Outbreak of *Salmonella* Serotype Hartford Infections Associated With Unpasteurized Orange Juice

Kim A. Cook, MD, MSPH; Thomas E. Dobbs, MD; W. Gary Hlady, MD, MS; Joy G. Wells, MS; Timothy J. Barrett, PhD; Nancy D. Puhr; Gayle A. Lancette; Dean W. Bodager, RS, MPA; Bill L. Toth, MPH; Carol A. Genese, MBA; Anita K. Highsmith, MS; Keith E. Pilot; Lyn Finelli, PhD; David L. Swerdlow, MD

Context.—Acidic foods such as orange juice have been thought to be unlikely vehicles of foodborne illness.

Objective.—To investigate an outbreak of *Salmonella enterica* serotype Hartford (*Salmonella* Hartford) infections among persons visiting a theme park in Orlando, Fla, in 1995.

Design.—Review of surveillance data, matched case-control study, laboratory investigation, and environmental studies.

Setting.—General community.

Participants.—The surveillance case definition was *Salmonella* Hartford or *Salmonella* serogroup C_1 infection in a resident of or a visitor to Orlando in May or June 1995. In the case-control study, case patients were limited to theme park hotel visitors and controls were matched to case patients by age group and hotel check-in date.

Main Outcome Measures.—Risk factors for infection and source of implicated food.

Results.—Sixty-two case patients from 21 states were identified. Both *Salmonella* Hartford and *Salmonella enterica* serotype Gaminara (*Salmonella* Gaminara) were isolated from stool samples of 1 ill person. Thirty-two case patients and 83 controls were enrolled in the case-control study. Ninety-seven percent of case patients had drunk orange juice in the theme park vs 54% of controls (matched odds ratio, undefined; 95% confidence interval, 5.2 to undefined). The orange juice was unpasteurized and locally produced. *Salmonella* Gaminara was isolated from 10 of 12 containers of orange juice produced during May and July, indicating ongoing contamination of juice probably because of inadequately sanitized processing equipment.

Conclusions.—Unpasteurized orange juice caused an outbreak of salmonellosis in a large Florida theme park. All orange juice was recalled and the processing plant closed. Pasteurization or other equally effective risk-management strategies should be used in the production of all juices.

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From the Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases (Drs Cook, Dobbs, Barrett, and Swerdlow and Mss Wells, Puhr, and Highsmith), and the Epidemic Intelligence Service, Epidemiology Program Office (Dr Cook), Centers for Disease Control and Prevention, and the US Food and Drug Administration, Southeast Regional Laboratory (Ms Lancette), Atlanta, Ga; the Florida Department of Health, Tallahassee (Dr Hlady and Mr Bodager); the Orange County Public Health Unit, Orlando, Fla (Mr Toth); and the New Jersey Department of Health and Senior Services, Trenton (Ms Genese, Mr Pilot, and Dr Finelli).

Reprints: Kim A. Cook, MD, MSPH, Centers for Disease Control and Prevention, 1600 Clifton Rd NE, MS A38, Atlanta, GA 30333.

AN ESTIMATED 2 to 4 million cases of salmonellosis occur annually in the United States.[1] Although foods of animal origin (eg, eggs, poultry, beef, dairy products) are the vehicles of transmission in most *Salmonella* outbreaks, contaminated fresh fruits and vegetables are now recognized as a source of salmonellosis and other foodborne diseases.[2-5] Unpasteurized acidic fruit juices were previously thought to be safe; however, recent highly publicized outbreaks of *Escherichia coli* O157:H7 infections and cryptosporidiosis occurring in 1996 in the northeast and western United States associated with unpasteurized apple cider and apple juice illustrate the potential for acidic juices to carry human pathogens.[6,7] We report an outbreak of *Salmonella enterica* serotype Hartford (*Salmonella* Hartford) infections associated with another popular unpasteurized fruit drink, orange juice.

