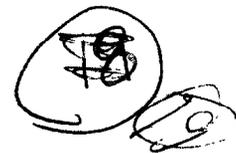


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A NATIONAL OUTBREAK OF *SALMONELLA ENTERITIDIS* INFECTIONS FROM ICE CREAM

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Abstract Background. In September 1994, the Minnesota Department of Health detected an increase in the number of reports of *Salmonella enteritidis* infections. After a case-control study implicated a nationally distributed brand of ice cream (Schwan's) in the outbreak, the product was recalled and further epidemiologic and microbiologic investigations were conducted.

Methods. We defined an outbreak-associated case of *S. enteritidis* infection as one in which *S. enteritidis* was cultured from a person who became ill in September or October 1994. We established national surveillance and surveyed customers of the implicated manufacturer. The steps involved in the manufacture of ice cream associated with cases of *S. enteritidis* infection were compared with those of products not known to be associated with infection matched for the date of manufacture. Cultures for bacteria were obtained from ice cream samples, the ice cream plant, and tanker trailers that had transported the ice cream base (premix) to the plant.

Results. We estimate that *S. enteritidis* gastroenteritis developed in 224,000 persons in the United States after they ate Schwan's ice cream. The attack rate for consumers was 6.6 percent. Ice cream associated with infection contained a higher percentage of premix that had been transported by tanker trailers that had carried nonpasteurized eggs immediately before ($P=0.02$). *S. enteritidis* was isolated from 8 of 266 ice cream products (3 percent), but not from environmental samples obtained from the ice cream plant ($n=157$) or tanker trailers ($n=204$).

Conclusions. This nationwide outbreak of salmonellosis was most likely the result of contamination of pasteurized ice cream premix during transport in tanker trailers that had previously carried nonpasteurized liquid eggs containing *S. enteritidis*. To prevent further outbreaks, food products not destined for repasteurization should be transported in dedicated containers. (N Engl J Med 1996; 334:1281-6.)

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IN the United States, *Salmonella enteritidis* has become the most commonly reported serotype of salmonella causing disease in humans.¹ A major factor in this change has been the consumption of undercooked eggs or egg products contaminated with *S. enteritidis*.²⁻⁶ Al-

though both homemade ice cream and unpasteurized commercially made ice cream have been identified as vehicles for salmonella infections in humans,^{5,6} ice cream made from pasteurized ingredients has not. We describe a nationwide outbreak of *S. enteritidis* infections due to the consumption of ice cream made by a large national producer. This is the largest common-vehicle outbreak of salmonellosis ever recognized in the United States.

METHODS

Background

The Division of Public Health Laboratories of the Minnesota Department of Health is the only reference laboratory for serotyping human salmonella isolates in Minnesota. Beginning in late September 1994, the laboratory received an increased number of *S. enteritidis* isolates from residents of southeastern Minnesota. On October 5 and 6, we conducted a case-control study of these cases to determine risk factors for illness. Patients were defined as persons with culture-confirmed *S. enteritidis* infection who resided in southeastern Minnesota and who became ill during September 1994. Control subjects were matched for age and telephone exchange. Schwan's ice cream had been eaten by 11 of 15 patients (73 percent), as compared with 2 of 15 controls (13 percent) (matched odds ratio, 10.0, 95 percent confidence interval, 1.4 to 434; $P=0.007$).⁷ No other risk factors were identified. On the basis of these results and the need for urgent

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intervention, the Minnesota Department of Health announced the findings on October 7, 1994. On October 9, the manufacturer initiated a nationwide recall of all ice cream made at its plant in Marshall, Minnesota. The Food and Drug Administration (FDA) and the Minnesota Department of Agriculture reported the first isolation of *S. enteritidis* from an unopened carton of ice cream on October 17, 1994. The ice cream plant remained closed until November 7, 1994.

