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Colorado Department
of Public Health
and Environment

Date: November 6, 2009

To: File, Colorado Department of Public Health and Environment (CDPHE), Communicable Disease Epidemiology Program
CDPHE Laboratory Services Division
CDPHE Consumer Protection Division
CDPHE Public Information Office
Montrose County Public Health
Mesa County Health Department
Eagle County Public Health
Eagle County Environmental Health
Garfield County Public Health
Pitkin County Environmental Health
Delta County Health Department
Ouray County Public Health

From: Kate Lujan, Alicia Cronquist, CDPHE Communicable Disease Epidemiology Program

Re: Outbreak # 2009-43-001 – Campylobacter Outbreak Associated with Consumption of Unpasteurized Milk from a Cow Share Operation, Montrose County 2009

Background

On April 2, 2009, the CDPHE field epidemiologist based in Grand Junction noted three recently reported laboratory-confirmed Campylobacter cases in the Colorado Electronic Disease Reporting System (CEDRS), one each in Montrose, Ouray, and San Miguel Counties. These counties are contiguous in the Western Slope of Colorado. Investigation of these cases by local public health nurses and the field epidemiologist using the routine CDPHE Campylobacter questionnaire revealed that all three consumed unpasteurized milk from the Kinikin Corner Dairy in Montrose County during the week before illness onset.

The sale of raw or unpasteurized milk is illegal in Colorado, however cow share programs are permitted (C.R.S. 25-5.5-117). Shareholders purchase a cow jointly and pay boarding fees for their cow. A dairy manager operates the herd. Shareholders are given a quantity of raw milk based on the number of shares the owner holds. The dairy must be registered with CDPHE, although CDPHE does not inspect or regulate these operations. Kinikin Corner Dairy has

available on their website <http://www.freshrawmilk.com/index.html> a copy of their contract, boarding agreement and standards that the dairy professes to uphold.

On April 3, 2009, a CDPHE dairy inspector, a CDPHE field epidemiologist, and the regional epidemiologist from Mesa County Health Department conducted an unannounced visit to the dairy. The operator allowed the team to visualize the milking parlor and the milk house where the product was handled. The CDPHE dairy inspector collected milk samples for testing at the state public health laboratory. The team requested a shareholder list and asked the operator to cease milk distribution, and to notify all shareholders about the association of *Campylobacter* illness with consumption of milk from the dairy. The operator agreed to both requests.

By April 6, 2009, seven additional laboratory-confirmed cases were reported through CEDRS among residents of the following counties: Delta, Eagle, and Garfield and Montrose. Historically, the counties of Delta, Eagle, Garfield, Montrose, Ouray, and San Miguel have an average of two lab-confirmed *Campylobacter* cases reported during March 15 through April 30. This was clearly an increase over what is expected at that time of year.

Laboratory-Confirmed *Campylobacter* Cases Reported March 15–April 30 by County and Year, Southwestern Colorado

County	2009	2008	2007	2006	2005
Delta	2	1	1	0	1
Eagle	2	0	1	0	0
Garfield	2	0	1	0	1
Montrose	4	2	0	0	0
Ouray	1	0	0	0	0
San Miguel	1	0	0	0	0

Campylobacter infection caused by *Campylobacter* bacteria and often results in an intestinal illness. Typical symptoms are diarrhea (sometimes bloody), abdominal pain, fever, fatigue, headache, nausea and vomiting. Symptoms usually last 2-10 days, and symptoms sometimes recur. Guillian-Barré syndrome is thought to be associated with *Campylobacter* infection. Not all infected persons show signs and symptoms. The incubation period can range from 1 to 10 days, but is usually 2 to 5 days.

A public health order (see Appendix 1) was issued to the implicated dairy by CDPHE on April 7, 2009 to cease distribution after CDPHE learned that the dairy manager had not contacted all shareholders and was continuing to distribute milk. The dairy manager stated that he had no right to withdraw the milk from distribution since he did not own the milk. The dairy manager ceased distributing the milk after receiving the public health order. In conjunction with case finding and a cohort study described below, the epidemiology team attempted to contact all shareholders on a list provided by the dairy operator to alert them to the outbreak and counsel them to discard all products from the dairy. The public health order was modified on April 10 to include conditions required to resume distribution. The dairy resumed distribution on April 22, 2009 after meeting the conditions for reopening stipulated in the public health order.

