



Published in final edited form as:

*Epidemiol Infect.* ; : 1–6. doi:10.1017/S0950268818002716.

## New Product, Old Problem(s): Multistate Outbreak of *Salmonella* Paratyphi B Variant L(+) Tartrate(+) Infections Linked to Raw Sprouted Nut Butters, October, 2015

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### Summary

A cluster of *Salmonella* Paratyphi B Variant L(+) Tartrate(+) infections with indistinguishable pulsed-field gel electrophoresis patterns was detected in October, 2015. Interviews initially identified nut butters, kale, kombucha, chia seeds, and nutrition bars as common exposures. Epidemiologic, environmental, and traceback investigations were conducted. Thirteen ill people infected with the outbreak strain were identified in 10 states with illness onset during July 18–November 22, 2015. Eight of 10 (80%) ill people reported eating Brand A raw sprouted nut butters. Brand A conducted a voluntary recall. Raw sprouted nut butters are a novel outbreak vehicle, though contaminated raw nuts, nut butters, and sprouted seeds have all caused outbreaks previously. Firms producing raw sprouted products, including nut butters, should consider a kill step to reduce risk of contamination. People at greater risk for foodborne illness may wish to consider avoiding raw products containing raw sprouted ingredients.

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**Conflict of Interest:** None.

## INTRODUCTION

Approximately one in six Americans become ill from foodborne infections each year; *Salmonella* spp. cause more than one million foodborne infections annually in the United States [1]. Sprouted seeds like alfalfa and clover, and sprouted mung beans have been repeatedly implicated as a cause of enteric disease outbreaks [2–7], and outbreaks linked to raw sprouted products, like sprouted, ground and dried chia seeds, are emerging [8]. Citing food safety concerns, some consumer advocacy groups support warning labels on packaging for sprouted seeds, beans, and other sprouted products; some companies refuse to sell sprouts altogether [9]. Despite these concerns, sprouted seeds may have nutritional benefits. The nutritional value of some types of sprouts are well-established; they often contain higher levels of some vitamins, minerals, and amino acids than their unsprouted counterparts, though this varies by sprout type [10]. Raw nuts [11–13] and nut butters are also known sources of foodborne illness and outbreaks [14–16]. Additionally, an outbreak linked to cashew cheese made with raw nuts was reported in 2014 [17].

On August 19, 2015, the Oregon Public Health Division (OPHD) began investigating two cases of *Salmonella* Paratyphi B variant L(+) tartrate(+) (*Salmonella* Paratyphi B dT+, and since this outbreak, referred to as *Salmonella* I 4,[5],12:b:-) infection with the same pulsed-field gel electrophoresis (PFGE) pattern. These cases occurred within a 30-day timeframe; a third case was identified on October 7, 2015. On October 26, 2015, Centers for Disease Control and Prevention's (CDC's) PulseNet, the national molecular subtyping laboratory network, identified seven additional *Salmonella* Paratyphi B dT+ infections with the same PFGE pattern from six additional states. This PFGE pattern was new to the PulseNet database, making it more likely that these illnesses shared a common source. CDC began investigating in coordination with OPHD, and other state and federal partners.

## METHODS

### Case definition and case finding

We defined a case as infection with *Salmonella* Paratyphi B dT+ PFGE *Xba*I pattern JKXX01.1538, with illness onset during July 1–November 30, 2015. State public health laboratories determined PFGE patterns of clinical isolates, and uploaded them to PulseNet, where the patterns were confirmed and named.

### Hypothesis generation

State and local health officials initially interviewed ill people with state-developed questionnaires or CDC's standard national hypothesis generating questionnaire (NHGQ). In Oregon, ill people were interviewed with an OPHD hypothesis-generating "shotgun" questionnaire. This questionnaire collects data on 884 food and animal exposures during the week before a person became ill, including a variety of health foods, meat, dairy, vegetables, fruits, processed foods, spices, foods eaten raw or intentionally undercooked, and foods eaten outside of the home.