Identification of Outbreak-Associated Cases of *S. enteritidis* Infection in Minnesota

An outbreak-associated confirmed case of *S. enteritidis* infection was defined as a culture-confirmed *S. enteritidis* infection occurring in September or October 1994 within one week after the consumption of Schwan's ice cream. We defined an outbreak-associated probable case as the occurrence of diarrhea (three or more loose stools in a 24-hour period) plus fever or chills within one week after product consumption. Confirmed cases were identified through laboratory-based surveillance at the Division of Public Health Laboratories. We attempted to interview all patients reported to have *S. enteritidis* infection in Minnesota during 1994 to assess their exposure to the implicated product.

National Surveillance for *S. enteritidis* Infections

The number of cases of *S. enteritidis* infection reported nationally was obtained from the national salmonella surveillance system at the Centers for Disease Control and Prevention (CDC), which regularly receives reports from state epidemiologists and directors of public health laboratories of salmonella strains isolated from humans. All state epidemiologists were contacted by the Foodborne and Diarrheal Diseases Branch of the CDC on October 18, 1994, to request reports of illnesses between July 1 and December 31, 1994, among persons who had eaten Schwan's ice cream within one week before the onset of illness.

Cross-Sectional Study of Consumers of Schwan's Ice Cream in Minnesota

Schwan's ice cream is distributed nationwide (all 48 contiguous states) through a household-delivery system. To determine the attack rate among ice cream consumers, we studied 200 randomly selected households in Minnesota that had purchased Schwan's ice cream between September 10 and September 20, 1994, using lists provided by the company. Telephone interviews were conducted with an adult household member between October 17 and October 20, and information on each household member was collected on products eaten and histories of diarrheal illness from the time of purchase to the time of interview (range, 27 to 40 days). For households that had ice cream left, we obtained the date and time of production of the ice cream from codes printed on the cartons.

To estimate the size of the outbreak, we multiplied the volume of ice cream distributed in Minnesota from September 1 to September 30, 1994 (reported by Schwan's Sales Enterprises, Inc.) by the number of consumers per gallon (3.8 liters) of ice cream (determined in this study) and then by the attack rate among consumers. To estimate the number of outbreak-associated cases nationwide, we used the estimated size of the outbreak in Minnesota and extrapolated on the basis of the total amount of Schwan's ice cream distributed in the United States during this same period.

Investigation of Ice Cream Production

Inspections of the Schwan's ice cream plant and the two facilities that produced the ice cream base (premix) were conducted by the Minnesota Department of Agriculture and the FDA between October 7 and October 31, 1994. Environmental samples were obtained for culture from the ice cream plant, some of the tanker trailers that carried ice cream premix, and the facilities that produced the premix.

To determine the source of the contamination, we compared the manufacturing process for case-associated products and matched products not associated with salmonellosis. A case-associated product

was defined as any Schwan's ice cream product made between July 1 and September 30, 1994, that was eaten either by a patient with confirmed *S. enteritidis* infection or by multiple persons with probable infection who had eaten one Schwan's ice cream product within seven days before the onset of illness. Comparison products were containers of Schwan's ice cream produced within the same period that were not known to have been eaten by persons with either probable or confirmed disease. We attempted to match the products according to flavor and size, using the closest available production date both before and after the date of production of each case-associated product. For example, for one case-associated product of a 1.5-gallon container of vanilla ice cream made on August 26, the comparison products were 1.5-gallon containers of vanilla ice cream made on August 15 and September 6, 1994. We identified 21 case-associated and 35 comparison products for this analysis. Two comparison products were found for each of 14 case-associated products; only 1 comparison product was found for the other 7. Data on the following were collected for each product: premix suppliers (of which there were 2), tankers that carried the premix to the ice cream plant (89), silos used to store the premix at the plant (10), flavor vats (18), and freezers (10). Data on production were provided by Schwan's, and shipping records from July 1 through September 30, 1994, were obtained from the trucking company that operated the tanker trailers.