Epidemiologists, Environmental Health Specialists and Public Health Nurses from CDPHE and local public health agencies on the Western slope worked together to investigate this outbreak. The objectives of the outbreak investigation were (1) to determine the magnitude of the outbreak, (2) to determine the source of the outbreak, and (3) to recommend control measures to prevent future outbreaks of this nature.

Methods

Case definitions: We used the following definitions:

Confirmed: A person with laboratory-confirmed *Campylobacter* infection with illness onset since March 15, 2009, who consumed products originating from Kinikin Corner Dairy.

Probable: A person with onset of a *compatible gastrointestinal illness* since March 15, 2009, who is epidemiologically-linked to a confirmed case or who consumed products from the Kinikin Corner Dairy within 10 days prior to onset. *Compatible gastrointestinal illness* was defined as a gastrointestinal illness lasting greater than one day with the following symptoms:

- Diarrhea accompanied by at least one other symptom: bloody stool, fever, or abdominal pain; **or**
- Three or more episodes of diarrhea within a 24-hour period.

In addition, cases were classified as primary or secondary using the following criteria:

Primary: A person who meets one of the case definitions and has the earliest illness onset within a given household.

Secondary: A person who meets one of the case definitions and has an illness onset one or more days after the “primary” case in a given household.

Case finding: We looked for additional laboratory-confirmed cases via daily surveillance of *Campylobacter* cases reported in CEDRS. For any newly reported *Campylobacter* cases residing on the Western slope, the regional epidemiologist contacted the appropriate local public health agency to inquire about whether the new case consumed raw milk. For non-Western slope case surveillance, we distributed information about the outbreak to other Colorado local public health agencies via the CDPHE weekly communicable disease newsletter and an e-mail to all local public health agencies, and to other states via EpiX and a report on the foodborne outbreak listserv. These agencies were asked to report cases that may be associated with the outbreak to CDPHE. Cases were also identified during interviews of shareholders as described below.

Foodnet Population survey comparisons: We used the 2007-2008 FoodNet population survey to estimate the frequency of consumption of unpasteurized milk among Colorado survey respondents. We compared the frequency reported in the population survey to the frequency of unpasteurized milk consumption among reported cases.

Cohort study: The dairy operator provided a list with contact information for approximately 200 shareholders in Montrose, Delta, San Miguel, Ouray, Garfield, Eagle, and Pitkin Counties. A cohort study using a standard questionnaire was conducted (see Appendix 1). The cohort consisted of persons who had received products from the dairy since March 1, 2009.

Interviewers were public health professionals with backgrounds in nursing, environmental health, epidemiology, or emergency management from Eagle, Delta, Garfield, Montrose, Pitkin and Mesa counties in addition to regional epidemiologists and CDPHE epidemiologists. All completed interviews were faxed to the Denver office of CDPHE for entry into an Access database. Analysis was performed using SAS 9.1. For descriptive analysis, we calculated frequencies, means and medians, as appropriate. For the cohort analysis, we calculated food specific attack rates and relative risks with 95% confidence intervals. We also used the Chi square test for linear trend for dose-response analyses. Exposure variables with a p-value ≤ 0.05 were considered statistically significant.

Laboratory methods: All symptomatic persons identified during shareholder or case interviews were asked to submit stool samples for Campylobacter culture at either a private laboratory or the state public health laboratory. Laboratories that reported outbreak-associated Campylobacter cases were asked to submit remaining isolates to the state public health laboratory for confirmation and pulsed-field gel electrophoresis testing.

The state public health laboratory performed testing on milk samples collected April 3 and April 14. Tests included standard plate count, somatic cell count, coliform, phosphatase, beta-lactam antibiotics, and Campylobacter PCR and culture.

