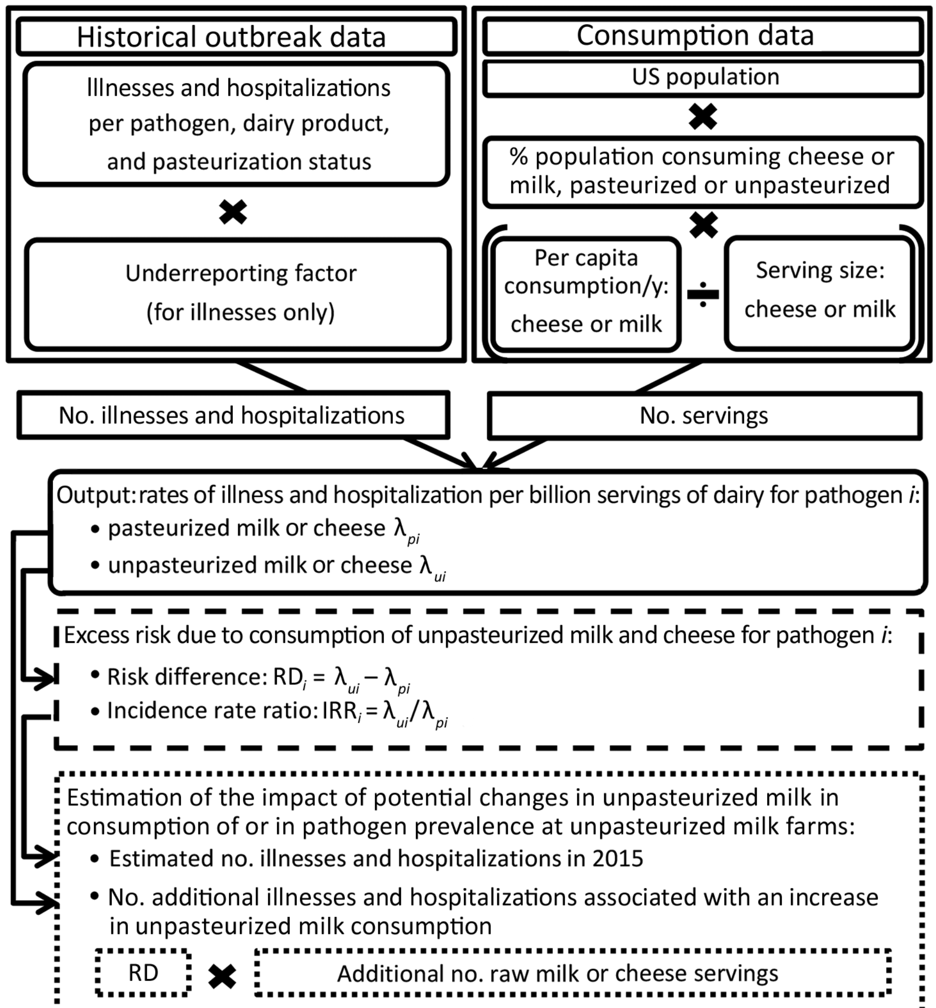

Figure 2. Stochastic model used to estimate the excess risk of outbreak-related illnesses and hospitalization due to unpasteurized dairy product consumption in the United States, 2009–2014. Model contains 3 main components: estimation of the incidence rates of illness and hospitalization for pasteurized and unpasteurized dairy products (elements in the boxes with solid lines), estimation of the excess risk associated with unpasteurized milk or cheese consumption (elements in box with dashed lines), and evaluation of the impact of hypothetical changes in consumption of unpasteurized dairy products (elements in boxes with dotted lines).

using FoodNet data, which is an active surveillance system assumed to include virtually all identified cases (online Technical Appendix 2). First, we extrapolated the total number of laboratory-confirmed cases in the US population during 2009–2013 using the incidence rates reported by FoodNet and considering the proportions of the US population included in FoodNet surveillance sites (*14*). Second, we estimated the total number of outbreak-related cases using the fraction of the US laboratory-confirmed cases that were outbreak-related (*15*). Third, we extracted the proportion of outbreak-related illnesses attributable to dairy (*16*). Fourth, we calculated the ratio of the number of outbreak-related, laboratory-confirmed cases linked to dairy consumption derived from the previously described calculations and the number of dairy-related, laboratory-confirmed cases reported through NORS to use as the underreporting factor in the analysis (online Technical Appendix 2). When estimating the underreporting factor, we assumed that the FoodNet surveillance population and reporting practices were representative of the entire United States and that the food source attribution pertaining to the illnesses from confirmed and suspected outbreaks (*16*) were equally relevant to laboratory-confirmed cases from outbreaks of confirmed status only. We used the sensitivity of the diagnostic tests as described in Scallan et al. (*15*) to estimate the proportion of false-negative, laboratory-confirmed cases from NORS (underdiagnosis factor). Finally, we derived the under-testing factor by using the ratio of laboratory-confirmed primary cases to the estimated total number of primary illnesses reported to NORS (*17*).

