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A Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Soy Nut Butter

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Abstract

Background: In 2017, we conducted a multistate investigation to determine the source of an outbreak of Shiga toxin-producing *Escherichia coli* (STEC) O157:H7 infections, which occurred primarily in children.

Methods: We defined a case as infection with an outbreak strain of STEC O157:H7 with illness onset between January 1 and April 30, 2017. Case-patients were interviewed to identify common

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Contributors' Statement Page

Ms Hassan developed the data collection instruments, coordinated the data collection, conducted the analysis, and drafted and revised the manuscript.

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Dr Jhung supervised coordination of data collection and analysis and critically reviewed and revised the manuscript.

Ms Peralta, Ms Booth, Ms Tewell, Ms Melius, Ms Gonzales, and Dr Vugia reviewed and revised data collection instruments, collected and interpreted epidemiologic data, coordinated product sampling, and critically reviewed and revised the manuscript.

Ms Olson and Ms Gladney conducted laboratory analyses, interpreted laboratory data, and critically reviewed and revised the manuscript.

Ms Seelman and Dr Whitney interpreted traceback data, conducted traceback analyses, and critically reviewed and revised the manuscript.

Ms. Sexton and Ms. Dwarka reviewed facility inspection data, reviewed inspectional evidence and data, and critically reviewed and revised the manuscript.

Ms Dowell drafted, revised, and coordinated dissemination of risk communication messages and critically reviewed and revised the manuscript.

Mr Vidanes and Dr Kiang coordinated product sampling, interpreted product testing data, and critically reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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exposures. Traceback and facility investigations were conducted; food samples were tested for STEC.

Results: We identified 32 cases from 12 states. Twenty-six (81%) cases occurred in children <18 years-old; eight children developed hemolytic uremic syndrome. Twenty-five (78%) case-patients ate the same brand of soy nut butter or attended facilities that served it. We identified three illness sub-clusters, including a childcare center where person-to-person transmission may have occurred. Testing isolated an outbreak strain from 11 soy nut butter samples. Investigations identified violations of good manufacturing practices at the soy nut butter manufacturing facility with opportunities for product contamination, although the specific route of product contamination was undetermined.

Conclusions: This investigation identified soy nut butter as the source of a multistate outbreak of STEC infections affecting mainly children. The ensuing recall of all soy nut butter products the facility manufactured, totaling over 1.2 million pounds, likely prevented additional illnesses. Prompt diagnosis of STEC infections and appropriate specimen collection aids in outbreak detection. Childcare providers should follow appropriate hygiene practices to prevent secondary spread of enteric illness in childcare settings. Firms should manufacture ready-to-eat foods in a manner that minimizes the risk of bacterial contamination.

Table of Contents Summary:

This investigation identified a novel vehicle, a commercial soy nut butter, as the source of a multistate outbreak of STEC infections affecting mainly children.

Introduction

Shiga toxin-producing *Escherichia coli* (STEC) O157 is an important cause of foodborne illness in the United States, causing an estimated 63,000 illnesses, 2,000 hospitalizations, and 20 deaths annually.[1] The highest incidence of laboratory-confirmed STEC O157 infection occurs in children less than 5 years old (3.72 infections per 100,000 persons in 2015).[2] Symptoms include abdominal cramps and diarrhea, which frequently becomes bloody by the second or third day of illness.[3] Symptoms typically begin 3–4 days after infection and last 6–8 days.[3,4] Approximately 5–10% of STEC infections are complicated by hemolytic-uremic syndrome (HUS), which is characterized by microangiopathic hemolytic anemia, thrombocytopenia, and acute renal failure.[3–6] HUS usually occurs a week after symptom onset when diarrhea is improving.[7] Among children under five years old infected with STEC O157, approximately 15% develop HUS.[6] Foodborne STEC O157 outbreaks have previously been associated with undercooked beef, raw produce such as leafy vegetables and sprouts, unpasteurized dairy and cider products, deli meats, raw dough, and dough mix.[8–11]

Peanut allergies have increased among U.S. children over the past decades, leading some childcare centers and schools to implement peanut-free policies.[12,13] In a 2014 survey, 36% of school districts banned foods due to allergies, and 97% of these districts specifically banned peanuts.[13] Consequently, peanut butter alternatives have gained popularity in the United States, as parents and caregivers seek to find safe alternatives for their children.[14,15] Peanut butter substitutes include spreads made from tree nuts, such as almonds, pistachios,

walnuts, and pecans, and nut alternatives such as sunflower seeds, sesame seeds, and soy beans.[14,15]

This paper reports findings from a rapid and collaborative investigation that identified a novel food vehicle, soy nut butter, as the source of a multistate foodborne illness outbreak, which mainly affected young children.