Salmonellosis caused by *Salmonella* Hartford, a serogroup C_1 *Salmonella* (*Salmonella* C_1), is uncommon. From 1984 to 1994, an annual mean of only 68 isolates were reported to the Centers for Disease Control and Prevention's (CDC) national *Salmonella* surveillance system, representing less than 0.2% of reported isolates.[8] In June 1995, a review of *Salmonella* serotype-based surveillance by the New Jersey Department of Health identified a cluster of *Salmonella* Hartford infections among 7 New Jersey residents returning from vacation in Orlando, Fla. None of them were acquainted with one another or had traveled together. One person was coinfected with *Salmonella* Hartford and *Salmonella enterica* serotype Gaminara (*Salmonella* Gaminara), a serogroup I *Salmonella* (*Salmonella* I), which is also exceedingly rare, with an annual mean of only 40 isolates reported to the CDC from 1984 to 1994. A preliminary investigation failed to identify a common hotel, restaurant, or food exposure among ill persons; however, all had visited a large tourist theme park in Orlando during May 1995. An investigation was conducted to determine the source and extent of the outbreak.

METHODS

Case Finding

To find cases, we reviewed the CDC's national *Salmonella* surveillance system for reports of *Salmonella* Hartford

infections since May 1995 and asked state health departments to interview patients with this infection. We also reviewed *Salmonella* surveillance system data to determine if there were significant increases in reports of *Salmonella* Gaminara or *Salmonella* I. All Florida local health departments and area health care facilities were notified of the outbreak and asked to immediately report any cases of *Salmonella* Hartford, *Salmonella* Gaminara, or *Salmonella* C_1 or I infections. A review of the theme park's employee and visitor medical clinic logs was also conducted.

A confirmed case was defined as *Salmonella* Hartford infection in a resident of or visitor to Orlando in May or June 1995. Because some laboratories serogroup *Salmonella* isolates but do not send all *Salmonella* isolates to their respective state's public health laboratory for serotyping, a probable case was defined as *Salmonella* C_1 infection in a resident of or visitor to Orlando in May or June 1995.

Case-Control Study

To determine risk factors for infection, we conducted a matched case-control study. For this study, a case was defined as diarrhea (3 or more loose stools in 24 hours) in a theme park hotel visitor who visited the park in May or June 1995, with documented *Salmonella* Hartford or *Salmonella* C_1 infection. Cases were limited to visitors to the theme park's hotels because most patients had stayed at 1 of these 13 hotels. If a family had more than 1 ill member, only the first ill person in the household was eligible. Cases were excluded if no matched controls could be identified.

We attempted to enroll 3 controls per case patient individually matched by age group, hotel, check-in date, and number of days spent visiting the theme park. Potential controls were identified using hotel records provided by the theme park and contacted by telephone. Potential controls were excluded if they gave a history of vomiting or diarrhea during their visit to the theme park or within 7 days of returning home.

A standard questionnaire was administered by telephone with trained interviewers. Information was collected on tourist attractions visited, foods eaten, beverages consumed, exposures to animals, and clinical illness.

Environmental Studies

Based on the results of our case-control study, we traced the implicated product, orange juice, back through its production process and conducted site inspections of the involved processing facilities and farms. Site inspections consisted of a review of processing procedures, production plant sanitary conditions and water quality, and an overview of growing and harvesting practices.

Laboratory Studies

Clinical isolates of the outbreak strains of *Salmonella* were obtained from the New Jersey and Florida departments of health laboratories and serotyping results were confirmed by the CDC.[9] Implicated orange juice samples were refrigerated and transported to CDC for examination. The pH of orange juice and the presence of fecal indicator bacteria (total coliforms, fecal coliforms, and *E coli*) were determined by standard methods.[10] Samples were examined for *Salmonella* in duplicate using tetrathionate broth with brilliant green dye (TET).[11] The TET was incubated at 35°C for 24 hours. It was then subcultured into fresh TET and incubated at 42°C for 24 hours before streaking onto Hektoen enteric and brilliant green agar.