The annual number of servings of milk or cheese of a given pasteurization status was calculated as the product of the number of servings of milk or cheese per person for a certain year, the resident population in the United States for that year (*18*) and the percentage of the population of dairy consumers that consume milk or cheese of a particular pasteurization status. The annual per capita consumption of a given dairy product (*19*) was divided by its average serving size (i.e., the amount of milk or cheese that is generally served) (*7*,*20*,*21*) to estimate the annual per capita number of servings of milk and cheese. These totals were then summed across the years of the study period. The per capita consumption data (*19*) were assumed to include both pasteurized and unpasteurized dairy products. Because unpasteurized dairy products constitute a small percentage of the total consumption, this assumption (if inaccurate) would likely have only a small effect on results. We also hypothesized that the serving sizes (*7*,*20*,*21*) were the same for pasteurized and unpasteurized dairy products.

The estimates of the proportion of dairy consumers that consume milk or cheese of a given pasteurization status were derived from the FoodNet Atlas of Exposure (*12*). Answers from this FoodNet survey are provided as aggregates per survey site, rather than per respondent. Therefore, answers regarding milk and cheese consumption were treated as independent. In addition, we assumed that respondents who reported consumption of unpasteurized milk or cheese did not consume pasteurized milk or cheese. Because the information to calculate the overall proportion of the US population consuming any type of cheese was unavailable, we assumed it to be equal to the proportion of the population reporting consumption of any cheese sold as or cut from solid blocks (i.e., the type of cheese consumed most commonly). We further assumed the proportion of the US population consuming unpasteurized cheese to be equal to the proportion reporting exposure to any cheese made from unpasteurized milk in the previous 7 days.

Estimation of the Excess Risks Attributed to the Consumption of Unpasteurized Milk and Cheese

We estimated the additional risks for illness and hospitalization for consumers of unpasteurized dairy products compared with consumers of pasteurized ones. We calculated excess risk using 1) risk difference (RD), which measures the absolute difference in the observed risks for illness and hospitalization between consumers of unpasteurized dairy products and consumers of pasteurized ones, and 2) incidence rate ratio (IRR), which provides a relative comparison of the risks for illness and hospitalization between the 2 exposure groups (*22*).

Effects of Hypothetical Changes in Consumption of Unpasteurized Milk or Cheese

We assessed the potential public health effects of hypothetical changes in unpasteurized milk consumption. We determined the number of illnesses in 2015 in the United States using the pathogen-specific rates of illnesses and hospitalizations per serving of dairy product. The number of hospitalizations was calculated as pathogen-specific fractions of these illnesses. The pathogen-specific probabilities of hospitalization in cases of illness were assumed unconditional on the pasteurization status of the dairy product involved, but rather dependent on the severity of illness (*23*,*24*).

We estimated the additional illnesses and the additional hospitalizations for each pathogen if a hypothetical increase in consumption of unpasteurized milk or cheese occurred using 1) the change in the proportion of the population consuming unpasteurized milk or cheese, 2) the number of servings of milk or cheese for 2015, and 3) the risk difference in illnesses per serving of dairy for that pathogen. We assumed that the overall proportion of the US population consuming milk or cheese did not change; therefore, the increase in the proportion of the US population consuming unpasteurized milk or cheese corresponded to a shift of dairy consumers from pasteurized to unpasteurized. Six hypothetical scenarios were considered: 10%, 20%, 50%, 100%, 200%, and 500% increases in the proportion of the US population consuming unpasteurized milk or cheese.

Scenario and Sensitivity Analyses

We performed a sensitivity analysis to identify the parameters that most influenced our estimates. The sensitivity of the estimates to the input parameter uncertainties was calculated by using conditional means as implemented in @RISK 6.1.2 (Palisade Corporation, Ithaca, NY, USA). In addition, we assessed the robustness of our sensitivity analysis with a scenario analysis in which we calculated our estimates with different sets of outbreak data. For the main analysis, the model was run on outbreaks of confirmed etiology and pasteurization status. In the scenario analysis, the model was then re-run with either of the 2 following sets of outbreaks added to the main data set: outbreaks of suspected etiology status (*17*) and outbreaks involving dairy products of unspecified pasteurization status assumed to be caused by pasteurized dairy products.

Model Implementation

The model was developed in Excel 2010 (Microsoft Corporation, Redmond, WA, USA) with the Monte-Carlo simulation add-in @RISK 6.1.2. Results are expressed as means and 95% credibility intervals (CrIs, a Bayesian equivalent to the confidence interval) or prediction intervals (PIs, which provides uncertainty bounds for predictions), unless stated otherwise.