Environmental health investigation: A CDPHE dairy inspector and an Environmental Health Specialist from Montrose County visited the dairy on April 3, 13 and 14 to observe dairy operations and provide recommendations for improvements. The CDPHE dairy inspector trained the Montrose environmental health specialist in milk sampling processes. Milk samples were obtained on the following dates: April 3, 14, 22, and May 1 and 6. Recommendations for improvements in the operation were provided verbally at the time of visits and in writing in the public health orders.

Results

Epidemiology: We compared the frequency of unpasteurized milk consumption among the first five reported cases to that found in the 2007-2008 FoodNet population survey. All five (100%) of the first Campylobacter cases reported during this outbreak (from Eagle, Montrose [2], Ouray, and San Miguel counties) had consumed unpasteurized milk during the 7 days before onset. In comparison, only 2.4% of Colorado respondents in the Population Survey had consumed unpasteurized milk in the preceding 7 days. Using the Population Survey respondents as a rough control group, there was a very strong association between infection and unpasteurized milk ($p < 0.0001$). Four of the five cases knew the milk was from Kinikin Dairy; the fifth did not know the source of the milk consumed.

We attempted to contact 208 dairy shareholders/consumers to inform them to discard products from the dairy and to interview them for case finding and the cohort study. The operator provided a list of 201 shareholders. Seven additional persons were identified as shareholders during the interview process, including four laboratory confirmed cases ascertained through routine surveillance who reported consuming unpasteurized milk from the dairy. Up to four telephone attempts were made for each shareholder. Interviewers left detailed voicemail

messages when unable to reach shareholders over the phone. Letters were mailed to 12 persons who did not have phone numbers listed or whose phone numbers appeared to be incorrect. In total, 159 shareholders were interviewed, for a response rate of 76%. Illness and food consumption information was collected for 372 persons in those 159 households. See Table 1 in Appendix 2 for more details.

Descriptive information about the types of products received from the dairy and how they are picked up are in Table 2. Among the 159 shareholders/consumers who were interviewed, 151 (95%) reported receiving milk from the dairy since March 1, 2009. Of these, 91 (60%) picked up their milk from a co-op or some other location other than the dairy. Only 39 (26%) picked up their milk directly from the dairy and 19 (13%) reported receiving their milk from someone else. Most shareholders/consumers (73%) reported receiving milk weekly. Thirty-nine respondents (28%) reported noticing some type of labeling on the milk jars. Of these, one person (3%) recalled seeing a label that indicated the milk was unpasteurized or raw and 29 (76%) recalled seeing a production or use-by date. Few shareholders/consumers reported receiving products other than milk.

In total, 81 cases were identified. Twelve cases were laboratory confirmed and 69 were probable (Table 3). There were 58 primary cases and 23 potential secondary cases. Fifty of the 151 (31%) shareholders/consumers who received milk from the dairy since March 1, 2009 reported at least one person in the household who met the confirmed or probable case definition. The median age of cases was 32 years (range 1-79 years); 36 (47%) were female. All identified cases resided in Western slope counties. Symptom information is summarized in Table 4. The most common symptoms were diarrhea (100%), fatigue (87%), abdominal cramps (86%), and fever (79%). Twenty-nine persons (40%) reported bloody diarrhea. One person was hospitalized and there were no deaths.

Symptom onset dates were between March 19 and April 24 (see epidemic curve in Appendix), with a peak during the last week of March. Most cases had onset before the outbreak was detected by routine surveillance. The case with onset on April 24 was a laboratory-confirmed case who reported consuming milk from Kinikin dairy and who had no exposure to ill persons before his onset. This case reported that he was aware of the outbreak but had not discarded his milk as advised and may have consumed raw milk during his incubation period that was received during the outbreak period.

