

Reduction in the Incidence of Invasive Listeriosis in Foodborne Diseases Active Surveillance Network Sites, 1996–2003

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Background. Listeriosis is a leading cause of death among patients with foodborne diseases in the United States. Monitoring disease incidence is an important element of listeriosis surveillance and control.

Method. We conducted population-based surveillance for *Listeria monocytogenes* isolates obtained from normally sterile sites at all clinical diagnostic laboratories in the Foodborne Diseases Active Surveillance Network from 1996 through 2003.

Results. The incidence of laboratory-confirmed invasive listeriosis decreased by 24% from 1996 through 2003; pregnancy-associated disease decreased by 37%, compared with a decrease of 23% for patients ≥ 50 years old. The highest incidence was reported among Hispanic persons from 1997 through 2001. Differences in incidence by age group and ethnicity may be explained by dietary preferences.

Conclusion. The marked decrease in the incidence of listeriosis may be related to the decrease in the prevalence of *L. monocytogenes* contamination of ready-to-eat foods since 1996. The crude incidence in 2003 of 3.1 cases per 1 million population approaches the government's Healthy People objective of 2.5 cases per 1 million population by 2005. Further decreases in listeriosis incidence will require continued efforts of industry and government to reduce contamination of food and continued efforts to educate consumers and clinicians.

Listeria monocytogenes causes serious illness, including sepsis, meningitis, fetal loss, and gastroenteritis. Infection during pregnancy may result in mild flulike illness for the mother but a severe outcome for the fetus, such as spontaneous abortion, premature delivery, stillbirth, or systemic infection [1]. Immunosuppressed adults, including persons with cancer, organ transplant recip-

ients, or persons with HIV infection, disproportionately experience invasive infection, although both invasive illness and gastroenteritis can occur in persons with competent immune systems. In 1999, it was estimated that >2500 persons are infected with *L. monocytogenes* in the United States each year, resulting in 500 deaths, a case-fatality rate among acute foodborne diseases second only to that associated with *Vibrio vulnificus* [2].

Nearly all cases of listeriosis are thought to be foodborne [2]. Sporadic cases and outbreaks have often been associated with consumption of ready-to-eat (RTE) foods, including delicatessen meat, hot dogs, and soft cheeses [3–7]. Repeated outbreaks of listeriosis associated with consumption of Mexican-style soft cheese (e.g., queso fresco) made from unpasteurized milk have

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occurred in the United States, primarily among pregnant Hispanic women [8–11].

The US Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) and Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition share federal responsibility for food safety in the United States. Together, USDA-FSIS and FDA enforce a zero tolerance policy for *L. monocytogenes* in RTE foods. In response to public health investigations of outbreaks and sporadic cases, USDA-FSIS and FDA have implemented several initiatives to reduce *L. monocytogenes* contamination of RTE foods. Following these initiatives, industry actions, and consumer education, invasive listeriosis decreased from 7.9 cases per million population in 1989 to 4.2 cases per million in 1993 [12]. The Healthy People 2010 national health objective for listeriosis was to achieve a 50% reduction in listeriosis incidence, from 5 cases per million population in 1997 to 2.5 cases per million population in 2010 [13]. In response to the determination that a highly publicized listeriosis outbreak in 2000 was caused by RTE turkey delicatessen meat [5], the government pledged to achieve this goal by 2005.

To determine the burden of disease and incidence of invasive *L. monocytogenes* infection from 1996 through 2003 by age and ethnicity, we analyzed surveillance data from the Foodborne Diseases Active Surveillance Network (FoodNet). We also assessed the consumption of foods previously identified as vehicles in listeriosis outbreaks among a large sample of residents living in the FoodNet catchment area.

METHODS

Active surveillance. The Centers for Disease Control and Prevention (CDC), USDA-FSIS, and FDA established FoodNet to monitor the effectiveness of food safety interventions [14]. Population-based active surveillance for laboratory-confirmed bacterial pathogens that are commonly transmitted by food, including *L. monocytogenes*, is a core activity of the FoodNet program. FoodNet active surveillance methods have been described elsewhere [15]. For all cases, surveillance officers completed a standard case report form that included demographic information, specimen information, and data on hospitalization and patient outcome.