An independent microbiologic evaluation of the implicated processing plant was conducted by the University of Florida Citrus Research and Education Center in August and September 1995. Specimen collection and culture methods are described elsewhere.[12]

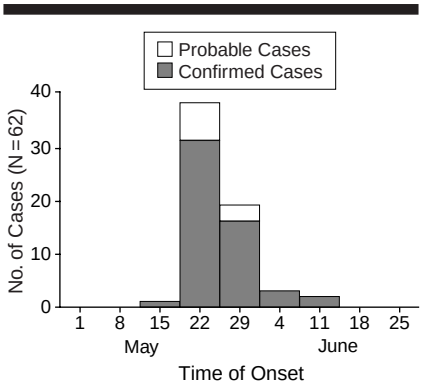
The US Food and Drug Administration (FDA), using a modified drag-swab environmental sampling method, collected whole fruit and environmental samples from 2 Florida farms supplying fruit to the implicated processor during the outbreak period.[13] To isolate *Salmonella* from swabs, the FDA used a modified culture method procedure with novobiocin supplemental plating media and delayed secondary selective enrichment.[13]

Antimicrobial susceptibility testing for chloramphenicol, trimethoprim-sulfamethoxazole, tetracycline, ciprofloxacin, nalidixic acid, ampicillin, sulfisoxazole, streptomycin, kanamycin, gentamicin, ceftriaxone, and amoxicillin–clavulanic acid was performed on representative human and environmental *Salmonella* isolates by standard disk-diffusion techniques.[14]

Pulsed-field gel electrophoresis (PFGE) was performed on isolates to subtype and characterize the outbreak strains using previously described methods for *E coli* O157:H7[15] and *Salmonella enterica* serotype Typhimurium (*Salmonella* Typhimurium).[16]

Statistical Analysis

Numerical data were entered and analyzed with Epi Info, Version 6.02 (CDC).[17] Mantel-Haenszel matched odds ratios (MORs) and 95% confidence intervals (CIs) were calculated to evaluate



Salmonella enterica serotype Hartford infections by week of diarrhea onset among travelers to Orlando, Fla, May and June 1995.

associations between categorical variables.[18] Fisher exact test lower 95% CIs were calculated for undefined MORs.[19]

RESULTS

Fifty-two confirmed and 10 probable cases of *Salmonella* Hartford infection were identified among visitors to Orlando from 21 states. All onset dates were in May and June and the peak of illness onsets occurred during the week of May 22 through 28 (Figure). No Orlando residents or theme park employees met the case definition and review of the theme park's clinical records showed no notable increase in the number of employees or visitors presenting there with gastrointestinal symptoms.

Forty-nine (83%) of 59 patients for whom hotel information was available stayed in 1 of the theme park's 13 hotels in the 7 days before illness onset; 2 persons reported eating all meals exclusively within the theme park. Patients' ages ranged from 1 to 63 years (median, 10 years) and 53% were male. *Salmonella* Hartford or *Salmonella* C_1 was cultured from stool (n = 58), urine (n = 1), blood (n = 2), or abscess (n = 1).

Both *Salmonella* Hartford and *Salmonella* Gaminara were isolated from the stool of 1 patient; however, no additional isolates of *Salmonella* Gaminara or *Salmonella* I were identified among persons with a recent travel history to Orlando and no significant increases were observed in reports of *Salmonella*. Gaminara or *Salmonella* I infection during the outbreak period from Florida or other states.

Case-Control Results

Among the 62 persons identified through case-finding efforts with probable or confirmed *Salmonella* Hartford infection, 32 were enrolled in the case-control study along with 83 matched controls. Thirty ill persons were excluded because they did not stay in a theme park

Table 1.—Association Between Cases of *Salmonella enterica* Serotype Hartford Infection and Selected Exposures Among Theme Park Hotel Guests, Orlando, Fla, May-June 1995