We calculated food-specific attack rates and relative risks for each food item available at the dairy using all cases, and two sub-analyses using only primary cases and only confirmed cases. Results were similar for all three analyses and are presented in Tables 5A, 5B and 5C. None of the food items was statistically significant, however consuming unpasteurized milk had a relative risk (RR) of 1.79 and approached significance with a confidence interval of 0.97 – 3.31. Milk had the highest attack rate among those who reported consuming it (24%) and the lowest attack rate among those who did not report consuming it (13%). Very few cases consumed food products other than milk. Seventy-one of 81 cases (88%) reported consuming milk. The next most frequently consumed product reported by cases was eggs, which only 3 cases reported consuming. Multi-variable analysis was not attempted due to small cell sizes for all foods except milk.

While drinking any milk was not statistically significant, there was a statistically significant dose-response relationship between illness and the reported quantity of milk consumed (Table 6). Compared to those who reported drinking no milk, ill persons were 1.37 times more likely to have reported drinking less than one cup per day, were 2.47 times more likely to have reported drinking 1-2 cups per day; and were 2.73 times more likely to have reported drinking greater than two cups per day. The Mantel-Haenszel chi square test for linear trend was statistically significant ($p=0.005$).

We asked shareholders/consumers to list the reasons why they chose to drink unpasteurized milk (Table 7). Categories were not mutually exclusive and included: more nutritious, tastes better, more natural, more creamy, boosts immune system, helps with allergies, and lactose intolerant. The most commonly reported responses were: More nutritious (43%); tastes better (35%); and more natural (29%). Other reasons stated included “doctor recommended,” “safer than pasteurized milk,” and “healthier.”

Laboratory Results: Six *Campylobacter* isolates from human stool specimens were submitted to the state public health laboratory. All were confirmed as *Campylobacter jejuni* and all six had identical PFGE patterns. The PFGE pattern was uploaded into the CDC’s PulseNet database. There were no matches within the CDC database within the previous 60 days.

Phosphatase testing on the milk sample obtained April 3 indicated that the milk was unpasteurized (i.e. phosphatase was positive). *Campylobacter* culture was negative. The standard plate count was $< 2,500$.

The milk sample collected April 14 was positive by PCR for *Campylobacter* but was negative by culture for *Campylobacter*. The PCR testing performed by the state laboratory on the milk was not a standard test for milk so those results were not considered conclusive. The standard plate count was 8,600, the somatic cell count was 210,000 and the coliform count was 1 CFU/ml. The milk was negative for beta-lactam antibiotics.

Three additional milk samples were collected on April 22, May 1 and May 6 but were rejected by the laboratory because they were not delivered in the necessary time frame or did not have documentation that they were held at the correct temperature during transit, which is required for formal regulatory milk testing, although is often not required during outbreak investigations.

Environmental Inspections: Environmental inspections were conducted by CDPHE initially and subsequently by Montrose County Environmental Health. At the time of the outbreak the operator maintained 30 cows on the property of which 15 were reportedly part of the cow share program. The operator clearly stated that the cows were not his property but owned by the cow share participants.

The environmental health report from the April 3 visit read as follows:

“The milking parlor was inadequately built/constructed shed which failed to meet the minimum standards prescribed in the Pasteurized Milk Ordinance or the Manufactured

Milk Regulations, as well as the standards described on the dairy's own raw milk website. The floor consisted of dirt and hay, and was soiled with manure. The interior was unfinished plywood, with openings directly to the outside around the door and other various points within the structure. Overall the structure was not clean nor in good repair. Animals other than cows (dog, chicken) entered the milking area during the visit. The milk room/house (storage area) was well constructed and had the minimum of equipment. There was evidence of manure being tracked into the milk house."

A milking machine consisting of a milk bucket covered by a single milk claw was used for the twice daily milking. The operator reported using a teat dip technique whereby the udder was cleaned with a rag soaked in iodine. A new rag was used for each cow. The milk, transported using the covered milking machine bucket, was carried across a dirt road to the milk house where it was poured through a filter into a refrigerated bulk milk tank. There were no handwashing facilities in the milking parlor. Sanitizing solution was not used to sanitize the Mason jars used to bottle the milk, and on the day of inspection, there was no chlorine sanitizing solution present.