Results

Incidence Rates and Increased Risks Associated with the Consumption of Unpasteurized Milk and Cheese

We used a total of 87 outbreaks causing 750 laboratory-confirmed illnesses and 215 hospitalizations in this analysis (Table 1). The incidence rates of STEC, *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*

Table 1. Dairy-related illnesses and hospitalizations from 87 outbreaks, National Outbreak Reporting System, United States, 2009–2014*

	Outbreaks associated with milk and cheese consumption, N = 87†					
	Pasteurized			Unpasteurized		
Pathogen	Outbreaks	Illnesses	Hospitalizations	Outbreaks	Illnesses	Hospitalizations
STEC	0	0	0	14‡	99	42
Salmonella spp.	0	0	0	8§	83	29
Listeria monocytogenes	10	100	87	1	1	1
Campylobacter spp.	1	2	0	53‡§	465	56
Overall	11	102	87	76	648	128

*Illnesses and hospitalizations had confirmed etiologies and were associated with the consumption of milk or cheese of known pasteurization status. STEC, Shiga toxin–producing *Escherichia coli*.
†Out of the 87 outbreaks, 10 outbreaks reported a total of 17 deaths, 16 of them were linked to *L. monocytogenes* and 1 to *Campylobacter* spp.
‡One outbreak (38 illnesses and 10 hospitalizations) had 3 cases with confirmed coinfection (STEC and *Campylobacter* spp.). These 3 cases were duplicated because they were assigned to each pathogen.
§One outbreak (4 illnesses and 1 hospitalization) involved 2 pathogens: 3 Illnesses and 1 hospitalization were linked to *Campylobacter* spp. and 1 illness and 0 hospitalizations were linked to *Salmonella* spp.

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 STEC, *Salmonella* spp., *L. monocytogenes*, and *Campylobacter* spp. were predicted to cause 761 (95% PI 598–994) outbreak-related illnesses and 22 (PI 13–32) hospitalizations in 2015. Unpasteurized dairy products caused 96% (PI 94%–98%) 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 STEC 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% PI 570–966) illnesses and 21 (95% PI 12–32) hospitalizations would be prevented per year in the United States. Of these prevented cases, 54% would be salmonellosis and 43% campylobacteriosis. The mean IRR of illnesses was 838.8 (95% CrI 611.0–1,158.0) overall from all 4 pathogens of interest (Figure 3), with 0.4 (95% CrI 0–1.2) from *L. monocytogenes* and 7,601 (95% CrI 3,711–15,346) from *Campylobacter* spp. The rate of hospitalization was higher for unpasteurized dairy consumers than for pasteurized dairy consumers (mean IRR 45.1, 95% CrI 33.7–59.2), with an IRR of 0.5 (95% CrI 0–1.7) for *L. monocytogenes*.

Effects of Hypothetical Scenarios

If the percentage of unpasteurized milk consumers in the United States were to increase to 3.8% and unpasteurized cheese consumers to 1.9% (i.e., an increase of 20%), the number of illnesses per year would increase by an average of 19% and the number of hospitalizations by 21%. If the percentages of unpasteurized milk and cheese consumers were to double, the number of illnesses would increase by an average of 96%, and the number of hospitalizations would increase by 104%, resulting in an additional 733 (95% PI 571–966) illnesses/year and 22 (95% PI 13–32) hospitalizations/year, which corresponds to a total of 1,493 (95% PI 1,180–1,955) illnesses/year (Figure 4), most caused by *Salmonella* spp. and *Campylobacter* spp.

Scenario and Sensitivity Analyses

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

Table 2. Incidence rates and risk differences for illness and hospitalization per 1 billion servings of milk or cheese, by pasteurization status and pathogen, United States, 2009–2014*

	Illnesses			Hospitalizations		
Pathogen	Unpasteurized	Pasteurized	Risk difference†	Unpasteurized	Pasteurized	Risk difference†
STEC	3.5 (2.7–4.5)	3.4×10^{-4} (3.1×10^{-7} to 1.7×10^{-3})	3.5 (2.7 to 4.5)	0.9 (0.6 to 1.2)	3.4×10^{-4} (3.0×10^{-7} to 1.7×10^{-3})	0.9 (0.6 to 1.2)
Salmonella spp.	49.1 (32.7–76.7)	3.4×10^{-4} (3.3×10^{-7} to 1.7×10^{-3})	49.1 (32.7 to 76.7)	0.6 (0.4 to 0.9)	3.5×10^{-4} (3.4×10^{-7} to 1.7×10^{-3})	0.6 (0.4 to 0.9)
Listeria monocytogenes	0.04 (0.003–0.100)	0.1 (0.08 to 0.12)	–0.06 (–0.11 to 0.02)	0.03 (2.2×10^{-3} to 0.1)	0.06 (0.05 to 0.07)	–0.03 (–0.06 to 0.04)
Campylobacter spp.	39.0 (30.8–48.3)	5.8×10^{-3} (2.4×10^{-3} to 1.1×10^{-2})	39.0 (30.8 to 48.3)	1.2 (0.9 to 1.5)	3.5×10^{-4} (3.5×10^{-7} to 1.7×10^{-3})	1.2 (0.9 to 1.5)
Overall	91.7 (71.8–120.9)	0.11 (0.09 to 0.13)	91.6 (71.7 to 120.8)	2.7 (2.2 to 3.3)	6.1×10^{-2} (4.9×10^{-2} to 7.5×10^{-2})	2.7 (2.2 to 3.2)

*Values are shown as mean incidence (95% credibility interval). STEC, Shiga toxin–producing *Escherichia coli*.
†Excess risk is attributable to unpasteurized dairy.