Outbreak Detection

State public health laboratories throughout the United States routinely perform molecular-based subtyping of clinical isolates using pulsed-field gel electrophoresis (PFGE).[16,17] Clinical isolates are obtained when clinicians order laboratory testing as part of a patient's diagnostic evaluation. PFGE patterns are uploaded by participating laboratories to PulseNet, the national molecular subtyping network for foodborne disease surveillance. CDC's PulseNet team detects potential multistate outbreaks of STEC and other enteric bacteria by identifying clusters of uploaded isolates with indistinguishable patterns, which are more likely to be from a common source. These clusters are referred to epidemiologists for investigation to determine whether the illnesses are linked to a common vehicle.

On February 17, 2017, PulseNet detected seven *E. coli* O157:H7 infections from Arizona, California, Maryland, and New Jersey with an indistinguishable PFGE *Xba*I/*Bln*I restriction enzyme pattern combination that had not been previously seen in the PulseNet database. Local and state health departments, the U.S. Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA) initiated an investigation to determine the source of the outbreak and prevent additional illnesses.

Methods

Case Definition and Case Finding

During the investigation, two STEC O157 infections with similar PFGE *Xba*I/*Bln*I pattern combinations were identified and added to the outbreak based on whole genome sequencing (WGS) showing that isolates were closely related to those in the initial cluster and an epidemiological link to the suspected vehicle. We defined an outbreak-associated case as infection with one of three *E. coli* O157:H7 PFGE *Xba*I/*Bln*I pattern combinations constituting the outbreak strains in a person with illness onset between January 1 and April 30, 2017. We used PulseNet throughout the investigation to identify additional cases.

Epidemiologic Investigation

Local and state health departments interviewed case-patients or their proxies (*e.g.,*parents, guardians, or care-givers) with state-specific enteric disease questionnaires or a modified version of the National Hypothesis Generating Questionnaire (NHGQ). The NHGQ includes questions on over 300 food and animal exposures in the week before illness, including fresh produce, meats, dairy products, and processed foods.[18] After early interviews narrowed the list of potential exposures, investigators interviewed case-patients with a focused questionnaire, which included detailed questions on suspected foods. Investigators attempted to identify illness sub-clusters, where two or more unrelated case-patients had exposure to

the same location or venue before illness, such as a childcare center or restaurant, in order to narrow the scope of suspected foods.

Product Traceback and Facility Investigations

Local, state, and FDA investigators conducted a traceback investigation of the suspected product and its ingredients through the distribution chain to determine if there was a common source. Local and state investigators collected food menus from childcare centers and other institutions attended by case-patients to identify foods in common. FDA conducted inspections at firms of interest, including the brand headquarters, contract manufacturing facilities, and ingredient suppliers. Product lot codes and best-by dates were used to identify common lots of interest.

Product Testing and Laboratory Investigations

State public health laboratories subtyped clinical STEC O157 isolates using standard PFGE methodology.[16,17] Local and state health departments collected opened, leftover products from case-patient homes and childcare centers and unopened products from retail locations. FDA collected finished product and ingredient samples during facility inspections. State public health and FDA laboratories tested food samples for STEC. STEC isolates were subtyped by PFGE.[16] Selected food and clinical isolates underwent WGS to further characterize genetic relatedness.[19–21]

Results

Outbreak Description

We identified 32 cases from 12 states [Figure 1]. Illness onset dates ranged from January 4, 2017 – April 18, 2017 [Figure 2]. Case-patients were 41% female, and ages ranged from 1–70 years (median: 9). Twenty-six (81%) case-patients were children < 18 years old, including 11 (34%) < 5 years. Twelve (38%) hospitalizations and no deaths were reported. Nine (28%) case-patients developed HUS; of these, 8 (89%) were children < 18 years old, including 3 (33%) children < 5 years old.

