Epidemiol. Infect. (2016), **144**, 2728–2731. © Cambridge University Press 2015
doi:10.1017/S0950268815003039

SHORT REPORT
Outbreak of *Listeria monocytogenes* infections linked to a pasteurized ice cream product served to hospitalized patients

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Received 28 July 2015; Final revision 21 October 2015; Accepted 11 November 2015; first published online 18 December 2015

SUMMARY

Two cases of hospital-acquired listeriosis were linked to a commercially produced, pasteurized ice cream mix. Manufacturers should implement safety measures from the Food Safety Modernization Act to minimize the risk of *Listeria* contamination. Dietary guidelines for persons at high risk of listeriosis may need revision to recognize the potential risk from pasteurized products.

Key words: Ice cream, *Listeria*, listeriosis, milk shake, outbreak.

Listeriosis is an uncommon, often severe foodborne illness caused by infection with the bacterium *Listeria monocytogenes*. Around 1600 human cases are reported each year in the United States, 94% of which result in hospitalization [1, 2]. Listeriosis is the third leading cause of foodborne-related deaths in the United States, with a case-fatality rate approaching 21%; the elderly, pregnant women, and persons with weakened immune systems are at highest risk for serious illness [1–4]. *Listeria* bacteria are ubiquitous in the environment and while optimal temperatures for growth are 30–37 °C, slow growth of *L. monocytogenes* has been recorded at temperatures as low as −1·5 °C, indicating that the organism can survive in both chilled and frozen foods [5, 6].

Dietary guidelines have been developed to help persons prone to invasive listeriosis minimize their risk of infection. Food protection agencies warn those at high risk for listeriosis against consumption of refrigerated delicatessen meats and hot dogs that are not subsequently reheated, unpasteurized milk and soft cheeses, smoked fish, and salads and other ready-to-eat foods made in commercial delicatessens. Pasteurized dairy products including milk shakes and ice cream are not currently listed as foods persons at higher risk for listeriosis should avoid [7–9]. While *L. monocytogenes* has been detected in ice cream [10], to our knowledge, this is the first report of listeriosis resulting from pasteurized ice cream products. We describe two cases of hospital-acquired listeriosis in Seattle, Washington in 2014 associated with consumption of

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a locally produced high-protein liquid ice cream mix made with pasteurized milk. Identification of these cases and closely related bacterial strains in finished product and the production environment led to a temporary closure and voluntary recall of all products produced by the manufacturer.

Patient 1, a non-Hispanic male in his fifties, was admitted to hospital A on 2 November 2014 and underwent heart transplantation on 3 November 2014 for end-stage cardiomyopathy; immunosuppressive medications included tracrolimus, prednisone, mycophenolate mofetil and anti-thymocyte globulin. Fifteen days post-transplant, the patient developed a fever and chills, and blood cultures were positive for *L. monocytogenes*. The patient was treated with intravenous ampicillin followed by oral amoxicillin-clavulanate and recovered without complications (Fig. 1).

Patient 2 was a non-Hispanic male in his fifties with multiple comorbidities including myelofibrosis managed with hydroxyurea. He was hospitalized at hospital A on 27 October 2014 for a gastrointestinal bleed complicated by enterococcal bacteraemia. Within 24 h following discharge on 4 December 2014, the patient developed fatigue, headache, fever and confusion and was readmitted. Blood cultures were positive for *L. monocytogenes* and the patient was treated with intravenous ampicillin and discharged to a skilled nursing facility for completion of treatment; he died 4 months later for reasons unrelated to his listeriosis.

Both patients were interviewed with the Centers for Disease Control and Prevention's standardized *Listeria* Initiative questionnaire [11]. Dietary records were reviewed and patients were questioned about consumption of food using information from hospital menus. Food items consumed by both patients included delicatessen meats (ham and turkey, respectively), cut cantaloupe and watermelon, milk, butter, ice cream, and milk shakes. Milk shakes were consumed almost daily by both patients during their hospital stays. Patient 1 reported ordering milk shakes 2–4 times per week while hospitalized. Patient 2 ordered two milk shakes per meal per day.

An environmental assessment of hospital A kitchen was conducted on 10–11 December 2014 by Public Health and the Washington Department of Health (WA DOH), and included review of food preparation practices for suspect food items and of cleaning and sanitizing procedures for food contact surfaces and equipment. Product source information was obtained to initiate traceback activities for suspect food items. Focused sampling was conducted targeting equipment and ingredients used to make suspect food items. Six food samples and 17 environmental samples were collected for testing. On 15 December 2014, unopened packages of ice cream mix (chocolate and vanilla) and a sample from the vanilla milk shake machine tested positive for *L. monocytogenes*.