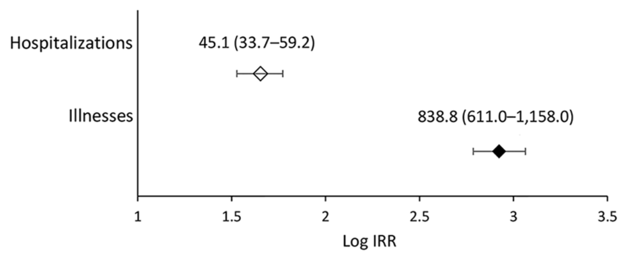

Figure 3. Forest plot showing, on a logarithmic scale, the excess risk for outbreak-related illnesses and hospitalizations caused by consumption of pasteurized and unpasteurized milk and cheese, United States, 2009–2014. Markers indicate mean log IRR of outbreak-related illnesses and hospitalizations caused by the food pathogens *Campylobacter* spp., *Listeria monocytogenes*, *Salmonella* spp., and Shiga toxin–producing *Escherichia coli* per 1 billion servings of unpasteurized milk or cheese relative to pasteurized products. Error bars indicate 95% credibility interval (CrI). Numbers above markers and bars are the IRR (not in log scale) and 95% CrI. log (IRR) = 0 indicates no difference in incidence rates between unpasteurized and pasteurized milk and cheese. IRR, incidence rate ratio.

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 STEC (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 710.1–1,049.6). 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 United States that occur annually because of dairy-related outbreaks caused by STEC, *Salmonella* spp., *L. monocytogenes*, and *Campylobacter* spp. More than 95% of these illnesses are salmonellosis and campylobacteriosis. Consumers of unpasteurized milk and cheese are a small proportion of the US population (3.2% and 1.6%, 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%. 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. STEC has been found in 2.5% (95% CrI 0.1%–9.1%), *Salmonella* spp. in 4.6% (3.7%–5.6%), *L. monocytogenes* in 2.5% (0.1%–9.0%), and *Campylobacter* spp. in 4.7% (2.8%–7.0%) 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 United States. Two studies have documented the fraction of outbreak-related cases among FoodNet laboratory-confirmed cases (*15*,*31*); the fraction ranges from 0.5% for *Campylobacter* spp. to 19.0% for STEC according to Ebel et al. (*31*). These data suggest that the number of sporadic illnesses caused by contaminated dairy products in the United States 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 United States, we assumed that the FoodNet surveillance population and reporting practices were representative of the entire United States. However, the FoodNet catchment population represents only 15% 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

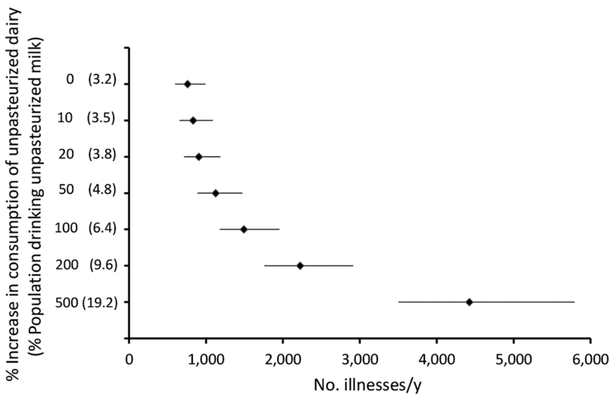

Figure 4. Number of dairy-related outbreak illnesses predicted per year in the United States if unpasteurized cow's milk and cheese consumption increases 0%, 10%, 20%, 50%, 100%, 200%, and 500%. Numbers in parentheses indicate percentage of total population consuming unpasteurized cow's milk. The illnesses graphed are those from outbreaks associated with cow's milk or cheese contaminated with Shiga toxin–producing *Escherichia coli*, *Salmonella* spp., *Listeria monocytogenes*, and *Campylobacter* spp. Markers indicate means; bars indicate 95% prediction intervals. The consumption estimates were based on the year 2015, and a 0% increase corresponds to the current proportion of the US population consuming unpasteurized dairy products.

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% 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% and 1.6%, 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 United States. Unpasteurized products are consumed by a small percentage of the US dairy consumers but cause 95% 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.

Acknowledgments

The authors thank collaborators E. Hovingh, D.R. Wolfgang, and H. Lysczek for their valuable input on milk production and consumption. We also thank the anonymous reviewers for their helpful suggestions.

This work was supported in part by a United States Department of Agriculture Special Research Grant (no. 2010-34163-21179) and the Pennsylvania Agricultural Experiment Station.

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Article DOI: https://dx.doi.org/10.3201/eid2306.151603

Outbreak-Related Disease Burden Associated with Consumption of Unpasteurized Cow's Milk and Cheese, United States, 2009–2014

Technical Appendix

Model structure

A stochastic model with 3 components was developed to estimate: the incidence rates of illness and hospitalization for pasteurized and unpasteurized dairy products, the excess risk associated with unpasteurized milk and cheese consumption, and the effect potential increases in consumption of unpasteurized dairy products would have on the outbreak-related disease burden. Estimations were stratified by pathogen and pasteurization status. For all equations below, Gamma distributions were parameterized as Gamma(Shape, Rate), and Beta distributions were parameterized as Beta(Shape 1, Shape 2). The parameterization of the Beta distributions used in this model assumes a noninformative Beta(1,1) prior to represent the lack of knowledge on the true value of p (i.e., p is equally likely to take values between 0 and 1).

