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A Multiple-Serotype Outbreak of *Salmonella* Infections Linked to Kratom, United States, 2017–2018

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Abstract

In early 2018, we investigated a large national multiple-serotype *Salmonella* outbreak linked to contaminated kratom, a raw minimally processed botanical substance. Kratom is a plant consumed for its stimulant effects and as an opioid substitute. A case was defined as a laboratory-confirmed *Salmonella* infection with one of the outbreak strains (serotypes I 4,[5],12:b:-, Heidelberg, Javiana, Okatie, Weltevreden, or Thompson) with illnesses onset during January 11, 2017–May 8, 2018. State and local officials collected detailed information on product consumption and sources. Suspected products were tested for *Salmonella* and traceback was conducted to determine product distribution chains and suppliers. We identified 199 cases from 41 states; 54 patients were hospitalized. Early interviews indicated kratom was an exposure of interest. Seventy-six (74%) of 103 people interviewed reported consuming kratom in pills, powders, or teas. Multiple serotypes of *Salmonella* were detected in samples of kratom collected from the homes of the patients and from retail locations. Several companies issued recalls of kratom products due to *Salmonella*

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Authors' Contributions

All authors contributed to the analysis or writing of the article.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Food and Drug Administration.

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contamination. To the authors' knowledge, this investigation is the first to establish kratom as a vehicle for *Salmonella* infection. Our findings underscore the serious safety concerns regarding minimally processed botanical substances intended for oral consumption and the challenges in investigating outbreaks linked to novel outbreak vehicles.

Keywords

Salmonella ; kratom; outbreak investigation; enteric disease

Introduction

Salmonella enterica IS a leading cause of multistate foodborne outbreaks and an important etiology of bacterial gastroenteritis in the United States with an estimated 1 million foodborne infections annually (Scallan et al, 2011). Symptoms of salmonellosis include diarrhea, fever, and abdominal cramps starting 1–6 days after exposure, with children and the elderly at greater risk for severe illness (Centers for Disease Control and Prevention [CDC], 2022). During 2010–2014, multistate *Salmonella* outbreaks were linked to more food categories than any other bacterial enteric pathogen (Crowe et al, 2015).

Outbreak vehicles included both plant and animal sources and range from nuts, fruits, and vegetables to beef, chicken, and turkey (Crowe et al, 2015). The diversity of potential outbreak sources can challenge investigators working to identify a foodborne outbreak vehicle and thereby prevent further illness. In addition to mitigating the extent of ongoing outbreaks, successful outbreak investigations are an important method for identifying novel food safety risks and preventing future illnesses.

Kratom (*Mitragyna speciosa*) is a Southeast Asian tree cultivated for centuries for use in traditional medicine but with recent and increasing use in western countries (Cinosi et al, 2015; Warner et al, 2016). Kratom leaves contain the psychoactive alkaloids mitragynine and 7-hydroxymitragynine, that when ingested, produce a dose-dependent opioid-like effect (Prozialeck et al, 2012; Warner et al, 2016). Surveys of kratom users indicate a perceived role as a mood enhancer and opioid substitute for self-managing chronic pain and symptoms of opioid withdrawal (Coe et al, 2019; Grundmann, 2017). Kratom is imported into the United States from overseas sources and is legal to purchase in all but six states and easily obtained from tobacco shops, service stations, and online sources (Eastlack et al, 2020).

Kratom use in the United States has climbed in recent years, evidenced by the 10-fold increase in kratom use reports to poison control centers during 2010–2015 (Anwar et al, 2016). The emergence of kratom on the U.S. market has drawn scrutiny from both regulators and public health officials due to safety concerns and reports of death associated with kratom use (Post et al, 2019; U.S. Food and Drug Administration [FDA], 2019). In 2014, the FDA issued a kratom-specific import alert allowing detention of products entering the United States due to significant or unreasonable risk of illness or injury from use (FDA, 2014). In addition to these safety concerns, there are also microbiological or enteric disease risks associated with kratom consumption. As a minimally processed and raw botanical product, kratom consumption can be considered a risk factor for enteric illness.

In 2018, a team of local, state, and federal partners investigated a large national *Salmonella* outbreak with multiple serotypes. This report describes the outbreak, epidemiological and laboratory findings, and subsequent public health response.

Methods

Outbreak detection

On December 26, 2017, PulseNet, the national molecular subtyping network for foodborne disease surveillance, detected a cluster of 14 cases of S. *enterica* serotype I 4,[5],12:b:- infection from 10 states. Bacterial isolates were characterized using pulsed-field gel electrophoresis (PFGE), a subtyping method that produces a DNA fingerprint that can be used to define outbreak strains. The PFGE pattern associated with the outbreak strain was uncommon in the PulseNet database, indicating bacterial isolates were likely associated with a common source.