The surveillance case definition was isolation of *L. monocytogenes* from a clinical specimen obtained from a resident of the FoodNet catchment area. A case of invasive listeriosis was defined as isolation of *L. monocytogenes* from a normally sterile site (e.g., blood, CSF, or amniotic fluid) or from the placenta or products of conception. Meningitis was defined as isolation of *L. monocytogenes* from CSF. *L. monocytogenes* isolates were forwarded to the CDC by the state health department laboratories for serotyping using the method of Seeliger and Hohne [16].

Consumer practices. We surveyed residents of the FoodNet

sites in 2000–2001 using methods identical to previous FoodNet Population Surveys [17, 18]. We analyzed questions related to the consumption of food items during the month before the interview that have been previously associated with outbreaks of listeriosis. Women of childbearing age were defined as those 15–44 years old. Immunocompromised persons were defined as those taking medications such as systemic steroids or cyclosporine, receiving radiation treatment or chemotherapy, or having any of the following medical conditions: cancer, diabetes, HIV infection or AIDS, receipt of a solid-organ transplant, or receipt of splenectomy.

Analysis. Incidence (cases per 1 million population per year) was calculated using US Census Bureau annual population estimates. Pregnancy-associated cases were defined as isolation of *L. monocytogenes* from a pregnant woman, a fetus, or an infant ≤ 31 days old. For incidence calculations, a mother-infant pair was counted as a single pregnancy-associated case. To compare FoodNet data with previously published incidence data, we used the population of children < 1 year old for the denominator for pregnancy-associated cases. To calculate incidence by ethnicity, we used the US Census Bureau list of 639 Hispanic surnames from the 1990 census to impute ethnicity for cases with missing data [19]. To account for the increased number of sites and greater population under surveillance since 1996 and the variation in the incidence of infections among sites, we used a negative binomial regression model to estimate the effect of time on pathogen incidence by treating calendar year as a categorical variable [15]. The mean annual incidence during the period 1996–1998 was used as the baseline for this analysis to minimize the impact of short-term fluctuations in incidence on the overall trend. To analyze the population survey data, we used the Surveyfreq procedure in SAS software (SAS Institute) to calculate weighted percentages that accounted for the multistage survey sampling design. To estimate the annual number of cases in the United States, we used the method of Mead and colleagues [2].

RESULTS

Active surveillance. A total of 804 cases of *L. monocytogenes* infection were ascertained in the surveillance population from 1996 through 2003. Of these, 38 noninvasive cases (5%) were excluded from the analysis. The 766 invasive cases are the subject of this report. Among the 766 *L. monocytogenes* isolates, 596 (78%) were from blood, 135 (18%) were from CSF, and 35 (5%) were from other sterile sites, including placenta (13 isolates), pleural fluid (8), peritoneal fluid (6), amniotic fluid (2), aortic aneurysm tissue (1), ascitic fluid (1), bone (1), central venous catheter (1), joint (1), and lymph node (1). Overall, 670 (94%) of the 715 patients with available data were hospitalized, and 153 (21%) of the 732 cases were fatal. Among the 766 cases, 122 (16%) were pregnancy-associated cases, 126

(16%) were not pregnancy-associated cases and occurred in patients <50 years old, and 518 (68%) occurred in patients ≥50 years old (table 1). *L. monocytogenes* was isolated from an infant in 80 (66%) of the 122 pregnancy-associated cases. Of the cases that occurred in infants, 53% occurred in male subjects, 53% were diagnosed within 1 day after birth, and 79% were diagnosed within 2 weeks after birth.

The number of listeriosis cases varied by season, age group, and ethnicity. A marked seasonal peak was evident for patients ≥50 years old, with 37% of cases occurring from August through October (figure 1). *L. monocytogenes* meningitis was less common among patients ≥50 years old than among other groups (14% vs. 26%; $P < .001$) (table 1). The case-fatality rate was higher among patients ≥50 years old, compared with all other age groups (24% vs. 14%; $P = .005$). Among pregnancy-associated cases, all 22 reported deaths were attributable to either fetal loss or the death of the infant. Among the 42 pregnancy-associated cases in which a culture from the mother yielded *L. monocytogenes*, 18 (44%) involved fetal loss.