On 15 December 2014, the Washington State Department of Agriculture (WSDA) and WA DOH notified the ice cream manufacturer of the test results and WSDA initiated an inspection at the processing facility. Ice-cream-mix processing records were reviewed and 63 environmental samples, three cases of unopened ice cream mix, and several single serving containers of ice cream were collected for testing. The manufacturer voluntarily ceased production and began contacting clients, instructing them to hold products pending further investigation.

Testing of food and environmental samples was performed at WA DOH PHL and WSDA. Preliminary screening of enriched food and environmental samples was performed on the VIDAS® instrument with the *L. monocytogenes* II (LMO2) kit (bioMérieux, USA). Confirmatory testing of clinical isolates from the case patients was performed at the WA DOH Public Health Laboratories (PHL). Confirmation for *L. monocytogenes* on all samples was performed using traditional culture-based and conventional biochemical identification methods at WA DOH PHL and using the VITEK instrument at WSDA Microbiology Laboratory. Pulsed-field gel electrophoresis (PFGE) analysis was performed at WA DOH PHL and at the Food and Drug Administration (FDA) Pacific Regional Laboratory Northwest (PRL-NW). PFGE methods have been described previously [12–14].

The clinical isolates for the case patients yielded closely related PFGE patterns that differed by two bands (patterns A and B). Ten ice cream product samples obtained from hospital A and the ice cream manufacturer and 36 environmental samples from the processing facility and equipment yielded *L. monocytogenes*. All positive product samples, including unopened chocolate and vanilla ice cream mix and a sample of the machine-dispensed vanilla milk shake from hospital A, and unopened chocolate ice cream mix and vanilla single-serving ice cream cups collected from the manufacturer, were indistinguishable from pattern A by PFGE. Twenty-four environmental samples from the ice cream manufacturer also yielded pattern A. Nine environmental samples from the manufacturer yielded PFGE pattern B. Three

https://doi.org/10.1017/S0950268815003039 Published online by Cambridge University Press