Epidemiologic Investigation

Among nine case-patients interviewed with state-specific questionnaires by February 23, six (67%) ate leafy greens, five (56%) ate ground beef, and two (22%) ate different pre-packaged smoothies. Five (56%) case-patients ate foods purchased from natural/health food stores. One case-patient noted regularly eating soy-based, dairy-alternative products.

On February 28, California investigators noted one case-patient, upon re-interview with the modified NHGQ, reported eating Brand A soy nut butter. The next day, two additional case-patients from California and Maryland reported eating Brand A soy nut butter upon re-interview, and investigators discovered through review of menus that all four Arizona case-patients attended two childcare centers that served Brand A soy nut butter and granola coated in soy nut butter.

In total, we identified three illness sub-clusters. One sub-cluster consisted of three two-year-old children who attended the same Arizona childcare center that served Brand A soy nut butter and soy nut butter coated granola. Specific food consumption histories for these children were not available. Another sub-cluster consisted of two adults who attended the same residential institution in Oregon that served Brand A soy nut butter: one case-patient reported eating soy nut butter while at the facility, and the other was unable to be reached for interview.

The third illness sub-cluster occurred at an Oregon childcare center and included six children aged 1–2 years old and one adult teacher; all attended or worked in the same classroom. Six illnesses began from March 2 to March 5, but one began over a week later on March 13. While the childcare center did not serve soy nut butter, one child ate Brand A soy nut butter at home and often brought it to the classroom for lunch; this child was the first in this sub-cluster to become ill. None of the remaining six case-patients or their proxies reported exposure to soy nut butter at home. While lunch seating was unassigned, five of the ill children, including the child who often brought soy nut butter for lunch, often ate at the same table with another child who did not become ill. The sixth ill child ate at a neighboring table. Each table had a compost bucket where children put leftover foods, and two children who became ill had a history of reaching into the bucket to eat leftover foods.

All 32 case-patients or proxies were interviewed; 25 (78%) reported eating Brand A soy nut butter at home in the week before they became ill (19 case-patients), attending a facility that served Brand A soy nut butter (2 case-patients), or attending childcare centers that served Brand A soy nut butter and granola (4 case-patients). All 23 case-patients with information reported the original creamy variety, and 13 of 14 available containers had best-by dates of August 30–31, 2018. Of the seven case-patients without reported exposure to soy nut butter, six were part of the Oregon childcare center mentioned above and one was not associated with any of the identified sub-clusters and denied eating soy nut butter.

During the outbreak, investigators identified two ill people who either developed HUS or had a culture-independent diagnostic test (CIDT) showing infection with STEC bacteria. In interviews, both patients reported eating Brand A soy nut butter in the week before illness. However, CDC did not include these people as case-patients because no bacterial isolates were available for molecular subtyping, so we were unable to confirm if they were infected with one of the outbreak strains.

Product Traceback and Facility Investigations

The product traceback investigation found that Brand A soy nut butter and Brand A granola were made by two different contract manufacturers in separate facilities. Both contract manufacturing facilities obtained ingredients from multiple suppliers with multiple product lots; however, the sole supplier of soy nut butter used to manufacture the granola was the contract manufacturer of the Brand A soy nut butter.

FDA conducted inspections at the soy nut butter contract manufacturer from March 3 to 15, 2017, and subsequently issued an FDA Form 483 to notify the firm of observed objectionable conditions that may be considered violations of the Food, Drug, and Cosmetic

Act and related Acts.[22,23] These included a failure to follow good manufacturing practices, poor cleaning and sanitation, evidence of pest and animal activity around food production equipment, opportunities for contamination, failure to ensure adequate heat treatment, and inadequate microbial testing.[23] FDA also conducted inspections at the granola manufacturing facility and at one ingredient supplier to the soy nut butter manufacturer, and no violations or issues were noted.