Ethnicity was reported for 506 patients (66%). Of these, 55 patients (7%) were Hispanic. After imputation of the ethnicity variable, 60 (8%) of the 766 patients were estimated to be Hispanic. Among the pregnancy-associated patients, 34 (28%) were of Hispanic ethnicity, compared with 26 (4%) among all other patients ($P < .001$).

The incidence of listeriosis decreased from 1996 through 2003. The crude incidence decreased 26%, from 4.1 cases per 1 million population in 1996 to 3.1 cases per 1 million population in 2003 (figure 2). Adjusting for changes in the FoodNet catchment area population, the overall incidence decreased by 24% (95% CI, -38% to -7%) from the 1996–1998 baseline period. The mean annual incidence for the study period was lowest in Tennessee (1.8 cases per 1 million population) and

highest in Connecticut (6.3 cases per 1 million population). The incidence among the Hispanic population was markedly higher than among the non-Hispanic population from 1997 through 2001, peaking at 1.8 times the incidence among the non-Hispanic population in 2000 (table 2). The incidence of pregnancy-associated listeriosis among Hispanic patients was markedly higher than among non-Hispanic patients, peaking at 5.1 times the incidence among non-Hispanic patients in 1998. The lowest-incidence years for Hispanic patients were 2002 and 2003, the last years of the surveillance period.

On the basis of these surveillance data, the estimated number of *L. monocytogenes* infections that occurred in the United States each year decreased from 2228 in 1996 to 1803 in 2003. Similarly, the estimated number of deaths or fetal losses due to *L. monocytogenes* decreased from 462 in 1996 to 378 in 2003. On average, there were an estimated 2000 cases and 420 deaths or fetal losses due to *L. monocytogenes* per year during the period 1996–2003.

Serotype results were available for 530 (69%) of the 766 cases. Among serotyped isolates, serotypes 1/2a (38% of isolates), 4b (36%), and 1/2b (23%) were the most common. Among serotypes, there were no significant difference with respect to patient age, ethnicity, hospitalization, or outcome. The distribution of serotypes did not change appreciably from 1996 through 2003.

Consumer practices. There were 14,647 respondents to the 2000–2001 FoodNet Population Survey. Of the 14,501 respondents with sufficient information for analysis, 715 (6%) reported Hispanic ethnicity, 175 (3%) reported that they were pregnant in the month before the interview, and 4794 (26%) were ≥50 years old. Among Hispanic respondents, 51% were of Mexican origin, 24% were of Caribbean origin, 10% were of Central American origin, 7% were of South American origin,

Table 1. Demographic and clinical characteristics of listeriosis cases, by patient age category, reported at Foodborne Diseases Active Surveillance Network sites, 1996–2003.

Variable	Pregnancy-associated cases ^a (n = 122)	Nonpregnancy-associated cases in patients <50 years old (n = 126)	Nonpregnancy-associated cases in patients ≥50 years old (n = 518)	All cases (n = 766)
Female sex	NA	67 (53)	246 (47)	393 (51)
Hispanic ethnicity	34 (28)	15 (12)	11 (2)	60 (8)
Specimen source				
Blood	75 (61)	91 (72)	430 (83)	596 (78)
CSF	32 (26)	32 (25)	71 (14)	135 (18)
Other	15 (12)	3 (2)	17 (3)	35 (4)
Hospitalization ^b	107 (97)	103 (88)	460 (94)	670 (87)
Fetal loss or death ^c	22 (19)	13 (9)	118 (24)	153 (21)

NOTE. NA, not applicable.

^a Pregnant women, fetuses, or infants ≤31 days old.

^b Among the 715 cases with available hospitalization information.

^c Among the 732 cases with available outcome information. All deaths among pregnancy-associated cases were caused by fetal loss.