After preliminary common exposures were identified, a single CDC interviewer conducted iterative open-ended interviews with people who became ill more recently. We chose to

conduct openended interviews because they allowed us to identify whether ill people ate foods that were not on state questionnaires or the NHGQ. We asked about foods the ill person generally avoided or disliked, foods (and brands) they commonly consumed, and where they usually purchased food (including grocery stores and restaurants). As more ill people were interviewed, we identified additional foods to include in subsequent interviews to help narrow our hypothesis.

We developed a focused questionnaire by combining suspected foods identified through open-ended interviewing with information collected from the OPHD shotgun interviews and the NHGQ. The focused questionnaire collected detailed information on brand, type, flavor, purchase date and location, best-by dates, lot codes, and whether leftover product was available for microbiological testing.

To evaluate exposures of interest, we compared foods reported among ill people in the seven days before illness began with seven day food exposure estimates from two different population-based surveys using a standard binomial probability model. First, we compared the frequencies of foods reported by ill people in this outbreak with the 2006–2007 FoodNet Population Survey, which collected information on foods reported by healthy people during the seven days before interview [18]. Second, for foods not included in the FoodNet Population Survey, we compared frequencies of foods reported by ill people in this outbreak with those reported by other ill people interviewed using the OPHD shotgun questionnaire database. This dataset includes interview data collected for both sporadic and cluster-associated cases of *Salmonella* and Shiga toxin-producing *E. coli* (STEC) infection since 2007. For this second comparison, we excluded sporadic infection among people that reported international travel in the 7 days before illness onset, infection among people without acute onset of either vomiting or diarrhea, and infections suspected to be secondary to another person's illness in the same household.

### Regulatory investigation

After we identified the suspected food vehicle, the Oregon Department of Agriculture (ODA) made an initial site inspection at the firm on November 24, 2015. ODA then conducted a joint inspection of the firm with the Food and Drug Administration (FDA) Seattle District office on December 1, 2015. FDA conducted a traceback investigation of select product ingredients. ODA made two additional visits to the firm, on December 14 and 22, 2015, as part of the regulatory response to the product recall.

### Laboratory investigation

Leftover, opened products from ill peoples' homes in California, Hawaii, and Oregon were collected for testing by the California Department of Public Health (CDPH) Food and Drug Laboratory Branch, the State Laboratories Division at the Hawaii State Department of Health (HSDH), and Deschutes County Health Services (Oregon), respectively. ODA collected samples of finished product during their initial inspection at the firm. The firm also provided OPHD with open samples of retained, finished product that contained 1 oz. or less of product. Additionally, OPHD purchased unopened finished product from a local store in Oregon. All samples and product ingredient samples collected from the firm and at retail

were cultured for *Salmonella* at a private laboratory for analysis on behalf of OPHD. ODA and FDA Seattle District Office collected environmental samples during the second inspection and during a subsequent follow-up inspection. Environmental samples were collected using sponges and Q-tips, and were cultured for *Salmonella* by FDA.

## RESULTS

### Case finding

We identified thirteen cases from ten states: California (1), Colorado (1), Georgia (1), Hawaii (1), Idaho (1), Illinois (1), Maine (1), North Carolina (1), New Jersey (1), and Oregon (4) (Figure 1). Illness onset dates ranged from July 18–November 22, 2015 (Figure 2). Ill people ranged in age from 1–79 years (median: 41), and 5 (38%) were female. Of twelve ill people with information, none were hospitalized, and no ill people died.