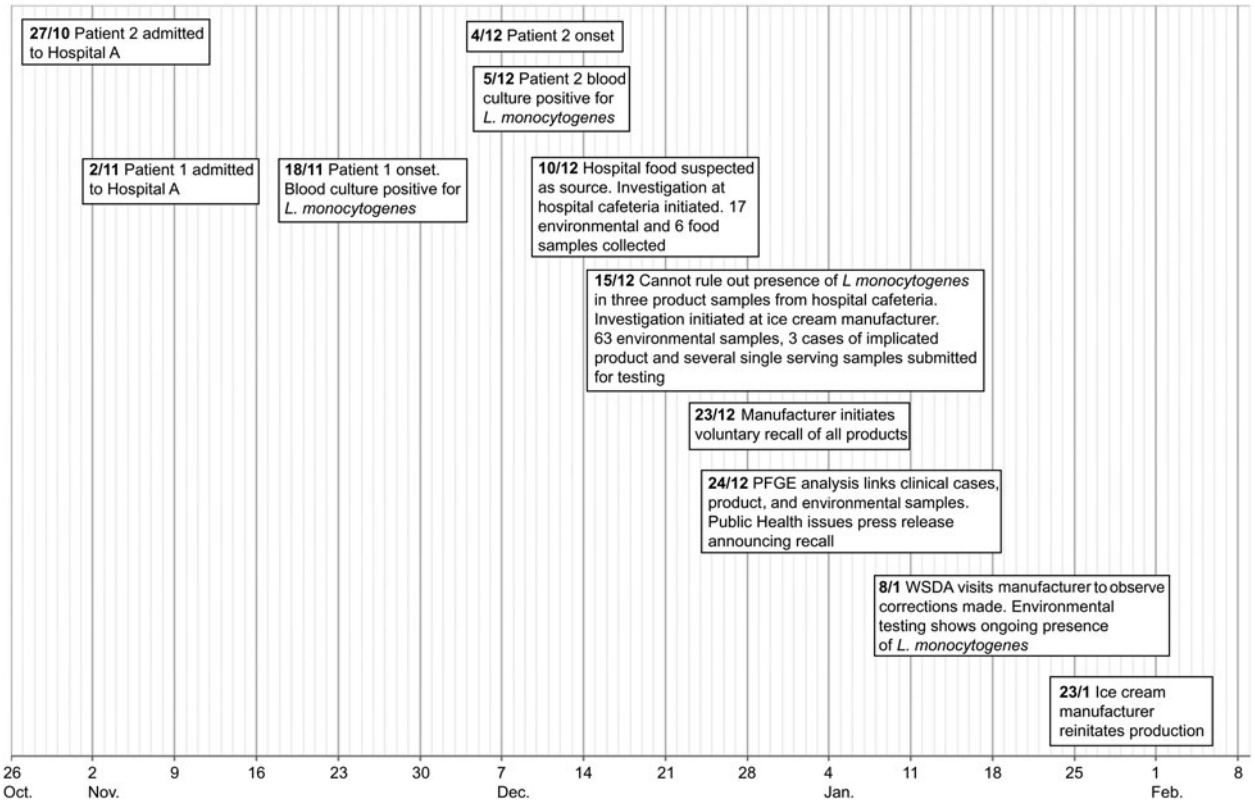

Fig. 1. Timeline of epidemiological, environmental, laboratory and regulatory actions in investigation of listeriosis in pasteurized ice cream product.

additional PFGE patterns (patterns C, D, E) were detected, each in a single environmental sample from the manufacturer that grew *L. monocytogenes*. A 6-month retrospective review of the national PulseNet PFGE database for patterns A–E yielded no additional outbreak-associated cases. *L. monocytogenes* was not detected in any of the environmental samples collected from hospital A.

Upon notification that *L. monocytogenes* contamination could not be ruled out in product and environmental samples, the ice cream manufacturer distributed a press release on 23 December 2014 notifying the public of their voluntary recall of all products produced on or after 1 January 2014. In Washington, local health jurisdictions, WSDA and the FDA Seattle District Office (FDA SEA-DO) contacted all retail outlets and food processors that received recalled products to verify removal from commerce and provide guidance on cleaning and disinfection of ice-cream processing equipment. The manufacturer hired a food safety consultant and contracted with an independent laboratory to initiate testing of incoming ingredients, finished product, and environmental samples. The production facility was disinfected, the floor of the manufacturing area upgraded, and employees were trained on food safety practices. On 23 January 2015, after repeat environmental and product samples showed no presence of *L. monocytogenes*, the ice cream manufacturer reintroduced its products into commerce.

Hospital A was instructed to disassemble their two milk shake machines in order to thoroughly clean and sanitize all surfaces. Following disinfection, culture sampling of the milk shake machines performed by hospital staff detected residual contamination with *L. monocytogenes*. Both machines underwent a second round of cleaning and disinfection and were resampled; no *L. monocytogenes* was found. Hospital staff reinitiated milk shake service using ice cream mix from a different manufacturer.

Two listeriosis infections were attributed to the same pasteurized, commercially produced liquid ice cream mix served in hospital milk shakes in Seattle, Washington during November–December 2014. In February 2015, a multistate outbreak of listeriosis affecting ten people over several years was reported; this was also attributed to commercial ice cream products and included hospital-acquired infections [15].

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Clinicians and public health officials should inquire about history of frozen and other dairy product consumption for suspected and confirmed cases of listeriosis. Ice cream and milk shakes made from pasteurized milk are not included on the U.S. FDA's list of foods to avoid for those at risk of developing invasive listeriosis. Further study is needed to determine whether the risk of listeriosis associated with pasteurized dairy products merits a revision in dietary guidelines for persons at high risk for listeriosis.

The application of new safety measures included in the Food Safety Modernization Act (FSMA) could help prevent *Listeria* infections. Intervention during food processing has the added benefit of not eliminating a nutritious food group from the diet of those at risk of infection. Implementation of a facility sanitation schedule, creation of an environmental monitoring programme, and finished product testing reflect best practices for addressing *L. monocytogenes* contamination in a food manufacturing facility. Currently these practices are included in the proposed rule for preventive controls under FMSA. Proactive adoption of these practices may assist food processors in better controlling hazards identified within their facility when manufacturing high-risk and/or ready-to-eat foods for both immunocompromised persons and the general public.

ACKNOWLEDGMENTS

The authors thank Lauri Serafin and Meagan Kay of the Communicable Disease Epidemiology and Immunization Section, Public Health – Seattle & King County for their investigative work and manuscript review, respectively. Thanks are also due to Claudia Coles, Lucy Severs, Mike Tokos, Keren LaCourse, and Candace Jacobs from the Washington State Department of Agriculture for their review of the manuscript, and Alicia Weitzel of the U.S. Food and Drug Administration for traceback and regulatory coordination throughout this investigation. The authors also thank William Glover, Ailyn Perez-Osorio, Jennifer Swoveland, and Kaye Eckmann of the Washington State Public Health Laboratories for laboratory testing and analysis expertise and manuscript review.

DECLARATION OF INTEREST

None.

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