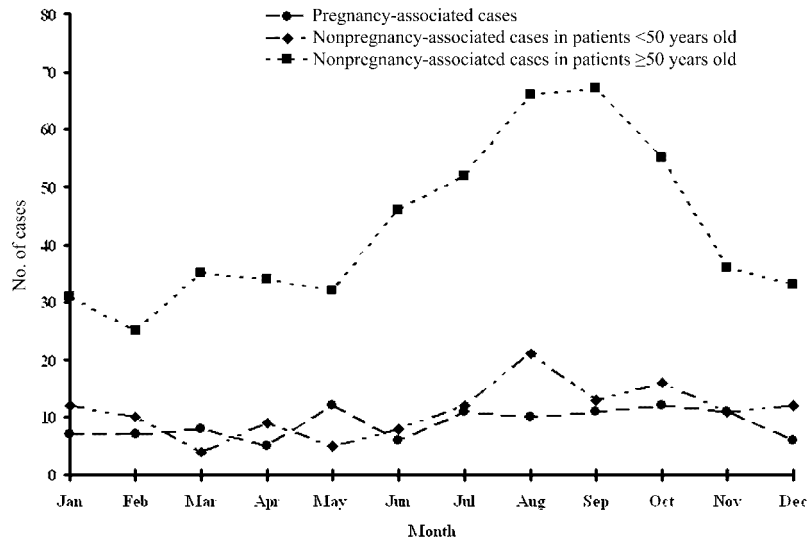


Figure 1. Cases of *Listeria monocytogenes* infection reported to Foodborne Diseases Active Surveillance Network sites, by month of specimen collection and by group, 1996–2003.

and 7% were of European origin. A higher proportion of Hispanic respondents reported consuming soft cheese made from unpasteurized milk and jellied meats than any other group (table 3). Pregnant Hispanic women were 4 times more likely to report consuming unpasteurized cheese than non-Hispanic pregnant women. Among non-pregnant women of child-bearing age, Hispanic respondents were more likely than non-Hispanic respondents to report eating soft cheese made from unpasteurized milk (23% vs. 11%; $P < .001$). In each age group,

persons of Hispanic ethnicity were less likely to have health insurance, compared with persons of non-Hispanic ethnicity.

DISCUSSION

The incidence of laboratory-confirmed listeriosis in the FoodNet sites decreased by 24% from 1996 through 2003. The decrease in listeriosis incidence continues the trend observed from 1989 through 1993 in some of the same population-based surveillance

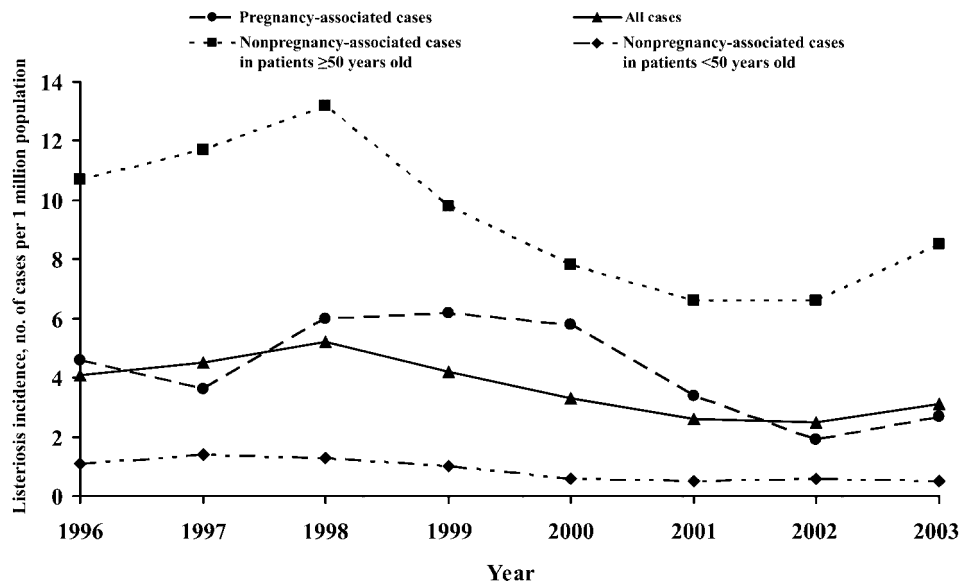


Figure 2. Crude incidence of laboratory-confirmed cases of listeriosis reported to Foodborne Diseases Active Surveillance Network, by patient age category, 1996–2003.