Foods Consumed	Cases, No./Total (%)	Controls, No./Total (%)	MOR (95% CI)*
Orange juice	31/32 (97)	43/80 (54)	Undefined (5.2 to undefined)
Waffles	16/30 (53)	26/81 (32)	4.9 (1.4-17.1)
Eggs	24/31 (77)	48/82 (59)	2.3 (0.9-6.0)
Chicken	26/31 (84)	54/80 (68)	2.0 (0.7-5.8)
Cheese	23/31 (74)	50/77 (65)	1.7 (0.6-4.6)
Sausage	18/31 (58)	34/78 (44)	1.6 (0.7-3.9)
Milk	19/32 (59)	41/83 (49)	1.4 (0.6-3.3)
Fruit	25/32 (78)	62/79 (78)	1.2 (0.4-2.6)
Ice cream	25/31 (81)	65/79 (82)	1.0 (0.4-2.6)
Beef	25/31 (81)	66/80 (83)	0.9 (0.3-2.4)
Lettuce	20/32 (63)	58/82 (71)	0.8 (0.3-1.9)
Tomatoes	11/31 (35)	36/82 (44)	0.7 (0.3-1.9)

*MOR indicates matched odds ratio; CI, confidence interval.

hotel (n = 7), were not the household's primary patient (n = 3), did not have diarrhea (n = 2), were identified after the study ended (n = 2), could not be reached by telephone (n = 15), or refused to participate (n = 1).

The symptoms and signs reported for the 32 persons enrolled in the case-control study included diarrhea (100%), abdominal cramps (97%), fever (97%), headache (73%), bloody stool (71%), and vomiting (66%). The median duration of illness was 7 days (range, 3-23 days), and 7 persons (22%) were hospitalized for a median of 3 days (range, 1-5 days); there were no deaths.

Consumption of orange juice in the theme park was strongly associated with illness (Table 1). Thirty-one (97%) of 32 ill persons drank orange juice compared with 43 (54%) of 80 matched controls (MOR, undefined; 95% CI, 5.2 to undefined, $P<.001$). The 1 case patient who reported no orange juice consumption was matched to controls who also reported no orange juice consumption; therefore, the MOR and the upper 95% CI are undefined. On univariate analysis, waffles were also statistically associated with illness but were consumed by only 16 (53%) of 30 ill persons. A significant positive association between orange juice and illness remained significant after those persons who reported eating waffles were excluded from the analysis.

"Character breakfasts" served in the theme park were the only specific event or meal associated with illness. Twenty-nine (91%) of 32 ill persons attended a character breakfast compared with 48 (58%) of 83 controls (MOR, 6.5; 95% CI, 1.8-23.3). All ill persons who attended a character breakfast reported drinking orange juice during their meal. Character breakfasts are special breakfasts unique to the theme park in which costumed cartoon characters visit with the guests. They are conducted in various locations throughout the park but most are held in the theme park's hotels; however, no single hotel accounted for the majority of illnesses. No other tourist attractions in the Orlando area or other pertinent exposures, such as swimming in water parks and hotel pools or direct contact with animals, were associated with illness.

Environmental Studies

The theme park received shipments of orange juice every other day and reportedly used all juice within 2 or 3 days of delivery. Orange juice was distributed and sold throughout the theme park and was not opened before being received by the park's hotels, restaurants, and attractions. Orange juice was served in sealed, single-serving containers, poured from larger containers into pitchers or glasses, or poured into self-serve juice dispensers. Eighty-eight percent of all orange juice served at the theme park and all orange juice served at character breakfasts was purchased from a local juice processor and was unpasteurized.

The company that provided all of the unpasteurized orange juice to the theme park is a small citrus juice processing plant (production capacity is approximately 40 000 L/d) located in a community adjacent to Orlando; the plant produced only unpasteurized juices. Approximately 75% of the juice company's orange juice was sold to the theme park and most of the remaining product was sold by local Florida distributors. At the juice company's processing plant, whole oranges were conveyed on moving pallets through a phosphoric acid wash and rinsed with water before being sliced in half and juiced. The juice was then chilled and bottled. The final product contained no added water, sugar, preservatives, or disinfectants and had a 12- to 17-day shelf life.