The initial outbreak case definition was an infection with the outbreak strain of *Salmonella* I 4,[5],12:b:- in a person with illness onset after October 1, 2017. However, as product testing and epidemiological evidence was evaluated, strains with other PFGE patterns associated with illness were identified. Not all *Salmonella* strains that were identified through product testing were added to the case definition.

These additional *Salmonella* strains were assessed for links to outbreak illnesses based on three criteria: whether the PFGE pattern was currently or previously investigated as part of a multistate *Salmonella* outbreak; whether the number of human clinical isolates with the PFGE pattern uploaded in the previous 60 days was greater than expected; or whether the strain was isolated from both patient and leftover product samples collected from the ill person’s home. The final outbreak case definition included a laboratory-confirmed infection with the outbreak strains of *Salmonella* serotypes I 4,[5],12:b:-, Heidelberg, Javiana, Okatie, Thompson or Weltevreden with an illness onset date during January 1, 2017 to May 8, 2018.

Federal and state partners reviewed exposures reported during initial patient interviews, which included questions about food and animal exposures within the 7 days preceding illness onset. A common exposure across all the initial cases was not identified; however, exposure to an uncommon powdered kratom product was noted by a single patient. After additional interviews revealed similar exposures, a set of questions was developed to systematically capture details of kratom and other botanical product exposures including brand, variety, and place of purchase. Local and state health investigators conducted patient interviews through telephone during the outbreak investigation. Interview responses were sent to the CDC for analysis.

Product testing

State health investigators collected kratom-containing products from patient homes and from retail locations where patients reported purchasing product. Samples of product were tested for *Salmonella* at state public health and partner laboratories; isolates were serotyped and PFGE was performed using standard PulseNet protocols (Ribot et al, 2006). Product isolate PFGE data were uploaded to the PulseNet national database and were compared with

human clinical isolates using BioNumerics software (Applied Maths, Sint-Martens-Latem, Belgium).

Traceback investigation and facility inspections

State and local health agencies collected detailed information regarding product type, purchase location, date, and packaging. Regulatory officials at the state and federal level used this information to identify product suppliers and collect purchase records to delineate product supply chains. FDA and state investigators visited product packaging facilities and conducted inspections.

Results

Outbreak description

A total of 199 cases were identified from 41 states (Fig. 1). The most common Salmonella serotype among cases was I 4,[5],12:b:- (n = 83), followed by Thompson (n = 59 illnesses), Okatie (n = 28), Javiana (n = 17), Weltevreden (n = 6), and Heidelberg (n = 6). Patients ranged in age from <1 to 75 years (median 38) and 92 of 191 patients (48%) were female. Fifty-four patients were hospitalized, and no deaths were reported. Illnesses were reported as early as January 2017, but a marked increase in the number of detected cases began in October 2017 (Fig. 2).

On February 9, 2018, CDC and state partners held a tele-conference to discuss exposures reported during routine patient interviews. Officials with the North Dakota Department of Health described an exposure to kratom powder reported during one of these routine interviews. Although investigators were unfamiliar with kratom powder, it was reminiscent of other low moisture powdered botanical products (e.g., moringa powder and chia powder) recently linked to national *Salmonella* outbreaks (Gambino-Shirley et al, 2018; Harvey et al, 2017).

Kratom became a vehicle of interest because it was an unusual exposure, previous outbreaks demonstrated plant-derived powders, such as kratom, were biologically plausible, and the North Dakota patient was adamant kratom was the source of their illness. The kratom hypothesis strengthened on February 12, 2018, when a second patient from Utah, reported consuming kratom during reinterview. Based on information provided by the North Dakota patient, health officials in Utah contacted the second patient to ask specifically about kratom use, since that exposure was not mentioned during the initial interview.

Subsequent patient interviews conducted by state and local officials included detailed questions on kratom use. Data from interviews quickly bolstered the kratom hypothesis and by mid-February 2018, epidemiological evidence indicated kratom was the likely source of the outbreak with 8 (73%) of 11 patients reporting kratom consumption. In total, state and local officials were able to assess kratom use for 113 patients and 85 (75%) reported consuming kratom before illness onset. Among patients with available information, consumption of loose powdered kratom was the predominant form reported (46 patients), followed by preformed capsules (14 patients); 1 patient reported consuming a bottled kratom drink. A majority (52%) of patients reported purchasing kratom from retail locations,

whereas others reported purchasing kratom from online sources. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.*

Product testing

On February 14, 2018, officials from the North Dakota Department of Health isolated the initial outbreak strain of *Salmonella* I 4,[5],12:b:- from leftover kratom provided by the patient who first reported kratom use. These laboratory findings confirmed the epidemiological link between kratom consumption and illness.