Estimation of the Incidence Rate of Outbreak-Related Illness and Hospitalization

For each pathogen and dairy product of a given pasteurization status, the incidence rates of illness and hospitalization in the United States per serving of dairy product are estimated using a Bayesian conjugate of the Poisson rate parameter λ based on a noninformative prior $\lambda^{-0.5}$(*1*), approximated as Gamma(0.5, 0.00001), as follows:

$$\lambda \sim \text{Gamma}(\alpha + 0.5, N_{serving} + 0.00001) \text{ (equation 1)},$$

where α is the estimated number of outbreak-related illnesses or hospitalizations caused by the pathogen during 2009–2014, and $N_{serving}$ is the number of servings of milk or cheese.

For α, the number of hospitalizations were directly obtained from the National Outbreak Reporting System (NORS) (*2*), while the number of illnesses was obtained after correction for pathogen-specific underreporting, under testing (i.e., the fact that samples are not collected from all suspected cases and not all samples are tested), and underdiagnosis (i.e., false negative). Sets of independent adjustment factors were sampled and combined as shown below to estimate illnesses:

$$\alpha = \alpha_{obs} \times \gamma \times \mu \times \rho \text{ (equation 2),}$$

where α_{obs} is the number of laboratory-confirmed cases as reported in NORS (*2*), γ is the underreporting factor, μ is the underdiagnosis factor, and ρ is the under-testing factor for a given pathogen. Another model structure was tested, where the adjusting factors were modeled using a hypergeometric process. However, a sensitivity analysis showed this did not affect the results, and thus the more parsimonious model structure shown in equation 2 was chosen. Means and credibility intervals for the adjustment factors and the data used for their calculation are shown in online Technical Appendix Table 2.

Estimation of the Underreporting Factor γ

We estimated the underreporting factor by comparing the total number of laboratory confirmed cases from dairy-related outbreaks ($N_{ODRcases}$) reported to NORS from 2009 through 2013 in the United States with the estimated number of laboratory-confirmed cases from outbreaks that were attributed to dairy consumption from FoodNet ($N_{LCcases}$) for the same period:

$$\gamma = \frac{N_{LCcases}}{N_{ODRcases}} \text{ (equation 3).}$$

In doing so, we assumed that FoodNet surveillance population and reporting practices were representative of the overall United States. $N_{ODRcases}$ was directly obtained from NORS. $N_{LCcases}$ was derived from estimated numbers of laboratory-confirmed cases for the US population ($N_{UScases}$), and adjusted to outbreak and dairy-related cases:

$$N_{LCcases} = N_{UScases} \times P_{ORcases} \times P_{DRcases} \text{ (equation 4).}$$

$N_{UScases}$ was estimated by extrapolating the yearly incidence rates of laboratory-confirmed cases in the FoodNet population ($R_{UScases}$) to the US population N_{resUS} and summing them for 2009–2013:

$$N_{UScases} = R_{UScases} \times N_{resUS} \text{ (equation 5)},$$

where N_{resUS} was calculated from the FoodNet study population ($N_{FoodNet}$) and the proportion of the US population this study population represents ($P_{FoodNet}$):

$$N_{resUS} = \frac{N_{FoodNet}}{P_{FoodNet}} \text{ (equation 6)}.$$

For the 4 pathogens of interest, the incidence rates of laboratory-confirmed cases in the FoodNet population ($R_{UScases}$) were given by:

$$R_{UScases} \sim \text{Gamma}\ (N_{FoodNetcases},\ N_{FoodNet}) \text{ (equation 7)},$$

where $N_{FoodNetcases}$ were the total number of laboratory confirmed cases reported by FoodNet. This estimated number of laboratory-confirmed cases in the US derived from FoodNet data ($N_{UScases}$) was then adjusted as described in equation 4, so as to only include the outbreak-related cases attributable to dairy.

Assuming that proportions of laboratory-confirmed cases that are outbreak-related ($P_{ORcases}$) are pathogen-specific and do not change over time, $P_{ORcases}$ were approximated using data from Scallan et al. (*3*):

$$P_{ORcases} \sim \text{Beta}\ (N_{ob} + 1\ ,\ N_{cases} - N_{ob} + 1) \text{ (equation 8)},$$

where N_{cases} was the total number of laboratory-confirmed cases, and N_{ob} was the number of these cases that were outbreak related, as reported to FoodNet for 2004–2008.

The pathogen-specific estimates of the proportion of outbreak-related illnesses that are attributable to dairy ($P_{DRcases}$) were derived from the study by Painter et al. (*4*):

$$P_{DRcases} \sim \text{Pert (minimum, most likely, maximun)} \text{ (equation 9)}.$$

This assumes that the proportion of outbreak-related illnesses caused by dairy products remained unchanged during 2004–2008 and 2009–2014 and that they applied to outbreaks associated with cow's milk and cheese only. The study by Painter et al. included complex and simple foods, but in the case of dairy products the large majority of outbreaks (99%) were caused by milk or cheese (i.e., simple foods) during our study period.