A site inspection of the juice company identified several deficiencies in its processing plant. The processing room was poorly sealed from the outside environment: cracks and holes were visible in the walls and ceiling, rodent and bird droppings were present, and there were reports of frogs being observed around processing equipment. In addition, despite reported twice-daily sanitization of equipment, a buildup of precipitate created from the mechanical reaming of the orange was observed on the inside of the fruit-squeezing machine. No problems were reported with the chlorinated municipal water used at the plant and no fecal coliforms were detected in a bacteriological analysis of the water conducted on August 1, 1995, by the Florida Department of Health's Public Health Laboratory.

Four citrus growers provided the juice company with oranges during the peak outbreak period in May; 1 grove (grove A) provided the majority (76%) of oranges. Four other Florida citrus groves provided oranges used to produce contaminated juice in July; 1 grove (grove B) provided most (63%) of these oranges. These 2 orange groves (groves A and B) used similar methods for growing, harvesting, and picking fruit. Oranges were typically hand-picked, dropped to the ground, collected in large bins, and shipped to the juice company within 24 hours without being cleaned or refrigerated. However, the groves were not associated with each other and did not use common water sources, fruit-picking crews, equipment, or transport. They are separated by approximately 96 km (60 miles) and sold different varieties of oranges to the juice company.

Laboratory Studies

Unopened and opened containers of fresh and frozen orange juice were collected from the theme park, the juice company, and a local supermarket (where the juice company's orange juice was also distributed) by public health officials. The pH of orange juice samples ranged from 4.1 to 4.5 (mean pH, 4.3). All juice samples tested contained coliforms (range, 5000 to >16 000 colony-forming units [CFUs] per 100 mL), fecal coliforms (range, 220-3500 CFUs per 100 mL), and *E coli* (range, 170-1700 CFUs per 100 mL). *Salmonella* Gaminara (range, 2-4 CFUs per 100 mL) was cultured from 10 (83%) of 12 juice containers representing 4 lots produced in May and July 1995 (Table 2).

Seventy samples were collected from the juice company's processing plant consisting of equipment swabs, fruit surface swabs, and juice and other environmental samples.[12] *Salmonella* Hartford and *Salmonella enterica* serotype Newport (*Salmonella* Newport) were isolated from a toad found just outside the juice-processing building. In addition, salmonellae were isolated from unopened bottled juice produced in July (*Salmonella enterica* serotype Rubis-

law), the surface of unwashed oranges held in cold storage for several weeks (*Salmonella enterica* serotype Saintpaul), and 4 tree frogs (*Salmonella* Newport) also found outside of the processing building.

All 95 oranges sampled from 19 different orange grove tracts (comprising approximately 250 acres) from groves A and B had negative test results for *Salmonella*. *Salmonella enterica* serotypes Braenderup and Muenchen, however, were isolated from 2 (11%) of 18 environmental swabs obtained from the soil surrounding 18 orange trees located in 2 of 6 tracts sampled from grove A. Neither of these serotypes was isolated from ill persons.

Antimicrobial susceptibility testing of human isolates of *Salmonella* Hartford (n = 17) and *Salmonella* Gaminara (n = 1), orange juice isolates of *Salmonella* Gaminara (n = 14), and the single toad isolate of *Salmonella* Hartford determined that all isolates were susceptible to all antimicrobials tested. Seven representative human isolates of *Salmonella* Hartford were indistinguishable by PFGE; however, the PFGE pattern of the toad isolate and 9 reference isolates were distinctly different from the outbreak strain. Two PFGE patterns (subtypes A and B) were identified from 10 *Salmonella* Gaminara isolates cultured by the CDC from juice samples. Isolates of *Salmonella* Gaminara with PFGE pattern A were identified in juice samples produced in both May and July. However, both juice subtypes were dissimilar from the subtype identified in the single human isolate of *Salmonella* Gaminara and from 5 reference isolates.