Product Testing and Laboratory Investigations

Local and state investigators collected 89 samples of Brand A soy nut butter and soy nut butter coated granola from case-patient homes, childcare centers, and retail locations. An outbreak strain of STEC O157 was isolated from 11 Brand A creamy soy nut butter samples. Multiple STEC isolates were identified from some samples. Nine samples were from opened, leftover products from case-patient homes in California, Oregon, and Washington, and two samples were from unopened containers from retail stores in California; all had best-by dates of August 30, 2018 (10 products) or August 31, 2018 (1 product). FDA collected 17 product samples from the soy nut butter manufacturer and a distribution center. Testing isolated STEC O134 and O180 from three Brand A creamy soy nut butter samples from the manufacturing facility, which were produced during the FDA inspection on March 6. A PulseNet query did not identify any clinical isolates with PFGE patterns indistinguishable from these non-O157 strains. No STEC was isolated from any granola samples tested. FDA collected five ingredient samples from one ingredient supplier; none yielded STEC. Fifteen clinical isolates representing all three outbreak strains and 13 food isolates were closely related genetically by WGS (0–6 hqSNPs) (Figure 3).

Control Measures

On March 3, 2017, CDC and FDA warned the public that Brand A soy nut butter and granola products were a likely source of the outbreak, advising that consumers not eat these products.[24,25] States and CDC also sent public health advisories to school and childcare center listservs to warn against serving implicated products.

On March 3, 2017, the company recalled certain best-by dates of Brand A original creamy soy nut butter.[25] This recall was subsequently expanded to encompass all Brand A soy nut butter products, including granola. In total, over 1.2 million pounds of products were recalled.[26–29] Additionally, two downstream product recalls were issued for products containing recalled soy nut butter.[30,31]

The soy nut butter contract manufacturer provided FDA a list of actions taken to correct the conditions reported in the FDA Form 483. However, FDA determined that these actions were insufficient to ensure that products were not contaminated with STEC; therefore, FDA issued a Suspension of Food Facility Registration Order on March 27, 2017.[32] While a suspension order is in effect, no food product can leave the facility for sale or distribution, and FDA will only reinstate the food facility registration when adequate grounds no longer exist to continue the suspension.[32] At the time this report was submitted for publication, the suspension order was still in effect.

Discussion

Epidemiological, traceback, and laboratory evidence identified soy nut butter as the source of a multistate outbreak of STEC O157 infections affecting mainly children. This is the first time a peanut butter alternative such as soy nut butter has been implicated as the source of an outbreak of STEC infections in the United States. Quick investigative work by local, state, and federal agencies led to initial product recalls and consumer advisories within two weeks of initiating the investigation, likely preventing additional illnesses.

This outbreak emphasizes the critical role health care providers play in detecting and investigating enteric illness outbreaks. Quick identification and sub-typing of bacteria such as STEC is essential to detecting outbreaks. Prompt diagnosis by clinicians not only aids treatment but is important for timely reporting of illnesses to public health officials. The use of CIDTs, such as multiplex polymerase chain reaction assays, immunoassays, or nucleic acid amplified tests, in clinical settings is increasing, since CIDTs allow clinicians to rapidly diagnose and treat the cause of a patient's diarrheal illness.[33,34] However, as PulseNet requires a bacterial isolate for molecular subtyping, increasing use of CIDTs without culturing positive specimens to isolate and characterize bacterial strains may hinder PulseNet's ability to detect foodborne outbreaks, particularly geographically dispersed outbreaks.[33–38] In this outbreak, we likely only recognized that the two additional ill people with STEC infection diagnosed by CIDT alone or had HUS without an isolate were likely associated with the multistate outbreak because soy nut butter was an unusual food. In order to facilitate rapid and reliable outbreak detection, several public health experts recommend that patient specimens which are positive for STEC by CIDT be cultured and isolates sent to a public health laboratory for further characterization.[35,38,39]

This outbreak also highlights the risk STEC infections pose to the pediatric population. Over a quarter of the case-patients developed HUS, and all but one were children under 18 years old. The minimum infective dose for STEC can be low, which increases secondary transmission risk in settings of close person-to-person contact.[40,41] We identified a sub-cluster in an Oregon childcare center where secondary transmission might have contributed to the spread of the outbreak, given the wide range of onset dates and the fact that soy nut butter was not served there. Even though we did not determine how all case-patients became infected with STEC, the use of compost buckets that were accessible to toddlers and the large number of diapered children are risk factors for infection. We hypothesize that case-patients might have become infected from eating leftover soy nut butter at the lunch table, cross-contamination from exposure to the compost bucket, person-to-person transmission, or a combination of these. This outbreak serves as a reminder to childcare providers of the importance of appropriate hand washing and hygiene practices to prevent the spread of infections in these settings.[42] Additionally, children with STEC O157 infection should be excluded from attending childcare centers until two stool cultures (obtained at least 48 hours after antimicrobial therapy, if given, has been discontinued) are negative for STEC.[7]