Estimation of the Underdiagnosis Factor μ

The underdiagnosis factor used in equation 2, μ, accounts for the rate of false negatives using the test sensitivity described in Scallan et al. (*3*):

$$\mu = 1 + (1 - Se) \text{ (equation 10)},$$

where

$$Se \sim \text{Pert (minimum, mode, maximum) (equation 11)}.$$

Estimation of the Under-testing Factor ρ

The under-testing factor in equation 2, ρ, accounts for the fact that in an outbreak investigation, samples are not collected from all suspected cases, and diagnostic tests are not conducted on all samples taken:

$$\rho \sim 1/\text{Beta}\,(\alpha_{obs} + 1,\ \ \beta_{obs} - \alpha_{obs} + 1) \text{ (equation 12)},$$

where β_{obs} is the number of estimated primary cases, and α_{obs} is the number of laboratory-confirmed cases (*2*,*5*). Because of the clustering of the cases by outbreak, the above estimation could potentially be biased.

In equation 1, the number of servings of a given dairy product and pasteurization status, $N_{serving}$, was calculated as:

$$N_{serving} = N_{resid} \times N_{pers\ serv} \times p_{cons} \text{ (equation 13)},$$

where N_{resid} is the total resident population in the United States (online Technical Appendix Table 3), $N_{pers\ serv}$ is the number of servings per person, and p_{cons} is the proportion of the population of dairy consumers who consume milk or cheese of a given pasteurization status. For example, $p_{cons,milk,unpast}$, the proportion of the population of dairy consumers that consumes unpasteurized milk, is calculated as:

$$p_{cons_{milk,unpast}} = \frac{P_{UnPcons,milk}}{P_{UnPcons,milk} + P_{Pcons,milk}} \text{ (equation 14)},$$

with $P_{UnPcons,milk}$ being the proportion of the US population consuming unpasteurized milk and $P_{Pcons,milk}$ being the proportion of the US population consuming pasteurized milk. $N_{pers\ serv}$ is estimated from the per capita consumption, C_o (online Technical Appendix Table 4), and the mean serving size, *s* (online Technical Appendix Table 1):

$$N_{pers\ serv} = \frac{Co}{s} \text{ (equation 15).}$$

Estimation of the Proportion of the US Population Consuming Milk or Cheese of a Given Pasteurization Status, $P_{UnPcons}$ and P_{Pcons}

The estimates of the proportion of consumers of milk or cheese of a given pasteurization status in the United States was derived from the FoodNet Population Survey Atlas of Exposures 2006–2007 (*6*). P_{Pcons} was calculated as the weighted average of $P_{c,state}$, the FoodNet state-specific proportion of consumers of milk or cheese of a given pasteurization status, and w_{state}, the proportion of the FoodNet survey population that is from that given state (online Technical Appendix Table 5):

$$P_{Pcons} = \sum(P_{c,state} \times w_{state}) \text{ (equation 16).}$$

$P_{c,state}$ is given by

$$P_{Pc,state} \sim \text{Beta}(N_{Pcons} + 1\ , N_{survey} - N_{Pcons} + 1) \text{ (equation 17),}$$

with N_{Pcons} being the number of respondents that indicated that they consumed the product in the last 7 days and N_{survey} the FoodNet survey population in the given state.

Estimation of the Excess Risks Associated with the Consumption of Unpasteurized Milk and Cheese

The additional risk of outbreak-related illness and hospitalization for consumers of unpasteurized dairy products, compared with consumers of pasteurized ones, was estimated using 2 measures of excess risk (*23*). The risk difference measures the actual difference in the incidence rates of illness and hospitalization between consumers of unpasteurized dairy products (λ_u) and consumers of pasteurized ones (λ_p):

$$\text{RD} = \lambda_u - \lambda_p \text{ (equation 18).}$$

The incidence rate ratio provides a relative comparison of the risks for illness and hospitalization between the 2 exposure groups:

$$\text{IRR} = \lambda_u / \lambda_p \text{ (equation 19).}$$

Impact of Hypothetical Changes in Consumption of Unpasteurized Milk or Cheese

A scenario analysis was performed for the year 2015 to assess the public health impact of hypothetical changes in consumption of unpasteurized dairy products. Six scenarios were considered: 10%, 20%, 50%, 100%, 200%, and 500% increases in the proportion of the US population consuming unpasteurized milk or cheese.

The number of annual outbreak-related illnesses associated with milk or cheese consumption, α_{pred}, was estimated as

$$\alpha_{pred} \sim \text{Poisson}(\lambda_u \times N_{serving,u} + \lambda_p \times N_{serving,p}) \text{ (equation 20).}$$

As shown in equation 13, the number of servings of milk or cheese for 2015 requires the estimation of the total US resident population and the per capita consumption for that year. Using a simple linear regression, we predicted these 3 values using historical data on the US resident population from 1996 through 2014 (online Technical Appendix Table 3) and milk and cheese consumption per capita from 2006 through 2014 (online Technical Appendix Table 4). The variability in the 2015 predictions for these 3 values when considering parameter uncertainty was modeled using a standard prediction interval calculation:

$$y = b0 + \beta_t x_t + t(n-2)\, Sy\sqrt{1 + \frac{1}{n} + \frac{(x_t - \bar{x})^2}{SSx}} \text{ (equation 21),}$$

where y is the prediction for the year 2015, $b0$ is the regression intercept, β_t is the slope for the year (i.e., the yearly growth or decline in y), x_t is the predicted year (i.e., year 2015), $t(n - 2)$ is the Student's t distribution with a sample size n and $n - 2$ degrees of freedom. Sy is the standard deviation of the residuals, and SSx represents the sum of squares for x. Random samples from the previously described Student's t distribution were used to generate samples from equation 21.