During February through May 2018, officials in several states collected kratom from patient homes and from retail locations to test for *Salmonella* contamination. Overall, 21 *Salmonella* serotypes and 85 PFGE patterns were isolated from kratom products by state and FDA laboratories. Most *Salmonella* serotypes isolated from kratom yielded a single PFGE pattern and were not associated with human illness, but outbreak strains *of Salmonella* serotypes I 4,[5],12:b:-, Heidelberg, Javiana, Okatie, Thompson, and Weltevreden were identified. The FDA conducted extensive kratom testing and *Salmonella* was detected in 33 of 66 (50%) kratom samples tested, some yielding more than one *Salmonella* serotype (FDA, 2018a).

Strains of serotype Okatie with the outbreak PFGE pattern isolated from kratom in Oregon were associated with a previously investigated but unsolved multistate outbreak of *Salmonella* illnesses in early 2018. Initial patient interviews did not identify kratom as a potential source, but reinterview during this investigation established an epidemiological link between patients and kratom consumption.

Product traceback

FDA traced back kratom products purchased from 7 online and 9 physical location points of sale (POS), where 24 patients reportedly purchased kratom. As kratom products contaminated with *Salmonella* were identified during the investigation, FDA conducted online surveillance and purchased products for label review and laboratory analysis. Online products were sold as capsules, liquids, or powder. Powder package sizes ranged from 28 g to 1 kg. Some POS sold other botanical products, other consumer goods, encapsulation machines, and empty capsules. Although many accepted credit card payments, some POS only accepted wire transfers, cash on delivery, or cryptocurrency. Some online and physical POS included a disclaimer that the products did not come with directions for use (e.g., “sold as bulk product with no instructions”) or were not intended for human consumption.

Product recalls and health communication

In response to the outbreak, FDA and state regulatory agencies coordinated recall activities among retail suppliers and distributors of kratom products linked to human illness. In total, 13 initial and expanded recalls occurred during March–June 2018 due to this outbreak investigation involving 67 kratom products from 26 distributors. Notably, on April 2, 2018, FDA ordered the first mandatory recall of food product in U.S. history, an authority granted by the 2011 Food Safety Modernization Act, to remove kratom from the market due to

*See e.g., 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

the risk of *Salmonella* infection (FDA, 2018b). This unprecedented action by FDA was in response to a company's refusal to voluntarily recall kratom products linked to illness.

CDC, FDA, and state agencies issued public health alerts and social media statements warning consumers of the risk of *Salmonella* infection from kratom and providing information on active kratom recalls and specific products that tested positive for *Salmonella* (CDC, 2018; FDA, 2018a). These warnings were updated routinely to provide consumers with relevant health information to guide decision-making and health behaviors. Both CDC and FDA advised consumers to avoid ingesting kratom products to reduce their risk of *Salmonella* infection.

Discussion

This outbreak investigation is the first to identify kratom as a vehicle for *Salmonella* transmission in the United States and adds to a growing list of low-moisture foods, spices, and supplements linked to enteric disease outbreaks (Gambino-Shirley et al, 2018; Harvey et al, 2017; Van Doren et al, 2013a). Aided by focused patient interviews and product testing, investigators worked to expand the investigation of a small outbreak of *Salmonella* I 4,[5],12:b:- infections into a larger multiserotype *Salmonella* outbreak event linked to multiple kratom products. By doing so, an important and previously undescribed food safety threat was identified, as evidenced by the extensive *Salmonella* contamination of kratom products revealed by state and FDA laboratory testing (Dixon et al, 2019; FDA, 2018a).

Central to hypothesis generation during outbreak investigations is identification of commonly reported exposures among a group of ill people. In foodborne outbreaks, patients with restricted diets due to health or food preference, or who report unusual exposures can provide critical clues to guide hypothesis generation by narrowing the scope of possible sources. This investigation was aided by the early report of kratom use during routine interview by officials in North Dakota, an unusual and notable exposure to outbreak investigators.

In addition, the patients were adamant that kratom was the source of illness, reporting to public health officials that they became ill soon after purchasing and consuming the product. This exposure information was captured in interview notes and shared among the multijurisdictional investigation team. These findings underscore the importance of a skilled interviewer and using an approach in which the patients describe their daily routine and what they believe made them ill. This information can provide critical clues in determining the source of a difficult-to-solve outbreak.