This investigation is subject to several limitations. First, we were unable to determine if case-patients in the Arizona and Oregon childcare center sub-clusters had eaten soy nut butter through interviews because of their young ages. However, since they were infected

with the novel outbreak strain and had several opportunities for primary or secondary exposure at the childcare center, we believe it is exceeding unlikely that they would all have an unknown exposure outside the childcare center. Additionally, while we identified Brand A soy nut butter as the cause of the outbreak, we were unable to determine how it became contaminated with STEC. Product contamination may have occurred through use of a contaminated ingredient or cross-contamination from contact with contaminated equipment or surfaces during manufacturing. However, as ingredient samples were negative and multiple objectionable conditions were identified during the facility's inspection, it was not possible to determine which specific route led to product contamination. Given the complexities of outbreak investigations and the time delay from when the contaminated product was manufactured until a facility inspection, it is generally uncommon to definitively identify routes of product contamination. Regardless, successfully identifying the contaminated product led to multiple product recalls and to the suspension of the firm's ability to sell or distribute food, ultimately stopping the outbreak.

Finally, this outbreak serves as a reminder of the important role manufacturers play in preventing foodborne outbreaks and the role brand owners have in overseeing their product safety. Soy nut butter is a ready-to-eat food with a long shelf life, and multiple foodborne outbreaks have been identified over the past few years linked to other ready-to-eat, long-shelf life foods, such as organic shake/meal products, sprouted nut butters, and chia powder.[43–45] Ready-to-eat foods are those that consumers would not typically further treat or process in a way that would minimize bacterial risk before eating (e.g., cooking to temperature).[46] In all these instances, consumers presume foods are safe to eat and do not require further processing or cooking, so they rely on manufacturers to produce foods in a way that eliminates bacterial contamination. Ready-to-eat foods, particularly those often fed to children, should be manufactured to minimize the risk of bacterial contamination. In addition, it is always important that consumers practice good hygiene to prevent the spread of infectious diseases, particularly in settings with vulnerable populations, such as childcare centers.

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Abbreviations:

CDC	U.S. Centers for Disease Control and Prevention
CIDT	culture-independent diagnostic test
FDA	U.S. Food and Drug Administration
hqSNP	high quality single nucleotide polymorphism

HUS	hemolytic-uremic syndrome
NHGQ	National Hypothesis Generating Questionnaire
PFGE	pulsed-field gel electrophoresis
STEC	Shiga toxin-producing *Escherichia coli*
WGS	whole genome sequencing

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What's Known on This Subject:

STEC O157 causes approximately 63,000 illnesses annually in the United States. The highest incidence is among young children, who are also at higher risk of severe infection. Foodborne STEC outbreaks are most commonly associated with undercooked beef and leafy greens.

What This Study Adds:

We identified soy nut butter as the source of a multistate outbreak of STEC infections affecting mainly children. This outbreak highlights the risk of STEC infection among young children and the critical role healthcare providers play in outbreak detection.