Table 2.—Results of Examination of Containers of Juice Company's Unpasteurized Orange Juice for *Escherichia coli* and *Salmonella* Species, May-July 1995

Production Date	Container Size, oz	pH	Results	
			Escherichia coli (CFUs/100 mL)	*Salmonella* (CFUs/100 mL)†
5/05/95‡	32	4.1	Not tested	Positive
5/05/95‡	32	4.1	Not tested	Positive
7/15/95	8	4.2	Positive (500)	Positive
7/15/95	8	4.3	Positive (300)	Negative
7/15/95	8	4.3	Positive (441)	Positive
7/15/95	8	4.3	Positive (800)	Positive (2)
7/15/95	8	4.3	Positive (170)	Negative
7/15/95	8	4.3	Positive (1100)	Positive
7/15/95	8	4.4	Positive (900)	Positive (4)
7/23/95§	8	Not tested	Positive (1700)	Positive
7/23/95	128	4.3	Positive (300)	Positive (2)
7/31/95‖	32	4.5	Positive	Positive

*Data are colony-forming units (CFUs) per 100 mL calculated for a sample of positive specimens using the most-probable-number method.

†*Salmonella enterica* serotype Gaminara was the only salmonellae serotype isolated.

‡These containers were frozen "vintage" samples provided by the juice company.

§This container was previously opened and sent to the Centers for Disease Control and Prevention by theme park officials for testing.

‖This container was collected from a retail store in Orlando, Fla (not affiliated with the theme park), that purchased the juice company's product through a local distributor.

COMMENT

This outbreak of diarrheal illness affected at least 62 visitors to a large tourist theme park in Orlando. The case-control study and laboratory findings support the hypothesis that unpasteurized orange juice contaminated with *Salmonella* was the vehicle of transmission.

The case-control study determined that orange juice was consumed by 97% of ill persons and was a strong risk factor for illness. The association between illness and attendance at any character breakfast, regardless of location, is explained by the fact that all such breakfasts served only the juice supplied by the park's principal juice supplier; other park venues served a variety of orange juice brands. Waffles were statistically associated with illness; however, only 53% of persons ate waffles and these persons also drank orange juice.

In the laboratory investigation, every lot of orange juice had positive findings for fecal indicator organisms and multiple lots contained *Salmonella*. Although *Salmonella* Hartford was not isolated from orange juice, only 2 samples of juice from the peak of the outbreak in May were available for analysis; nevertheless, these samples and multiple other samples from July did yield *Salmonella* Gaminara, a very rare serotype isolated from 1 ill person who had a dual infection with *Salmonella* Hartford. *Salmonella* Gaminara isolated from orange juice obtained in an Orlando supermarket not affiliated with the theme park suggests that the outbreak may have extended beyond the theme park. However, no patients infected with *Salmonella* Hartford or *Salmonella* Gaminara reported consumption of orange juice purchased outside the theme park.

The dissimilarity of PFGE patterns between human and toad isolates of *Salmonella* Hartford and between human and juice isolates of *Salmonella* Gaminara is likely explained by 1 of several factors. First, the PFGE pattern reported for each isolate was based on the testing of only a single colony; therefore, we did not determine if multiple subtypes of *Salmonella* Hartford or *Salmonella* Gaminara existed within a single specimen. Second, although *Salmonella* Hartford and *Salmonella* Gaminara are rarely isolated from humans, they may be common in this environment, with a significant amount of heterogeneity present among serotypes. Nevertheless, our PFGE analyses do not alter our main conclusion that unpasteurized orange juice contaminated with salmonellae was the cause of this outbreak.

Although the true magnitude of the outbreak is undetermined, a review of human salmonellosis by Chalker and Blaser[20] estimated that only 1% to 5% of actual cases are reported. Given a 1% to 5% case-ascertainment rate and 62 culture-confirmed cases, we estimate that between 1240 and 6200 cases of salmonellosis could have resulted from this outbreak. The unusually high percentage of persons with salmonellosis enrolled in our case-control study with bloody stool (71%) also suggests many milder illnesses were not detected. It is likely that only those persons who were the most severely ill with bloody diarrhea would have sought medical treatment and been evaluated with a stool culture.