Microbiologic Investigation

All isolates of salmonella submitted to the Division of Public Health Laboratories were serotyped.⁸ Stools submitted to the Division of Public Health Laboratories from patients with probable salmonellosis were cultured for salmonella, shigella, campylobacter, and *Escherichia coli* O157:H7.⁹ Ice cream and environmental samples were cultured at the Minnesota Department of Agriculture or FDA laboratories.¹⁰ Serotyping of nonhuman isolates was performed at the FDA laboratory.¹⁰ The Minnesota Department of Agriculture laboratory measured the concentrations of microorganisms in the samples.¹⁰ Phage typing was performed at the CDC.¹¹

Statistical Analysis

Univariate odds ratios, tests for trend, and exact 95 percent confidence intervals were determined with Epi-Info, version 6 (CDC, Atlanta). The chi-square test or the two-tailed Fisher's exact test was used to compare differences in categorical variables. McNemar's chi-square test was used in the matched analysis (Epi-Info, version 6, CDC).

RESULTS

Outbreak-Associated Cases of *S. enteritidis* Infection in Minnesota

A total of 150 confirmed cases of outbreak-associated salmonellosis were identified in Minnesota. These represented 78 percent of the 192 cases of *S. enteritidis* infection diagnosed during September and October 1994 (Fig. 1) and 54 percent of the 277 cases reported for all of 1994. None of the 26 patients whose cases were diagnosed between January 1 and June 30, 1994, reported eating Schwan's ice cream; 4 of 18 patients (22 percent) whose cases were diagnosed during July and August reported eating Schwan's ice cream, as did 1 of 12 patients (8 percent) whose cases were diagnosed in November and December.

The median age of the patients with outbreak-associated confirmed salmonellosis was 13 years (range, 5 months to 84 years); 93 (62 percent) were male. All patients with confirmed salmonellosis reported symptoms of gastroenteritis, with fever reported by 131 of 144 (91 percent), chills by 95 of 124 (77 percent), and bloody stools by 57 of 135 (42 percent). The median du-

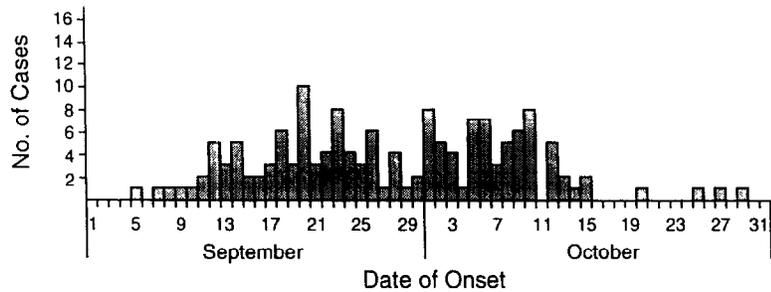


Figure 1. Outbreak-Associated Confirmed Cases of *S. enteritidis* Infection in Minnesota in September and October 1994, According to the Date of Onset.

One hundred fifty cases were reported.

ration of diarrhea was 8 days (range, 1 to 21). Hospitalization was reported by 30 of 112 patients (27 percent); there were no deaths reported.

Residents of southeastern Minnesota accounted for 94 of the 150 Minnesotans with outbreak-associated confirmed cases (63 percent). The patients from southeastern Minnesota did not differ with regard to age, sex, or clinical characteristics from those from the other four geographic regions of Minnesota. The ratio of outbreak-associated confirmed cases among residents of southeastern Minnesota per 100,000 gallons (380,000 liters) of ice cream sold was almost 14 times higher than the ratio in the other four regions combined (303 cases vs. 22 cases per 100,000 gallons of ice cream sold; rate ratio, 13.6; 95 percent confidence interval, 9.6 to 19.2; $P < 0.001$). Patients from southeastern Minnesota were more likely to report having eaten Schwan's ice cream made on August 26, 1994, than patients from the other four regions (odds ratio, 10.5; 95 percent confidence interval, 1.4 to 100.7; $P = 0.005$). During the outbreak, the rate of cases of *S. enteritidis* infection not associated with the outbreak was also higher in southeastern Minnesota than in the other regions (2.5 cases vs. 0.9 case per 100,000 population; rate ratio, 2.9; 95 percent confidence interval, 1.4 to 5.8; $P < 0.001$), suggesting increased testing for salmonella in that region.