### Hypothesis generation

Information from state questionnaires and the OPHD shotgun questionnaire revealed that several health foods were reported by two or more ill people in this outbreak the week before they became ill: kale (5 ill people), almonds (3), seaweed (2), and organic foods (2). Six ill people reported shopping at various health food stores. This “healthy eater” signal suggested that the outbreak vehicle might not be captured on the NHGQ, so we conducted open-ended interviews. We completed four open-ended interviews during November 13–23. All four ill people reported eating nut butters, and two reported the same product: cacao-flavored Brand A raw sprouted nut butter (Figure 3). The remaining two ill people reported eating peanut butter (1 ill person) and almond butter (1 ill person). Other commonly reported foods were kale (3), nutrition bars (3, same brand), chia seeds (3, two of the same brand), and kombucha (2 ill people, same brand). To further investigate Brand A raw sprouted nut butter as a possible outbreak source, we developed a focused questionnaire to specifically ask ill people about this exposure. Brand A raw sprouted nut butter, other nuts butters, and the other commonly report foods above, and specific brands, were included in the focused questionnaire.

Seven ill people were interviewed or re-interviewed with the focused questionnaire, including the two ill people who reported nut butter during open-ended interviews but had not spontaneously reported eating Brand A raw sprouted nut butter (Figure 3). All seven reported eating nut butters, which was significantly higher when compared with peanut butter consumption from the FoodNet population survey (100% vs. 58%,  $p=0.04$ ). We used peanut butter consumption, which likely overestimates consumption of other nut butters, as a proxy since no data were available for other nut butters in the FoodNet Population Survey. However, the OPHD shotgun questionnaire included a question about “ground nut butters, pastes, or spreads” other than peanut butter, which would include nut butters made from both roasted and raw nuts; 9.2% of ill people interviewed using the OPHD shotgun questionnaire reported this exposure. We rounded up to 10% for a conservative estimate, and the binomial probability was significant (100% vs 10%,  $p<=0.0005$ ), supporting nut butters as a suspected food vehicle for this outbreak. Of the seven ill people who reported eating nut butters, five (71%) were exposed to Brand A raw sprouted nut butter. Four of the five reported eating

Brand A raw sprouted nut butter, including one ill person who did not spontaneously report this brand during an open-ended interview. The fifth ill person was a child who did not eat Brand A raw sprouted nut butter but whose parent did; the child may have been exposed through cross-contamination in the household. Two of five (40%) ill people reported eating chia seeds, two of four (50%) reported nutrition bars (different brands), and none of five reported kombucha.

### Identification of the outbreak source

By the end of the investigation, eight of ten (80%) ill people interviewed with any type of questionnaire were exposed to Brand A raw sprouted nut butters (Figure 3). Four flavors of Brand A raw sprouted nut butters were available for purchase during this outbreak. Information on flavors consumed was available for seven ill people; six (86%) reported cashew almond butter (four ate only this flavor), three (43%) reported hazelnut cacao butter (one ate only this flavor), and one each reported two different flavors of almond butter. Purchase information was available for five ill people. One ill person ate Brand A raw sprouted nut butter as part of a dish served at a restaurant, one received a sampler pack in the mail, one sampled it at a farmers market, one purchased it from an online store and a health food store, and one purchased it only from a health food store. Lot information was available for two Brand A raw sprouted nut butters purchased by ill people; different lots were reported.

### Regulatory investigation

A single facility in Oregon produced Brand A raw sprouted nut butters. Nut butters were made by sprouting raw organic cashews, almonds, and hazelnuts. The nuts were soaked in water under refrigeration to initiate the sprouting process, then dehydrated and ground. The firm did not apply a kill step to reduce pathogens. All other ingredients, according to the firm, were raw and certified organic; none were sprouted. For the purposes of this outbreak investigation, we defined raw items as those which did not undergo heat or other treatment sufficient to kill pathogens. The firm reported the shelf life of the products was one year.

During the initial ODA investigation on November 24, 2015, three critical violations requiring immediate attention were noted: a lack of sanitation of food contact surfaces, unclean food processing equipment, and no preventive pest control program in place. The firm was not actively in production at the time of this visit and agreed to halt further food processing in light of these critical violations and the suspected association of their product with this outbreak.