The original source of the *Salmonella* is unknown; however, salmonellae are found in a broad variety of hosts, including insects, reptiles, amphibians, birds, and mammals, and may survive long periods in soil or water contaminated with animal feces. Amphibians such as the toad from which *Salmonella* Hartford was isolated could easily have entered the poorly sealed processing facility and contaminated oranges and processing equipment. In addition, because oranges are frequently harvested after being dropped to the ground, the exterior of oranges may have become contaminated with *Salmonella* directly from animals or indirectly from soil, surface water used for irrigation, or improperly prepared manure used as fertilizer. Although the implicated *Salmonella* serotypes (Hartford and Gaminara) were not isolated from the exterior of oranges tested in this investigation, several limiting factors must be considered. The oranges collected in our environmental investigations were unripe, obtained more than 2 months after the peak outbreak period, and picked primarily from the

trees and not the ground. Other *Salmonella* serotypes were isolated from unwashed orange surfaces and environmental swabs collected from soil surrounding orange trees in 1 grove providing oranges to the juice company.

Regardless of the environmental source and means of contamination, once *Salmonella* was introduced into the processing plant, inadequate cleaning and sanitization of processing equipment probably contributed to production of contaminated juice. The presence of a specific fecal indicator organism in all samples of orange juice tested indicates improper sanitation in the processing plant. The identification of the same subtype of a rare *Salmonella* serotype (Gaminara) in juice produced during a 3-month span (May-July) suggests that there was an ongoing source of *Salmonella* within the plant.

Orange juice and other acidic fruit juices are generally believed to be unusual vehicles of transmission for human pathogens. Although varying by season, the average pH level of Florida orange juice is 3.7 (range, 3.4-4.0).[21] While the pH of orange juice implicated in this outbreak was less acidic than expected (mean pH, 4.3), the FDA does not consider foods with a pH level of 4.6 or less to be "potentially hazardous."[22] The FDA *Food Code* also states that a food that does not support the rapid and progressive growth of infectious or toxigenic microorganisms is not considered potentially hazardous even though the food may contain infectious or toxigenic organisms at a level sufficient to cause illness. However, recent outbreak investigations challenge these suppositions.

Orange juice has been identified as the vehicle of transmission in at least 5 previous foodborne outbreaks. Orange juice was first reported as a vehicle of transmission in an outbreak of typhoid fever at a hotel in Cleveland, Ohio, in 1944.[23] Subsequently, it has been implicated in outbreaks of hepatitis A virus in a hospital in St Louis, Mo, in 1962,[24] probable viral gastroenteritis among spectators at a football game in California in 1966,[25,26] typhoid fever at a resort hotel in New York in 1989,[27] and enterotoxigenic *E coli* in India in 1992.[28]

Other acidic fruit juices have also been implicated in outbreaks of gastroenteritis. Unpasteurized apple cider and apple juice were associated with outbreaks of *Salmonella* Typhimurium infection,[29] *E coli* O157:H7 infection,[6,7,30] postdiarrheal hemolytic uremic syndrome (likely caused by *E coli* O157:H7 infection),[31] and cryptosporidiosis.[7,32]

Laboratory studies of the survival of *Salmonella* and other bacterial pathogens in orange juice also support the hypothesis that acidic juices can be vehicles of pathogen transmission. Survival studies of salmonellae in orange juice using, in part, strains isolated from case patients and orange juice described in this outbreak investigation showed that salmonellae survived in detectable numbers up to 27 days at pH 3.5, 46 days at pH 3.8, 60 days at pH 4.1, and 73 days at pH 4.4.[33] In a review by Mitscherlich and Marth,[34] investigators inoculated samples of orange juice (pH of 3.0-3.1 held at 5°C) each with 10^6/mL viable cells of *Salmonella* species, *Shigella sonnei*, and *E coli*. Four decimal reductions in the number of viable organisms required 27 days for *Salmonella* species and *E coli* and 35 days for *S sonnei*. Investigators in 1 of the aforementioned orange juice–associated typhoid fever outbreaks inoculated orange juice with the outbreak strains and recovered viable bacilli up to 6 days later.[27] *Salmonella enterica* serotype Typhi has survived on the surface of cut and whole oranges for 6 and 14 days, respectively.[34]