The traceback component of the investigation was complicated by poor record keeping, extensive repacking and co-mingling of kratom product, and a lack of cooperation by kratom importers, distributors, and retailers. The diversity of both *Salmonella* serotypes associated with reported infections as well as brand names and sources reported by patients is likely reflective of the complex network of multiple large- and small-scale operators engaging in kratom distribution and sale. Despite these challenges, some kratom products linked to

illness were traced by FDA to multiple U.S.-based distributors and product recalls were initiated to protect public health.

Epidemiological evidence was key to identifying kratom as the likely outbreak source, but product sampling and *Salmonella* testing confirmed the association between kratom and salmonellosis. Kratom testing identified multiple *Salmonella* serotypes associated with illness and expanded the scope of the outbreak investigation. Illustrating this point was the isolation of *Salmonella* Okatie, previously linked to an unsolved multistate outbreak, from kratom products in Oregon. Interviews during the initial *Salmonella* Okatie outbreak investigation did not identify kratom as a possible source, although some patients were asked at least one question about dietary supplements. This is perhaps due to the patient not recalling kratom use when initially interviewed about food exposures or reluctance to admit consuming kratom to public health officials. Laboratory findings from kratom testing provided the basis for follow-up interviews of patients infected months after their illness, which supplied epidemiological evidence linking these illnesses to kratom.

Although the ultimate source and manner of kratom contamination is unknown, the high *Salmonella* prevalence and diversity of bacterial strains isolated from kratom samples indicate widespread contamination. Investigators were unable to inspect overseas facilities to assess kratom production practices and potential sources of contamination. However, kratom repackaging facilities in the United States were inspected, and regulators observed poor controls to reduce the risk of bacterial contamination. Similar to herbs and spices, kratom may be exposed to a host of microbial contaminants during pre- or postharvest and in processing and storage.

During any step in the production process, kratom may have been exposed to *Salmonella* contamination from reservoirs, including wildlife, livestock, contaminated water, and human waste. Kratom and other leaf-derived products may be at particular risk for *Salmonella* contamination based on findings from imported spice sampling conducted by FDA. These studies found 11% of leaf-derived spices to be contaminated with *Salmonella*, among the highest of product categories tested (Van Doren et al, 2013b). *Salmonella* contamination of raw, minimally processed, and low moisture foods, herbs, and spices linked to outbreaks continue to pose a public health concern. In the absence of a microbial kill-step, these low-moisture products may provide a stable environment for extended bacterial survivability often leading to protracted outbreaks.

Conclusions

This investigation highlights a major challenge faced by foodborne outbreak investigators—that the universe of potential outbreak vehicles is sizable and can go beyond traditional well-recognized sources. It is a reminder that novel outbreak vehicles can cause substantial illness and be difficult to identify as an outbreak source. Future investigations, particularly of rare or emerging bacterial strains, which may indicate recent pathogen introductions into the U.S. food supply chain, should pay close attention to atypical exposures.

Investigators must also be willing to follow up iteratively with patients to better assess the validity of unusual hypotheses, especially when traditional outbreak sources have already been evaluated and dismissed. This outbreak also underscores the illness risk associated with raw or minimally processed botanical products of indeterminant source and quality. Consumers should be aware of the food safety risk when choosing to consume these products, and public health plays an important role in promulgating awareness. Finally, and as this outbreak demonstrated, it is due to the combined work of local, state, and federal health officials, and the willingness of the public to answer investigative questions that outbreaks are solved, and public health is protected.