National Surveillance for *S. enteritidis* Infections

In 1994, 10,009 *S. enteritidis* infections were reported to the CDC, an increase of 21 percent over the 1993 total of 8258 cases. During September and October, the peak outbreak months, 3299 *S. enteritidis* infections were reported, representing a 71 percent increase over the 1929 cases reported during the same period in 1993. Overall, 593 confirmed cases with no deaths were reported among persons who ate Schwan's ice cream; 41 states reported confirmed or probable cases.

Cross-Sectional Study of Consumers

Of the 200 randomly selected households that had purchased Schwan's ice cream between September 10 and September 20, 1994, 29 were excluded because they could not be located or denied purchasing ice cream

during the period. Interviews were completed for 159 of the 171 eligible households (93 percent), comprising 541 persons. A gallon of ice cream was consumed by a median of 3.2 household members (range, 0 to 13). Persons who ate Schwan's ice cream were much more likely to have diarrhea and fever or chills than those who did not (30 of 452 [6.6 percent] vs. 0 of 89; relative risk, undefined; 95 percent confidence interval, 1.2 to ∞ ; $P = 0.01$).

The proportion of households from each of the five regions in Minnesota was similar to the proportion of ice cream distributed to that region. Residents of southeastern Minnesota received 11 percent of the ice cream distributed to Minnesota in September 1994 and represented 12 percent of the ice cream eaters in our cross-sectional study and 13 percent of those with probable cases of *S. enteritidis* infection. Therefore, these results, unlike those for the rates of confirmed cases in each region, are generalizable to all Schwan's customers.

We estimate that in Minnesota, 29,100 persons became ill with *S. enteritidis* gastroenteritis after eating Schwan's ice cream that had been shipped between September 1 and September 30, 1994 (138,000 gallons \times 3.2 consumers per gallon \times an attack rate of 6.6 percent). Since approximately 87 percent of the ice cream produced by Schwan's during the outbreak was distributed outside Minnesota (Coleman W: personal communication), we estimate that *S. enteritidis* gastroenteritis developed in 224,000 persons nationwide as a result of their eating this product.

Investigation of Ice Cream Production

The ice cream plant in Marshall, Minnesota, is the primary production facility for the door-to-door distribution system of Schwan's ice cream. Ice cream was made from premix purchased from two suppliers; no defects were noted during inspection. The premix was transported to the Marshall plant in tanker trailers, transferred to storage silos on arrival, and then moved to flavor vats and freezers to be made into ice cream. A median of 7 tanker-trailer loads of premix (range, 2 to 19) was used in the manufacture of each product. Neither the premix nor other ingredients were pasteurized after delivery to the plant.

Inspection of the ice cream plant revealed no problems with equipment, quality-assurance measures, or coliform tests of the products. Tests for salmonella routinely performed on chocolate flavoring and French-vanilla premix before use were negative. No cause of salmonella contamination could be found in the plant.

The tanker trailers that transported the premix were also used to carry nonpasteurized liquid eggs, oils, molasses, corn syrup, and pasteurized dairy products. The

trucking company reported undertaking a new contract beginning around July 1, 1994, that greatly increased the amount of nonpasteurized eggs they were transporting from egg-breaking plants in Nebraska and Iowa to processing facilities in Minnesota. After July 1, backhauling a load of nonpasteurized eggs after transporting a load of ice cream premix became a common practice.

Neither the production steps studied in the ice cream plant nor either premix supplier was significantly associated with ice cream consumed by the case patients. However, there was a significant dose-response relation between case-associated ice cream products and the proportion of loads of premix used that had been transported by tanker trailers that had just carried liquid, nonpasteurized eggs (Table 1).

Written procedures called for the washing of tanker trailers after the delivery of liquid eggs and specified that the interior of the tanker trailer was to be washed and sanitized and the outlet valve removed for hand cleaning plus sanitization before premix was loaded. Officials of the FDA and the Minnesota Department of Agriculture noted soiled outlet-valve gaskets, inadequate record keeping, and the lack of routine inspection of the interior of the tanker trailer. Documentation of cleaning was absent for seven tanker trailers on seven occasions during the outbreak period. Egg residue was discovered in one tanker trailer after cleaning. To save time, drivers could elect to bypass the cleaning procedure after unloading eggs. Cracks were noted in the lining of five tanker trailers, including one associated with products consumed by the case patients. Four of 21 case-associated products (19 percent) contained premix hauled by this tanker trailer, as compared with none of 35 comparison products (odds ratio, undefined; $P=0.02$).