Servings were then counted as pasteurized ($N_{serving,p}$) or unpasteurized ($N_{serving,u}$) depending on the relative proportions of the population of dairy consumers that are consuming products of a given pasteurization status. For example, for milk consumption we assumed that the proportion of the US population consuming unpasteurized milk ($P_{UnPcons,milk}$) increases by a certain percentage, P_{inc}, but the overall proportion of the US population consuming milk (whether pasteurized or not) remains the same. Thus, we defined $\Delta P_{UnPcons}$, the change in the proportion of the population of dairy consumers that are eating unpasteurized milk, as

$$\Delta P_{UnPcons} = \frac{P_{inc} \times P_{UnPcons,milk}}{P_{UnPcons,milk} + P_{Pcons,milk}}$$ (equation 22).

And the fraction of milk servings that are unpasteurized milk servings is the sum of $P_{UnPcons,milk}$ and $\Delta P_{UnPcons}$.

The number of hospitalizations per year was modeled as a fraction of illnesses (α_{pred})

$$\alpha_{hosp} \sim \text{Binomial}(\alpha_{pred}, \rho_{hosp})$$ (equation 23),

where the uncertainty in the probability of hospitalization in case of illness is modeled using the conjugate prior:

$$\rho_{hosp} \sim \text{Beta}(\alpha_{obshosp} + 1, \alpha - \alpha_{obshosp} + 1)$$ (equation 24),

where $\alpha_{obshosp}$ is the number of reported outbreak-related hospitalizations due to illnesses from a given pathogen.

Finally, the additional illnesses or hospitalizations following a hypothetical increase in consumption of unpasteurized milk or cheese were estimated as follows:

$$\alpha_{created} \sim \text{Poisson}[\text{RD} \times \Delta P_{UnPcons} \times \sum(N_{serving,p} + N_{serving,u})]$$ (equation 25).

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Technical Appendix Table 1. Model parameters, values, and references*

Parameter	Symbol	Parameter subgroup	Value		Source
No. US laboratory-confirmed cases from outbreaks related to milk or cheese consumption 2009–2013	$N_{ODRcases}$	Pathogen	No. confirmed cases		NORS database (*2*)
		Campylobacter spp.	*365*		
		Listeria monocytogenes	98		
		Salmonella spp.	72		
		STEC	92		
Population under surveillance (and corresponding % of the US population)	$N_{FoodNet}$ ($P_{FoodNet}$)	Year	No. under surveillance (% US population)		FoodNet (*7*)
		2009	46,859,541 (15.3)		
		2010	47,145,373 (15.2)		
		2011	47,505,580 (15.2)		
		2012	47,898,745 (15.3)		
		2013	48,231,023 (15.2)		
FoodNet cases 2009–2013	$N_{FoodNetcases}$	Year	No. *Campylobacter* spp. cases		FoodNet (*7*)
		2009	6,058		
		2010	6,372		
		2011	6,785		
		2012	6,812		
		2013	6,622		
		Year	No. *Listeria monocytogenes* cases		
		2009	157		
		2010	131		
		2011	141		
		2012	123		
		2013	123		
		Year	No. *Salmonella* spp. cases		
		2009	7,023		
		2010	8,273		
		2011	7,813		
		2012	7,842		
		2013	7,307		
		Year	No. STEC cases		
		2009	747		
		2010	896		
		2011	984		
		2012	1,090		
		2013	1,126		
Proportion of outbreak related cases	$P_{ORcases}$	Pathogen	Beta(Shape1; Shape2)	95% CrI	Scallan et al. (*3*)
		Campylobacter spp.	123; 28,757	0.4%–0.5%	
		Listeria monocytogenes	10; 643	0.7%–2.6%	
		Salmonella spp.	2122; 31,557	6.0%–6.6%	
		STEC	561; 2,934	14.9%–17.3%	
Proportion of dairy-related cases	$P_{DRcases}$	Pathogen	Pert(minimum; most likely; maximum)		Painter et al. (*4*)
		Campylobacter spp.	61.8; 64.8; 65.2		
		Listeria monocytogenes	15.7; 15.9; 16.3		
		Salmonella spp.	6; 7.2; 18.6		
		STEC	2.1; 2.3; 3		
Diagnostic test sensitivity	*Se*	Pathogen	Pert (minimum; mode; maximum)		Scallan et al. (*3*)
		Campylobacter spp.	0.6; 0.7; 0.9		
		Listeria monocytogenes	0.55; 0.71; 0.83		
		Salmonella spp.	0.6; 0.7; 0.9		
		STEC	0.6; 0.7; 0.9		
Under-testing factor 2009–2013	ρ	Pathogen	1/Beta(Shape1; Shape2)	95% CrI	NORS database (*2*,*5*)
		Campylobacter spp.	468; 435	1.82–2.06	
		Listeria monocytogenes	102; 16	1.09–1.25	
		Salmonella spp.	86; 10	1.06–1.21	
		STEC	100; 15	1.08–1.25	
Serving size of dairy product	*s*	Dairy product	Serving size, lb.		USDA-ERS surveys (*8–10*)
		Milk	4.86×10^{-1}		
		Cheese	7.44×10^{-2}		

*CrI, credibility interval; NORS, National Outbreak Reporting System; STEC, Shiga-toxin–producing *Escherichia coli*; USDA-ERS, United States Department of Agriculture Economic Research Service.