On December 17, 2015, and after their inspection, FDA issued FDA Form 483, which documented observations of objectionable conditions at the firm, including certain failures to protect against contamination and to take effective measures to exclude pests. FDA's traceback investigation identified the United States, Indonesia, and Turkey as the countries of origin of the raw almonds, cashews, and hazelnuts, respectively. No investigation of whether other firms that may have received the same lots of these nuts used to make Brand A sprouted nut butter (traceforward) occurred. ODA returned to the production facility at the firm's invitation on December 14, 2015, to review the correction of the violations discovered

on November 24th. Although production was supposed to have been halted, inspectors found that the firm had resumed production earlier that morning and that a proper inspection of previously unsanitary equipment could not be conducted. Nut butter produced between November 24 and December 14 (a total of 882 pounds), and all nuts that had already been soaked and dehydrated were placed under embargo by ODA and prevented from being sold over concern of possible *Salmonella* contamination.

### Laboratory investigation

*Salmonella* was not isolated from any of the three open, leftover samples collected from ill people's homes. Of note, Brand A raw sprouted nut butter collected from the ill person in Hawaii was not the same jar as was consumed before the person became ill. Samples of nut butter ingredients were collected at the firm, and included coconut sugar and dried, sprouted cashews, hazelnuts, and almonds. Five samples of raw sprouted nut butters ready for distribution retained from the firm were collected, and included each of the four flavors that were sold at the time, and one flavor that had been discontinued. None of the retained product or product ingredient samples yielded *Salmonella*. Four unopened retail samples of four flavors of Brand A raw sprouted nut butters also did not yield *Salmonella*.

Environmental samples collected during the December 1, 2015, visit included samples from processing surfaces, all nut grinders, all dehydrators and screens, bulk ingredient containers, storage shelving, and various other equipment throughout the facility. None of these 104 environmental samples yielded *Salmonella*. Additional environmental samples were collected on December 5, with an emphasis on areas that might periodically become wet (providing an ideal environment for *Salmonella* growth); sampled areas included an equipment washing sink, drain pipes, floor sinks, and a loose metal support leg beneath a sink used for food processing. Culture of these 96 environmental samples did not yield *Salmonella*.

### Recall and Public Health Impact

On December 2, 2015, the firm announced a voluntary recall of all Brand A raw sprouted nut butters distributed between June and November 2015. CDC and FDA posted outbreak notices and consumer warnings on their websites. The recalled products were distributed nationwide in retail stores, through mail order, and also sold online via the firm's website and online retailers.

## DISCUSSION

While sprouts are a known source of foodborne outbreaks [2–7], raw sprouted nut butters are a novel outbreak food vehicle. Open-ended interviewing helped identify Brand A raw sprouted nut butter as the likely source of this outbreak of *Salmonella* Paratyphi B dT+ infections, though the outbreak strain was not cultured from food samples or the production environment. Raw sprouted nut butters are biologically plausible vehicles for *Salmonella*: contaminated raw nuts, nut butters, sprouted seeds and beans, and sprouted seed products have all caused outbreaks in the past [2–8, 11, 12, 14–17, 19]. Our findings add to the



growing body of evidence that any raw products made using raw sprouted ingredients may carry a risk of foodborne illness similar to that posed by sprouts.

*Salmonella* was not identified in any Brand A nut butter samples tested, nor from the production environment or nut butter ingredients. Reasons for this may have included transient contamination of the production environment, uneven contamination of raw nuts used to make sprouted nut butter, uneven contamination of lots, or inadequate amount of leftover product available for testing. A study examining *Salmonella* contamination of raw California almonds noted that *Salmonella* cells were distributed unevenly [20]. Another study found *Salmonella* cells in peanut butter aggregated in clumps around water/lipid suspensions [21]. Therefore, it is possible that *Salmonella* bacteria were present in Brand A sprouted nut butter, but not in the samples that were collected and tested.