Microbiologic Investigation

Of 11 *S. enteritidis* isolates from case patients in Minnesota, 9 were phage type 8 (82 percent), 1 was type 13a (9 percent), and 1 was type 1 (9 percent).

Two hundred sixty-six unopened ice cream products made on 32 days during the period from July 21

through October 7, 1994, were sampled for culture: eight (3 percent) were positive for *S. enteritidis*, and one was positive for *S. thompson*. The eight cultures positive for *S. enteritidis* were obtained from products manufactured on four days (August 25 and 26 and September 12 and 15). Phage typing was performed on five of these eight isolates; all were phage type 8. Cultures of 29 flavorings and ingredients did not yield salmonella.

The concentration of salmonella in four samples positive for *S. enteritidis* was determined (Table 2). The highest level of contamination (most probable number of organisms per gram of ice cream, 0.093) was measured in ice cream products that contained premix from the same loads (August 25 and 26). Three of the four tanker trailers that had delivered the loads of premix used in these products had carried nonpasteurized eggs immediately before carrying the premix. Environmental samples were obtained for culture at the two premix suppliers ($n=47$), from tanker trailers ($n=204$), and at the ice cream plant ($n=157$); all were negative. On October 12 through 18, 1994, the FDA obtained samples of liquid eggs from three egg-production facilities served by the trucking company. Three yielded *S. enteritidis*: one was phage type 8 and two were type 13a.

DISCUSSION

This nationwide outbreak of *S. enteritidis* gastroenteritis, the largest ever recognized in the United States as due to a common vehicle, was caused by the consumption of contaminated ice cream. Our investigation suggests that cross-contamination of pasteurized ice cream premix occurred during transport in tanker trailers that had previously hauled nonpasteurized liquid eggs containing *S. enteritidis*. These conclusions are supported by several findings. First, a case-control study demonstrated that *S. enteritidis* infections were associated only with the consumption of Schwan's ice cream. Second, a study of Schwan's customers showed an increased risk of gastrointestinal illness after consumption of Schwan's ice cream. Third, the outbreak ended after sales of contaminated ice cream stopped. Fourth, *S. enteritidis* was isolated from unopened ice cream products. Finally, a dose-response relation was demonstrated between the proportion of a product's premix that had been carried in tanker trailers immediately after an egg load and the likelihood of that product's being associated with illness. Ice cream premix was not repasteurized after transportation; thus, any contamination that occurred during transport would not have been eliminated at the ice cream plant.

In estimating the size of this outbreak we assumed that the attack rate calculated from the study of Schwan's customers in Minnesota was representative of all ice cream consumers and that the number of people eating each gallon of ice cream was constant. In addition, we did not account for the possible effect of multiple exposures. However, we believe that our estimates are conservative because they were based only on ice

Table 1 Percentage of Loads of Premix Used in Schwan's Ice Cream That Were Transported by Tanker Trailers Immediately after Raw Eggs Had Been Transported, According to the Status of the Product.

PERCENTAGE OF LOADS OF PREMIX HAULED AFTER AN EGG LOAD	PRODUCTS			ODDS RATIO*
	IMPLICATED IN THE OUTBREAK	CONTROL PRODUCTS	number	
0	2	6	10	
1-24	7	17	12	
25-50	5	9	17	
51-100	7	3	7.0	
Total	21	35		

*Chi-square test for trend, 5.2, $P=0.02$

Table 2. Concentration of *S. enteritidis* in Samples of Schwan's Ice Cream Produced in August and September 1994.