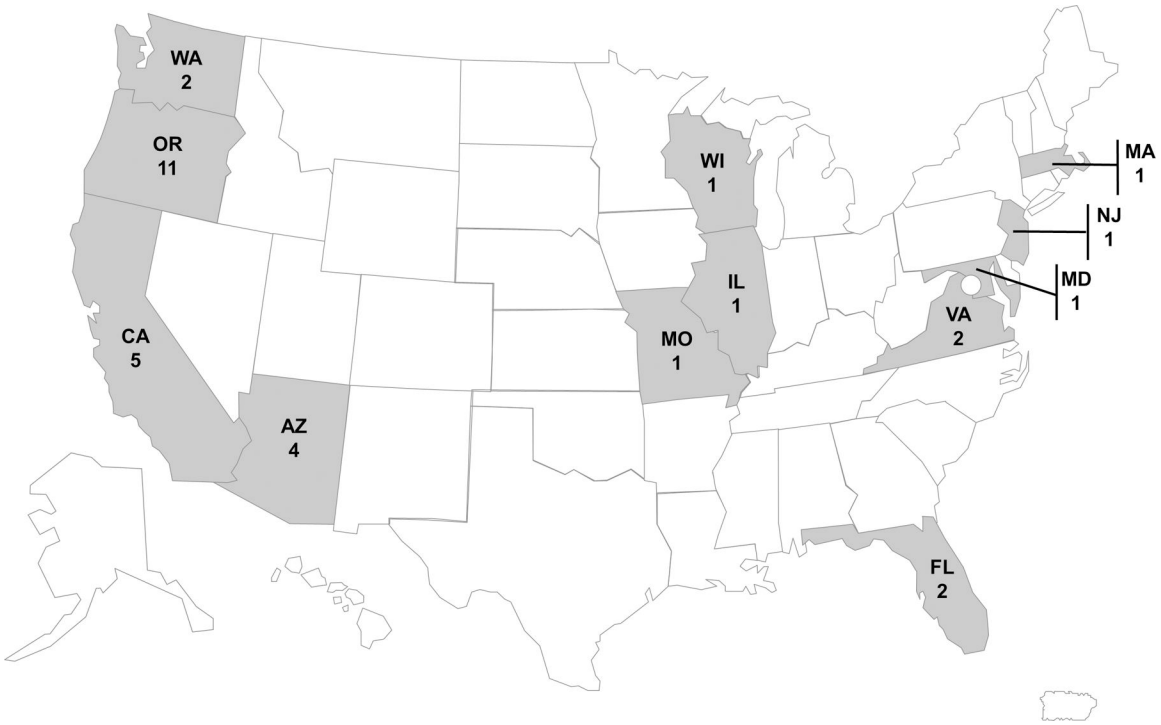

Figure 1:
People infected with the outbreak strains of *E. coli* O157:H7 (n=32), by state of residence, United States, 2017

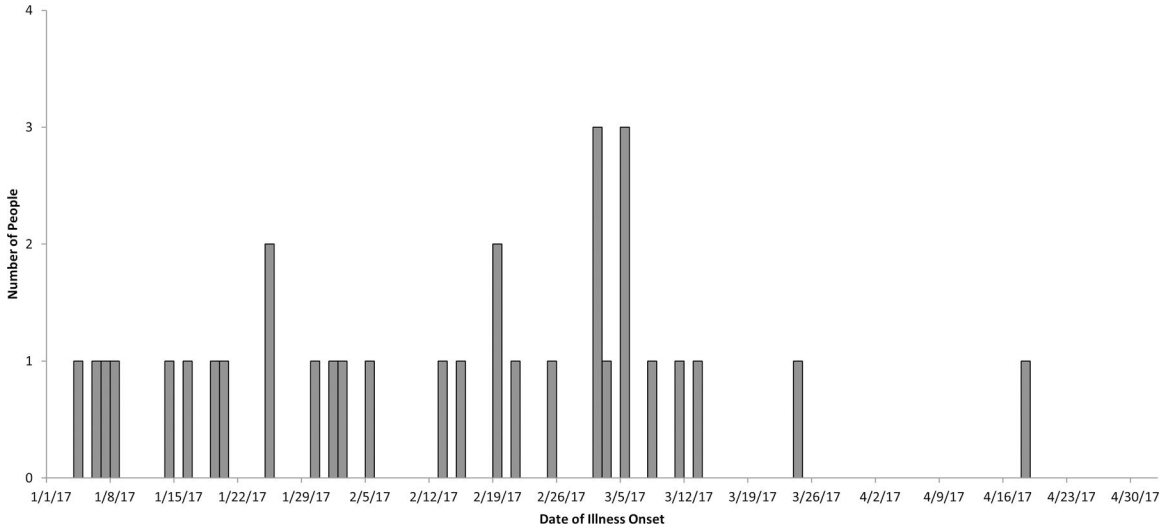

Figure 2:

People infected with the outbreak strains of *E. coli* O157:H7 (n=32), by date of illness onset, United States, 2017