Table 2. Incidence of laboratory-confirmed listeriosis, by patient age category, reported at Foodborne Diseases Active Surveillance Network sites, 1996–2003.

Year	Pregnancy-associated cases ^a			Nonpregnancy-associated cases in patients <50 years old			Nonpregnancy-associated cases in patients ≥50 years old			All cases		
	Hispanic patients	Non-Hispanic patients	All patients	Hispanic patients	Non-Hispanic patients	All patients	Hispanic patients	Non-Hispanic patients	All patients	Hispanic patients	Non-Hispanic patients	All patients
1996	2 (10.4)	7 (4.0)	9 (4.6)	1 (1.4)	11 (1.1)	12 (1.1)	0 (0.0)	38 (11.0)	38 (10.7)	3 (3.6)	56 (4.2)	59 (4.1)
1997	2 (8.7)	6 (3.0)	8 (3.6)	3 (3.6)	13 (1.2)	16 (1.4)	2 (14.8)	46 (11.6)	48 (11.7)	7 (7.1)	65 (4.3)	72 (4.5)
1998	6 (22.1)	11 (4.3)	17 (6.0)	2 (2.1)	17 (1.2)	19 (1.3)	1 (6.3)	70 (13.4)	71 (13.2)	9 (7.8)	98 (5.0)	107 (5.2)
1999	7 (22.3)	15 (4.6)	22 (6.2)	2 (1.8)	17 (1.0)	19 (1.0)	0 (0.0)	67 (10.0)	67 (9.8)	9 (6.8)	99 (4.0)	108 (4.2)
2000	6 (12.9)	18 (4.9)	24 (5.8)	2 (1.2)	12 (0.6)	14 (0.6)	3 (14.8)	61 (7.7)	64 (7.8)	11 (5.7)	91 (3.2)	102 (3.3)
2001	7 (10.7)	10 (2.3)	17 (3.4)	1 (0.4)	12 (0.5)	13 (0.5)	2 (6.8)	60 (6.6)	62 (6.6)	10 (3.8)	82 (2.5)	92 (2.6)
2002	2 (3.0)	8 (1.7)	10 (1.9)	1 (0.4)	16 (0.7)	17 (0.6)	1 (3.1)	67 (6.7)	68 (6.6)	4 (1.4)	91 (2.6)	95 (2.5)
2003	2 (2.8)	13 (2.9)	15 (2.7)	3 (1.1)	13 (0.5)	16 (0.5)	2 (5.7)	98 (8.6)	100 (8.5)	7 (2.3)	124 (3.2)	131 (3.1)

NOTE. Data are no. of cases (no. of cases per 1 million population). Catchment area increased over the surveillance period.

^a Cases involving pregnant women, fetuses, or infants ≤31 days old per 100,000 population within a 1-year period.

sites [12]. Increases in incidence in 1998 and 1999, particularly among pregnancy-associated cases, were likely to be associated with a large outbreak that occurred in multiple states, including FoodNet sites in Connecticut and New York [4].