DATE OF PRODUCTION	CONCENTRATION OF SALMONELLA	
	MOST PROBABLE NO OF ORGANISMS/GRAM OF ICE CREAM (95% CI)*	MOST PROBABLE NO OF ORGANISMS/HALF-CUP OF ICE CREAM†
August 25	0 093 (0 079-1 013)	6 0
August 25‡	<0 003	<0 2
August 26	0 093 (0 079-1 013)	6.0
September 12	<0 003	<0 2

*CI denotes confidence interval

†One half-cup (65 g) is the serving size identified on the package labeling

‡The ice cream premix used in this sample came from different tanker-trailer loads than the other sample produced on August 25

cream distributed in September 1994 and on a conservative case definition (diarrhea combined with fever or chills).

The identification of this nationwide outbreak followed the recognition of a cluster of cases in southeastern Minnesota. This sentinel event was probably the result of increased distribution of the most highly contaminated ice cream products and increased culturing of ill persons living in that region. Despite intense local and national press coverage of the outbreak and enhanced case-finding efforts, only 150 culture-confirmed cases associated with the outbreak were reported in Minnesota and 593 nationwide. These represent approximately 0.5 percent of the estimated cases in Minnesota and 0.3 percent of the cases estimated to have occurred nationally. This degree of underdetection has been described previously and is an example of the insensitivity of our current surveillance systems for enteric disease at the local, state, and national levels.¹² The occurrence of this outbreak emphasizes the need to enhance public health surveillance of infectious diseases at all levels.

When the Minnesota Department of Health announced the association between the consumption of Schwan's ice cream and *S. enteritidis* infection on October 7, 1994, the evidence implicating this product was limited to a single case-control study of 15 matched pairs. Laboratory isolation of *S. enteritidis* in samples of ice cream was not reported until 10 days later. Had our announcement been delayed until the receipt of this confirmation, many more people would have become ill after eating this product. Therefore, public health officials should not require confirmation of microbial contamination of a product before taking action when sufficient epidemiologic evidence implicates that product. Our experience in Minnesota has repeatedly demonstrated the power of the case-control study to identify a contaminated vehicle in the absence of supporting laboratory evidence.^{1,13-25}

The highest level of product contamination documented in this outbreak was only six organisms per

half-cup (65-g) serving of ice cream. Prior reports of outbreaks of salmonellosis have suggested the presence of similarly low levels of contamination.^{24,26} Because ice cream is distributed, stored, and eaten in a frozen state, the concentration of *S. enteritidis* measured in the ice cream is likely that which was ingested by consumers. This finding confirms that low-level contamination of foods by salmonella, and thus extremely low infectious doses, can cause disease in humans. Current quality-assurance programs, such as the one in the Schwan's ice cream plant, appear to be inadequate in detecting very low levels of contamination. Improved techniques are needed in the food industry to ensure product safety.

Increasing emphasis is being placed on improving food safety through Hazard Analysis and Critical Control Point (HACCP) programs. These programs are based on the identification of potential hazards and critical control points at which these hazards may be prevented or eliminated. The process is intended to review each step from the procurement of raw materials to the point of consumption. A critical control point in the production of this ice cream was the transportation of pasteurized premix in tanker trucks that had previously carried nonpasteurized eggs. Had the ice cream manufacturer or the premix suppliers implemented comprehensive HACCP programs, this critical control point could have been recognized and the outbreak prevented. All responsible state and federal regulatory agencies should require that food-grade products be repasteurized after transportation or be transported in dedicated tanker trailers.

Foodborne diseases continue to present a major challenge to public health authorities in carrying out the core functions of outbreak detection and control, which rely on timely disease surveillance. Surveillance for foodborne illness requires that clinicians have a high index of suspicion and thus order appropriate laboratory tests and requires timely reporting of positive culture results to public health agencies. Although an individual stool culture may yield limited clinically useful information, multiple stool cultures from a community can be critical in detecting and limiting ongoing outbreaks, as illustrated in this investigation. We encourage health care providers and payers to consider this point when deciding which diagnostic tests are appropriate for a patient with a possible foodborne or waterborne illness. Methods to enhance surveillance include promoting awareness of foodborne illness among the public and providers, encouraging appropriate microbiologic testing in suspected cases, ensuring timely and centralized disease reporting by adequate numbers of trained public health staff, using serotype-specific identification of isolates with further molecular subtyping, and coordinating control efforts regionally and nationally.

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