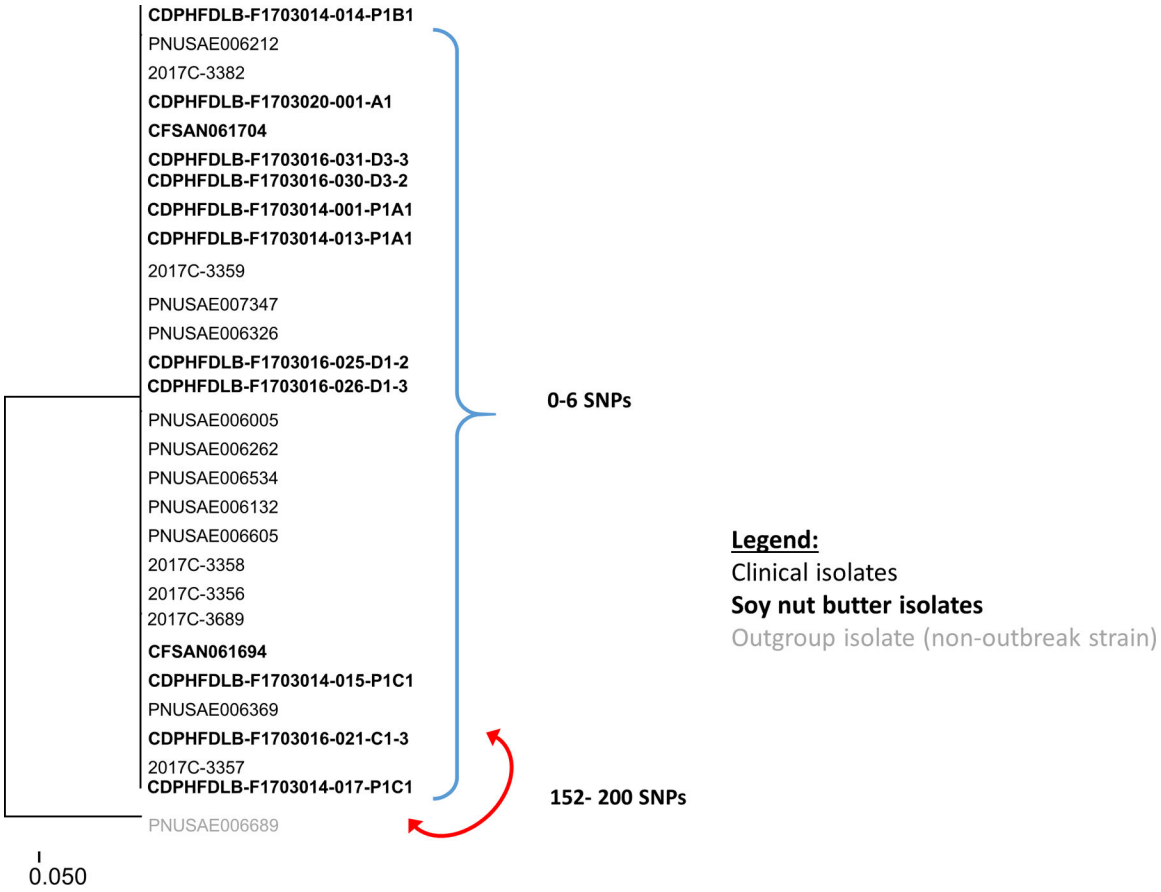

Figure 3: *E. coli* O157:H7 Whole Genome Sequencing Analysis

Phylogenetic analysis of *E. coli* O157:H7 genomes. Maximum likelihood phylogenetic tree constructed from 223 whole genome high quality single nucleotide polymorphisms (hqSNPs) using Lyve-SET version 1.1.4f and the Sakai chromosome (BA000007) as a reference. hqSNP analysis was performed using Lyve-SET version 1.1.4f with the O157:H7 Sakai strain as a reference for the SNP-calling and the following options specified: --mask-phages, --min_coverage ‘20’, --min_alt_frac ‘0.95’, and --allowedFlanking ‘5’ bp. The phylogenetic tree was visualized using MEGA 7. Genomes in bold are from soy nut butter isolates, genome PNUSAE006689 in gray is a non-outbreak associated outgroup, and the remaining are clinical genomes. The relevant SNP differences are noted on the right of the outbreak clade and between the outbreak clade and the outgroup genome. Fifteen clinical genomes representing the three outbreak PFGE pattern combinations and 13 soy nut butter genomes are closely related genetically (0–6 hqSNPs). More than one isolate was identified from some soy nut butter samples.