Orange juice is the most popular fruit drink in the United States. In 1995, Americans consumed an estimated 20.7 L (5.45 gal) of orange juice per person, which accounted for 60% of all fruit juice consumed.[35] Although consumption data on unpasteurized orange juice are limited, the FDA recently estimated that 44.5 million L (11.7 million gal) or 187 million 240-mL (8-oz) servings per year of unpasteurized orange juice are consumed in the United States.[36] Thus, less than 1% of all orange juice is consumed unpasteurized.

After our investigation, the theme park decided to sell only pasteurized orange juice. In addition, Florida public health officials ordered a temporary closing of the orange juice processor and, with the assistance of the FDA, a recall of the plant's unpasteurized orange juice. The Florida Department of Citrus enacted new rules regulating the production of fresh-squeezed unpasteurized orange juice, including banning the use of oranges picked from the ground for the production of juice, washing fruit with an acid wash or other equivalent cleaning method, rinsing fruit with hypochlorite or other equivalent bactericide, completely enclosing the juice-processing area, conducting routine microbiologic surveillance of unpasteurized juice, and establishing documented quality control, good manufacturing practices, or a Hazard Analysis Critical Control Point (HACCP) program.[37] Hazard Analysis Critical Control Point is a preventive system of hazard control whereby food producers are responsible for identifying and evaluating food safety hazards that can affect the safety of their products and instituting controls. Small Florida producers, such as gift-fruit shippers, retail processors, and roadside stand operators, are exempt from these new regulations. Additional research is needed to determine to what extent these measures improve the safety of unpasteurized juice, how widely and consistently they are practiced, and what other possible interventions need to be considered.

The potential role of fruit and vegetable juices in foodborne disease has recently begun to receive national attention. United States federal governmental agencies primarily responsible for preventing foodborne disease (ie, CDC, FDA, US Department of Agriculture, Environmental Protection Agency), are now collaborating on a national food safety initiative. In a report to President Clinton in May 1997, development of new preventive measures for fresh fruit and vegetable juices was proposed.[38]

As a consequence of recent outbreaks associated with juices, the FDA recently proposed new rules to improve the safety of fresh and processed fruit and vegetable juices and juice products.[39] The FDA's proposal would mandate the application of HACCP principles to the processing of these foods to prevent bacterial, chemical, and physical contamination. Similar HACCP regulations have already been enacted by the FDA for seafood, meat, and poultry processors. Under the proposed regulations, juice processors would be required by the FDA to demonstrate that their HACCP program reduces the numbers of pathogenic bacteria to the same degree as that achieved by pasteurization. Until the final rule is implemented, the FDA has also proposed regulations (effective November 5, 1998) that require packaged juice not pasteurized or otherwise processed to control pathogenic microorganisms to bear a warning statement informing consumers of the potential risk of foodborne illness associated with the product. However, in the current version of the proposal very small processors who manufacture fewer than 152 000 L (40 000 gal) of juice per year would be exempt from HACCP requirements, and retailers that sell juice by the glass would be exempt from both HACCP and labeling regulations.

We describe the largest reported outbreak of salmonellosis associated with unpasteurized orange juice. Although the vast majority of orange juice and other fruit and vegetable juices produced within the United States are pasteurized and safe to consume, this outbreak illustrates the importance of the current national debate and regulatory activity regarding the safety of unpasteurized juices. Pasteurization or other risk-management strategies proven to be at least as effective as pasteurization should be

used in the production of juices, including those previously thought to be too acidic to transmit infection. Consumers need to be aware that all unpasteurized juices may potentially transmit enteric infections. Until production methods at least as effective as pasteurization are developed, evaluated, and implemented, consumers can reduce their risk for illness by drinking only pasteurized fruit and vegetable juices.

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