Our analysis demonstrates that, from 1997 through 2001, listeriosis disproportionately affected persons of Hispanic ethnicity, and that this was most prominent among pregnancy-associated cases. A population-based assessment of consumption of high-risk foods in the FoodNet sites suggests that variation in dietary patterns, particularly increased consumption of unpasteurized soft cheese, may have contributed to this disparity. Consumption of cheese made from unpasteurized (raw) milk is a well-documented cause of listeriosis [8–11]. These cheese products have also caused outbreaks of multidrug-resistant *Salmonella* serotype Typhimurium definitive type 104 [20, 21] and have been associated with *Brucella melitensis* [22, 23] and *Mycobacterium bovis* [24–26] infections among Hispanics in the United States. Following 3 outbreaks of *S. Typhimurium* definitive type 104 infection in 1997, researchers in Washington developed a safe recipe for queso fresco using pasteurized milk and implemented a successful peer education campaign to teach the recipe to others in the Hispanic community [27]. Following an outbreak of listeriosis in North Carolina in 2000 [9], the FDA used Spanish language radio and television and participated in health fairs at retail stores to educate pregnant women about the dietary risks for listeriosis [28]. From 2001 through 2003, the incidence of listeriosis decreased among persons of Hispanic ethnicity. The reason for the decrease is unknown, but it could be the result of public education interventions that followed repeated outbreaks of illness caused by raw-milk cheese or the result of efforts by federal and state food safety officials to remove unsafe products from markets. However, these data may not represent a true

decrease in listeriosis among persons of Hispanic ethnicity, because of the small number of Hispanic patients and the resulting statistical uncertainty in the incidence calculations.

Seasonal differences in the number of listeriosis cases in the United States have not been previously reported [8, 12, 29]. However, increases in the number of listeriosis cases during the late summer and early autumn have been reported in the United Kingdom [30] and Israel [31]. No seasonal patterns of *L. monocytogenes* isolation in RTE foods [32] or hot dogs [33] have been reported. The reasons for seasonal increases in listeriosis among persons ≥50 years old, but not among patients with pregnancy-associated cases, are unknown.

The FoodNet surveillance data suggest that efforts by industry and regulators can make RTE food products safer. In 1996, in response to outbreak investigations, the USDA-FSIS implemented a major change in food safety regulation by requiring that hazard analysis critical control point systems be implemented by all meat and poultry processing establishments. Following this, the proportion of USDA-FSIS-tested samples of RTE meat and poultry with cultures that yielded *L. monocytogenes* decreased from 1990 through 2000 [34, 35]. In particular, the proportion of sliced ham and luncheon meat cultures that yielded *L. monocytogenes* decreased from 7.7% in 1990 to 3.1% in 2000 [34]. In a study conducted in 2 FoodNet sites (California and Maryland) during 2000–2001, <2% of >31,000 RTE food samples yielded *L. monocytogenes*, and 71% of these positive samples contained low levels of contamination (<0.1 cfu/g) [32]. The downward trend in *Listeria* contamination of RTE meat and poultry products suggests that substantial improvements in production have been achieved. To prevent distribution of contaminated product, processing establishments often voluntarily hold product lots until regulatory tests have negative results. For example, >90% of the RTE

Table 3. High-risk food exposures in the month before interview, underlying medical conditions, and health insurance status, by patient age category, among respondents to the Foodborne Diseases Active Surveillance Network Population survey, 2000–2001.

Variable	No. (%) of patients					
	Pregnant		<50 years old		≥50 years old	
	Hispanic (n = 20)	Non-Hispanic (n = 132)	Hispanic (n = 584)	Non-Hispanic (n = 9033)	Hispanic (n = 108)	Non-Hispanic (n = 4624)
Dietary factor						
Unpasteurized cheese ^a	6 (29)	12 (6.9)	154 (28)	1058 (9.3)	32 (32)	587 (12)
Unpasteurized milk	0 (0)	2 (0.6)	14 (3.0)	123 (1.4)	2 (3.2)	48 (1.2)
Any delicatessen meat	15 (58)	86 (63)	351 (59)	5634 (61)	51 (49)	2487 (53)
Jellied meat	3 (8.9)	4 (2.6)	42 (9.0)	174 (2.1)	6 (8.1)	106 (2.1)
Hot dog	7 (37)	77 (63)	275 (53)	4556 (60)	32 (31)	2263 (52)
Oysters	0 (0)	4 (2.4)	47 (7.7)	564 (5.6)	6 (5.5)	314 (6.9)
Smoked fish	2 (6.3)	14 (7.5)	69 (8.0)	280 (2.5)	15 (17)	670 (13)
Immunosuppression ^b	0 (0)	8 (5.3)	43 (6.1)	704 (6.3)	24 (23)	1181 (26)
Health insurance	13 (66)	122 (91)	447 (72)	7999 (90)	93 (84)	4306 (92)

^a Soft cheese made from unpasteurized milk (e.g., brie, camembert, and queso fresco).