The ultimate source of contamination of Brand A raw sprouted nut butter remains unknown; we hypothesize that sprouted raw nuts were the most likely source for two reasons. First, raw nuts can become contaminated with bacteria like *Salmonella* during harvest. Nuts like almonds and walnuts are harvested by shaking them from trees to the ground, where they can become contaminated by grazing animals, wildlife, irrigation water, or even poor worker hygiene practices [13]. Two studies of raw California almonds sampled at processors before processing found *Salmonella* prevalence ranging from 0.83% to 1.6%, with estimated most probable number (MPN)s of 1 to 18.3 per 100g [20, 22]. Another study determined the prevalence of *Salmonella* in retail samples of raw cashews and macadamia nuts was 0.55% and 4.23%, respectively [23]. Second, low-level contamination of raw nuts could have been amplified during the sprouting process. We found no data on the microbial safety of sprouted nuts. However, an assessment of *Salmonella* growth during sprouting of naturally contaminated alfalfa seeds found that an initial *Salmonella* concentration of  $<1$  MPN/g in the seeds eventually increased to a maximum of  $10^4$  MPN/g within two days of sprouting [24]. However, since all ingredients, leftover product and environmental samples that were collected were negative, it cannot be ruled out that another common ingredient, pests, equipment or the environment may have been the source of product contamination.

Producing nut butter that is raw, sprouted, and consistently free of *Salmonella* may be challenging. Roasting and blanching nuts reduces *Salmonella* bacteria on raw nuts but would result in a product that is not considered raw. Treatment with propylene oxide, another means to reduce *Salmonella* contamination, would potentially leave the product in what may be considered a raw state, but would result in a non-organic product, which may be important for companies that are interested in producing an organic product. Sprouting carries risk for bacterial contamination, because the warm, moist, and nutrient-rich conditions required to produce sprouts are also ideal for the proliferation of pathogens, such as *Salmonella*, if present. Because of this risk, FDA recently established sprout-specific production requirements (in 21 CFR Part 112, Subpart M), as part of implementing the FDA Food Safety Modernization Act (FSMA), as well as a Draft Sprout Guidance. These requirements include treatment of seeds or beans used to grow sprouts to reduce microorganisms of public health significance, testing spent sprout irrigation water or sprouts for pathogens, and monitoring the sprout growing, harvesting, packing, and holding environments for *Listeria* or *L. monocytogenes*. FDA often refers collectively to everything

sprouted to produce sprouts for human consumption, simply as “seeds.” References to “seeds” in this FDA’s Draft Sprout Guidance should not be read to exclude other things that are sprouted to produce sprouts for human consumption. At the time of this outbreak, FDA policy was unclear as to whether sprouted nuts would be regulated under these sprout-specific requirements of Subpart M. As sprouting nuts is an emerging production practice, FDA is evaluating this issue in light of the Produce Safety Rule and Subpart M to determine the best approach in terms of food safety policy. Whether sprouting seeds, beans, or nuts, producers should be aware that the sprouting environment and process may amplify even low levels of bacteria present.

Several methods for mitigating the risk of *Salmonella* contamination after sprouting exist, but they too have limitations. Testing spent irrigation water and/or sprouted nuts for *Salmonella*, as required by 21 CFR § 112.144(b), is one such measure. However, if every lot of sprouted nuts is not tested, sprouted nuts are tested improperly, or contamination is uneven, contamination may not be detected. A second method, grinding dehydrated sprouted nuts at a temperature high enough to kill pathogens, would result in a non-raw product. Furthermore, the water content of dehydrated nuts might be low enough that *Salmonella* is not easily destroyed even if high temperatures are applied [25]. Finally, the final raw sprouted nut butter product could be heat-treated, but this process might not eliminate *Salmonella*, especially if the bacterial load is high. The low water activity and high fat content of peanut butter may increase the heat resistance of *Salmonella* within the product [24, 26]. A study found that some heat-resistant *Salmonella* strains could survive in peanut butter for the duration of its shelf life, even when exposed to temperatures as high as 194°F (90°C) for 50 minutes [26]. A study assessing inpackage thermal inactivation of *Salmonella* spp., including this outbreak strain, inoculated in Brand A nut butters determined that treatment at >90°C with a 30 minute hold-time achieved a >5 log CFU/g reduction, though there were changes in texture, which the authors noted may make the final product unacceptable [27].