Technical Appendix Table 2. Adjustment factors (means and 95% CrI) used for the estimation of the incidence rates of outbreak-related illnesses

Pathogen	Underreporting (γ)	Underdiagnosis (μ)	Under-testing (ρ)
STEC	1.15 (1.00–1.35)	1.28 (1.17–1.38)	1.15 (1.08–1.25)
Salmonella spp.	19.58 (13.64–30.13)	1.28 (1.17–1.38)	1.12 (1.05–1.21)
Listeria monocytogenes	1*	1.30 (1.20–1.40)	1.16 (1.09–1.25)
Campylobacter spp.	1.61 (1.34–1.90)	1.28 (1.17–1.38)	1.93 (1.81–2.06)

*Our calculations comparing FoodNet and National Outbreak Reporting System data suggested that there was no underreporting of *L. monocytogenes*, probably because of the severity of cases. CrI, credibility interval; STEC, Shiga-toxin–producing *Escherichia coli*.

Technical Appendix Table 3. Total US resident population (N_{resid}), 1993–2014*

Year	Population, millions
1993	259.919
1994	263.126
1995	266.278
1996	269.394
1997	272.647
1998	275.854
1999	279.04
2000	282.193
2001	285.108
2002	287.985
2003	290.85
2004	292.805
2005	295.517
2006	298.38
2007	301.231
2008	304.094
2009	306.772
2010	309.33
2011	311.592
2012	313.914
2013	316.427
2014	318.907

* The total US population for most years are estimates from the US Census Bureau, with the exception of 2000 and 2010, which are results of the US census *(1)*.

Technical Appendix Table 4. Per capita consumption of milk and cheese (C_o), 2006–2014*

Year	Milk, lb.	Cheese, lb.†
2006	183.63	32.43
2007	181.20	32.94
2008	179.10	32.39
2009	178.46	32.48
2010	177.42	32.92
2011	173.86	32.23
2012	169.90	33.49
2013	165.03	33.63
2014	158.88	34.17

*Data from US Department of Agriculture Economic Research Service *(11)*.
†Total cheese (does not include ricotta cheese).

Technical Appendix Table 5. Probability density functions of the proportion of the population consuming pasteurized or unpasteurized milk and cheese ($P_{c,state}$) and percentage of FoodNet population (w_{state}) by state, 2006–2007*

State	Proportion of population consuming milk				Proportion of population consuming cheese				FoodNet population, %
	Pasteurized		Unpasteurized		Pasteurized		Unpasteurized		
	Beta(Shape1; Shape2)	95% CrI	Beta(Shape1; Shape2)	95% CrI	Beta(Shape1; Shape2)	95% CrI	Beta(Shape1; Shape2)	95% CrI	
CA	434; 132	73.1%–80.1%	34; 1,057	2.1%–4.2%	323; 204	57.1%–65.4%	28; 1,063	1.7%–3.6%	7.07
CO	723; 183	77.2%–82.4%	45; 1,798	1.8%–3.2%	624; 315	63.4%–69.4%	27; 1,816	1.0%–2.0%	5.88
CT	739; 178	78.0%–83.1%	50; 1,754	2.0%–3.6%	522; 367	55.4%–61.9%	30; 1,774	1.1%–2.3%	7.62
GA	720; 213	74.4%–79.8%	70; 1,743	3.0%–4.8%	489; 393	52.2%–58.8%	21; 1,792	0.7%–1.7%	20.77
MD	698; 233	72.1%–77.7%	56; 1,783	2.3%–3.9%	499; 411	51.6%–58.1%	27; 1,812	1.0%–2.0%	12.23
MN	785; 145	82.0%–86.7%	43; 1,773	1.7%–3.1%	549; 339	58.7%–65.0%	26; 1,790	1.0%–2.1%	11.31
NM	687; 219	73.0%–78.6%	61; 1,711	2.7%–4.4%	562; 306	61.6%–67.9%	45; 1,727	1.9%–3.3%	4.29
NY	744; 191	76.9%–82.1%	65; 1,775	2.8%–4.4%	541; 366	56.5%–62.8%	32; 1,808	1.2%–2.4%	9.29
OR	684; 216	73.2%–78.8%	51; 1,745	2.1%–3.7%	644; 254	68.8%–74.6%	26; 1,770	1.0%–2.1%	8.15
TN	723; 202	75.4%–80.7%	63; 1,715	2.7%–4.5%	456; 399	49.9%–56.6%	28; 1,750	1.0%–2.2%	13.4

*Data derived from the FoodNet Population Survey Atlas of Exposures (*6*). CrI, credibility interval.