^b Treatment with immunosuppressive medication or any of the following conditions: cancer, diabetes, HIV infection or AIDS, receipt of a solid-organ transplant, or receipt of splenectomy.

products that are cultured by the USDA-FSIS and yield *L. monocytogenes* never leave the plant [35]. This test-and-hold system contributes to protecting public health by preventing contaminated products from entering the marketplace, thereby reducing human exposure to *L. monocytogenes*.

The extent to which the decrease in listeriosis can be attributed to the zero tolerance policy is unknown. During the period 1990–2000, the average incidence of listeriosis was lower in England and Wales (2.1 cases per 1 million population), countries without a zero tolerance policy for *Listeria*, than in the United States (4.9 cases per 1 million population) [36]. Since 2000, the average incidence has increased in England and Wales (to 3.5 cases per 1 million population) and has decreased in the United States (to 2.7 cases per 1 million population). The zero tolerance policy has been criticized because the level of microbiological contamination found on commercial products is generally very low [37].

Outbreak detection and investigation have had a critical role in identifying specific improvements needed to further lower the incidence of listeriosis. Toward the end of the 1990s, several large multistate outbreaks of listeriosis caused by RTE foods occurred, despite the downward trend in *L. monocytogenes* infection associated with RTE meat and poultry products. As a result of outbreaks associated with hot dogs in 1998 and 1999 and an outbreak associated with turkey delicatessen meat in 2000 [5], the FDA and USDA-FSIS reviewed ongoing prevention and control activities for *L. monocytogenes* and developed a *Listeria* action plan in 2001. Following a second outbreak associated with turkey delicatessen meat in 2002 [3], the USDA-FSIS introduced an interim final rule that required federally inspected facilities producing certain (RTE) meat and poultry

products to take steps to further reduce the incidence of *L. monocytogenes* infection [38]. In 2003, the FDA updated the *Listeria* action plan to reduce listeriosis associated with the consumption of RTE foods within the regulatory purview of the FDA [39]. The revised *Listeria* action plan focuses on high-risk foods and includes strategies for guidance, training, research, education, surveillance, and enforcement.

There are important limitations to the FoodNet surveillance data. Surveillance for *L. monocytogenes* is limited to laboratory-confirmed cases. Therefore, persons without access to health care and persons whose illness was not confirmed by culture are excluded from this surveillance system. However, invasive listeriosis may cause life-threatening illness that would likely prompt an affected person to seek medical care regardless of health insurance status. Data from the FoodNet sites may not be generalizable to the entire United States because of differences in the demographic profiles of these sites. For example, the overall proportion of Hispanic residents in the FoodNet sites is 6%, compared with 12% in the United States overall [15]. Although the incidence among Hispanics according to the FoodNet data was lower than the incidence among non-Hispanics in 2002–2003, the small number of Hispanic patients limits our ability to draw statistical inference with respect to comparisons to non-Hispanic patients. The imputation of Hispanic ethnicity for one-third of our cases, mostly occurring during the period 1996–1999, further increases the uncertainty for incidence estimates by ethnicity. We were unable to assess the role of changes in high-risk food consumption on the decrease in listeriosis incidence, because these data were not consistently collected during the surveillance period. In the absence of complete national reporting for *L. monocytogenes* infections,

however, FoodNet data represent the most accurate and complete surveillance system for this pathogen.

Public health, industry, and regulatory efforts to reduce the prevalence of *L. monocytogenes* in RTE foods have led to a decrease in the incidence of listeriosis in the FoodNet sites. Further decreases in the incidence of listeriosis will require continued efforts by industry and regulatory agencies, continued laboratory-based surveillance, and prompt investigation of clusters of illness.

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