Milking Parlor



Refrigerators in Milk House



The temperature of the bulk milk tank was 37 degrees F. The bottling occurred in the milk room. The milk was poured into Mason jars via mechanical means. The operator or a volunteer washed the Mason jars after the jars were returned from the shareholders. The room contained three domestic refrigerators and a commercial sanitizing dishwasher, which was being operated without sufficient hot water and no sanitizing solution. An on-demand hot water heater was used to heat the water that came from a cistern. The cistern was filled with water from the community water system, Project Seven, using ordinary hoses. Per the operator, a private lab tested the milk monthly and those results were posted on the dairy website for shareholders to review.

Bulk Milk Tank



Shareholders conducted distribution of the product. Jars were placed into coolers with ice by a volunteer or by the operator and transported to pick up points. No thermometers were in the coolers to monitor temperatures of the milk. The cooler that had been packed for delivery at the time of inspection had no ice. The pick up points were located in multiple counties and settings such as Community Supported Agriculture (CSA) pickup points and farmers markets. Labels on the jars indicated the production date. There was no label indicating that the milk was raw.

Cooler loaded for distribution



Discussion

There were a total of 81 cases identified in this *Campylobacter* outbreak, which is most likely due to consumption of unpasteurized milk from the cow share program at Kinikin Dairy. Thirty-one percent of all shareholder households reported at least one person with illness that met the case definition, which is a substantial attack rate.

The initial case interviews strongly suggested an association with unpasteurized milk. We tested this association informally by using the FoodNet Population survey as a control group. As the association between unpasteurized milk and illness was very strong and all cases who knew where the unpasteurized milk had come from reported Kinikin Dairy, we focused the investigation on this dairy and conducted a cohort study to determine exposures associated with illness.

In the cohort analysis, drinking any milk was not statistically significantly associated with illness, however it was by far the product most frequently consumed by the cases. Further, we identified a dose-response relationship between consumption of milk and illness that remained significant when the analysis was limited to only primary cases or only adults. Ill persons had higher odds of consuming more milk than persons who remained well. Last, all six PFGE-matched cases had consumed unpasteurized milk from this dairy but did not have other exposures in common, making the dairy the most likely source of infection.

The dairy operator was found to be knowledgeable of sanitary standards and testing methods. However, sanitary measures such as having hand washing stations, the use of bleach for sanitizing bottles, proper dishwashing water temperatures, and monitoring of transport temperatures were not implemented. In addition, the milking parlor was partially open to the elements, had a dirt floor, and milk was hand carried from the parlor to the bottling house. After the multiple potential routes of contamination were reviewed with the operator, he installed a temporary hand sink in the milk parlor, added bleach to the dishwasher, and labeled the jars indicating that the milk was unpasteurized.

Most cases had onset before public health became aware of the outbreak. No additional cases associated with this dairy have been reported since the implementation of the environmental safeguards with the exception of the one case with onset on April 24 who did not heed the recommendation to discard his milk.

This investigation had several limitations. Although we attempted to contact all shareholders, we may not have ascertained all cases associated with this outbreak. The focus of case ascertainment was on laboratory-confirmed cases in Western slope counties and persons on the shareholder list provided by the manager. Case ascertainment for other regions in the state and in other states was more passive and we were not able to interview all shareholders. Further, it is clear from the survey that milk is distributed widely through a network of other persons, CSA's and farmers' markets so the true number of persons potentially exposed to the milk is not known. Four laboratory-confirmed cases that reported drinking the raw milk from the dairy were not on the shareholder list.

The FoodNet population survey enrolls participants only from the Denver metropolitan area (Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas and Jefferson counties) so it does not capture food preferences for most rural Colorado residents. This means it may underestimate the true proportion of persons who consume unpasteurized milk during a seven-day period. However, even if the proportion of raw milk drinkers in Western Colorado were 30% (far higher than reported by any other state in the Population Survey), this is far less than the 100% reported by the first five cases we used in our comparison and would still be statistically significant.