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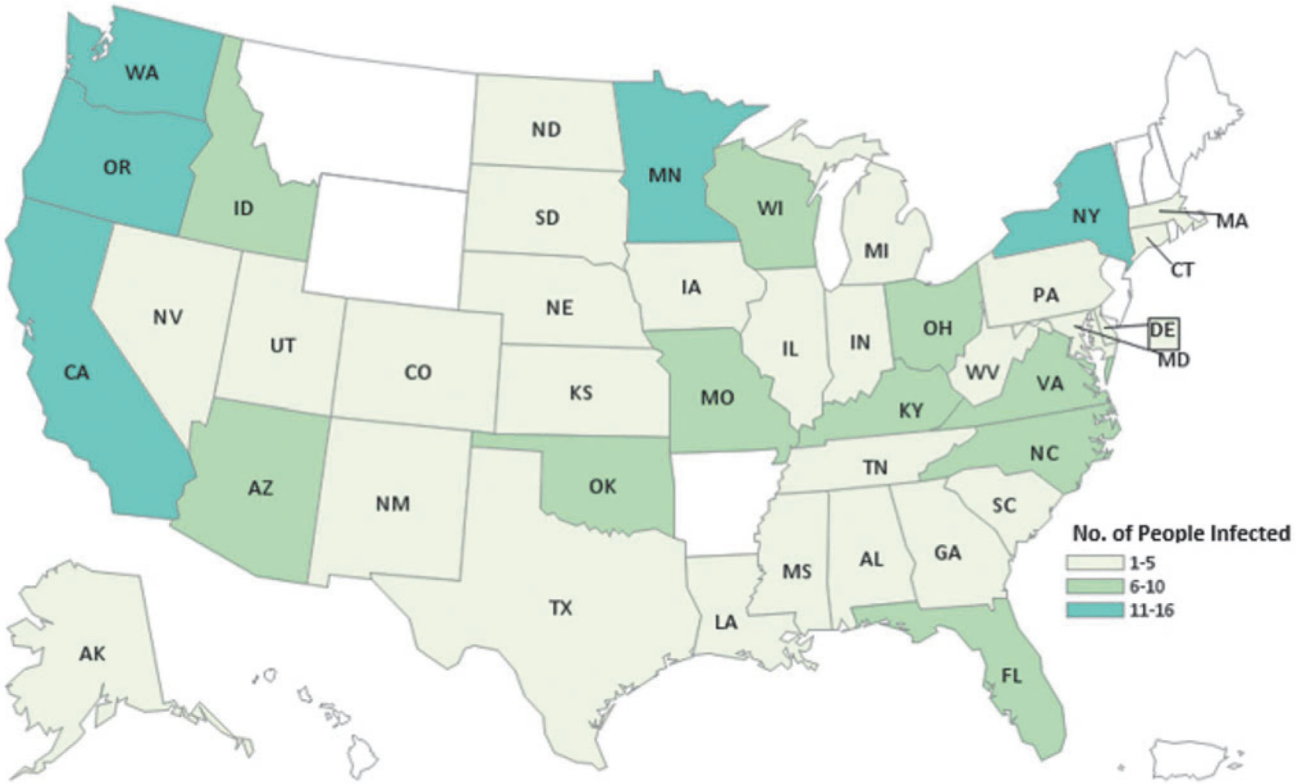

FIG. 1.
Number of reported cases of salmonellosis by state.

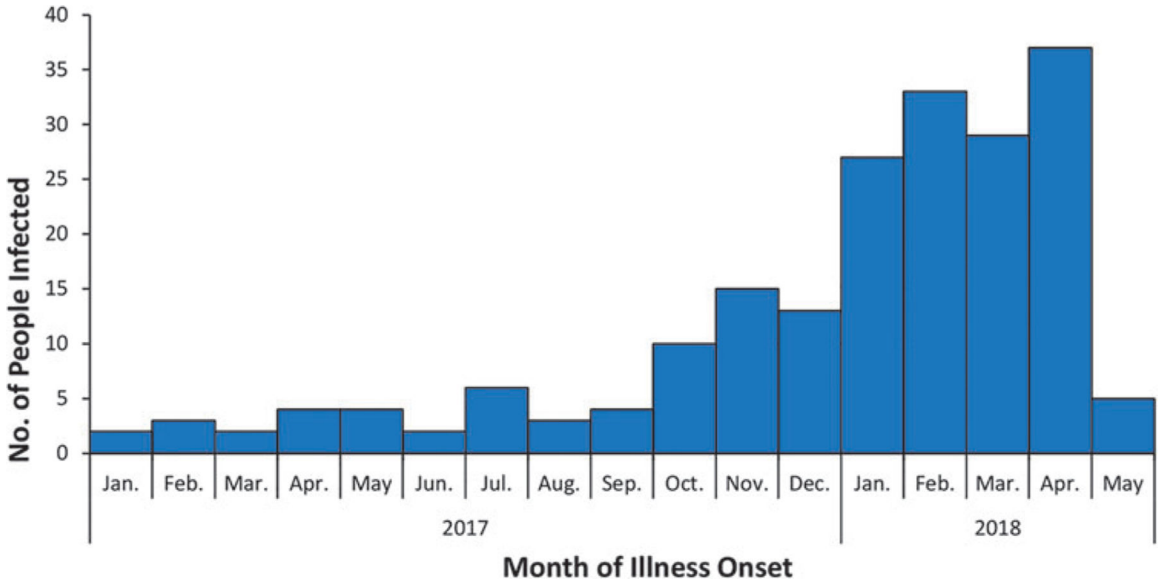

FIG. 2.

Number of reported cases of salmonellosis by month from January 11, 2017 to May 8, 2018.