Because milk is often consumed daily and even multiple times per day, it was not possible to calculate incubation periods. Further, in many households one container of milk will likely be consumed over multiple days. It was also difficult to determine whether cases occurring after the first case in a household were due to person-to-person transmission within the household (which is very rarely documented for *Campylobacter*) or whether additional cases were also due to consumption of contaminated milk with either longer incubation periods or later dates of exposure. For this reason, we used a conservative approach and considered all cases in a household with an onset date one or more days after the first case to be potential secondary cases and excluded them from analysis, thus decreasing the study's power to detect associations.

Finally, cultures of milk obtained during the April 3 visit to the dairy did not yield *Campylobacter*, however, the epidemiologic data pointing to unpasteurized milk are quite strong. Most cases had occurred before the outbreak was detected on April 2 so it is possible that the *Campylobacter* was no longer present in the milk by the time milk testing at the CDPHE laboratory began. Further, isolating *Campylobacter* from milk is technically difficult and the sensitivity of such testing may be low. While cultures were not positive on April 3 or April 14, the milk collected on April 14 was positive for *Campylobacter* by PCR. PCR is not part of standard milk testing used for regulatory purposes, however it has been used by the state public health laboratory in outbreak investigations on a variety of food items. The PCR indicates that DNA of *Campylobacter* bacteria were present in the milk, however PCR testing does not indicate whether any viable bacteria (i.e. able to cause infection) were present at the time of testing.

The April 10 public health order stipulated that, after resuming operations, the dairy's milk would be sampled for testing twice a week for two consecutive weeks and that this milk must meet certain sanitary standards including negative cultures for *Campylobacter*. In order to perform the *Campylobacter* cultures, the milk needed to be tested at the state public health laboratory. Although attempts were made to ensure the integrity of the samples, including chain of custody logs, ice packs, and use of a courier service, the distance from the dairy to the state public health lab in Denver proved to be a significant challenge. Three milk samples taken at the dairy were rejected for testing by the state lab. These stipulations were found to be unfeasible and were not pursued further by CDPHE.

Conclusions

Unpasteurized milk has been the source of numerous outbreaks in the past, in Colorado and other states. Another *Campylobacter* outbreak associated with unpasteurized milk from a cow share operation occurred in Larimer County in 2005. Outbreaks of *Salmonella*, *E. coli* O157 and *Listeria* associated with unpasteurized milk have been documented in other states and have

resulted in deaths and cases of hemolytic uremic syndrome. Fortunately this outbreak involved only one hospitalization and no deaths. With the increasing number of cow share programs, outbreaks associated with unpasteurized milk are likely to continue in Colorado. In addition to the human costs of illness, the public health costs of investigating this type of outbreak are significant.

Unpasteurized milk is an inherently risky food. Raw milk producers must be meticulous with all sanitary procedures during milking, transport, bottling and storage. In this outbreak, there were several areas for improvement including the physical layout of milking parlor, lack of hand sinks, and lack of sanitizer. It is strongly encouraged that raw milk producers follow all sanitary procedures as if they were producing Grade A milk. The Department does not have the authority to inspect or regulate cow share operations. However, even with excellent handling, milk that is not pasteurized can cause outbreaks. No major deficiencies were noted during the 2005 Larimer county outbreak, yet an outbreak due to the unpasteurized milk still occurred.

Since raw milk cannot be made safe unless it is pasteurized it is very important for consumers to be aware of the risks of consuming it. Anyone can become ill from consuming unpasteurized milk, however persons who are under 5 or over 65 years old, pregnant women, and persons who have a weakened immune system or who use medication that weakens the immune system should especially avoid unpasteurized milk.

All unpasteurized milk should be clearly labeled, which was not the case in this outbreak. The Colorado raw milk statute stipulates that milk should not be distributed beyond the cow share shareholder, who should be fully informed of what he/she is consuming, however this outbreak demonstrated that the milk is often distributed beyond the actual shareholder and originating farm.

While this outbreak may have been ending on its own by the time public health became aware of it, the subsequent investigation yielded several recommendations for the dairy to follow to decrease the risk of a recurrence in the future.