This investigation identified sprouted nut butter as the likely source of a multistate outbreak of *Salmonella* Paratyphi B Variant L(+) Tartrate(+) infections, adding to the growing list of outbreaks linked to raw sprouted products. The number and frequency of outbreaks linked to sprouted seeds and raw sprouted products is concerning. Consumers continue to perceive sprouted products as a health food with nutritional benefits. However, the risks associated with consuming sprouted seeds in particular are well-documented, and children, the elderly, pregnant women, and people with weakened immune systems should avoid eating raw sprouts of any kind [28]. Given this risk, firms that produce foods containing raw sprouted ingredients should consider implementing a kill step to reduce bacterial contamination and subsequent foodborne illness. People at greater risk for foodborne illness should not only avoid eating raw sprouts, but should also consider avoiding eating any products made with raw sprouted ingredients that have not undergone a kill step.

## Acknowledgements

Tasha Poissant and Paul Cieslak (Oregon Public Health Division, Portland, OR, USA), Matthew Wise, Christine VanTubbergen, CDC’s PulseNet Next Generation sequencing laboratory, April McDaniel, and Darlene Wagner (Centers for Disease Control and Prevention, Atlanta, Georgia, USA), State and local health departments.

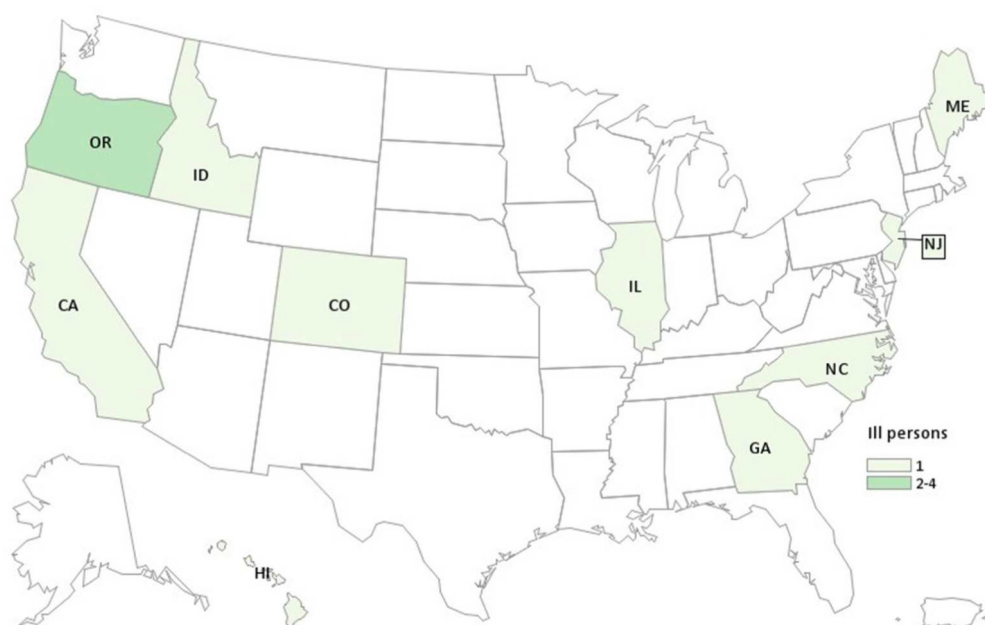


**Financial support:** This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

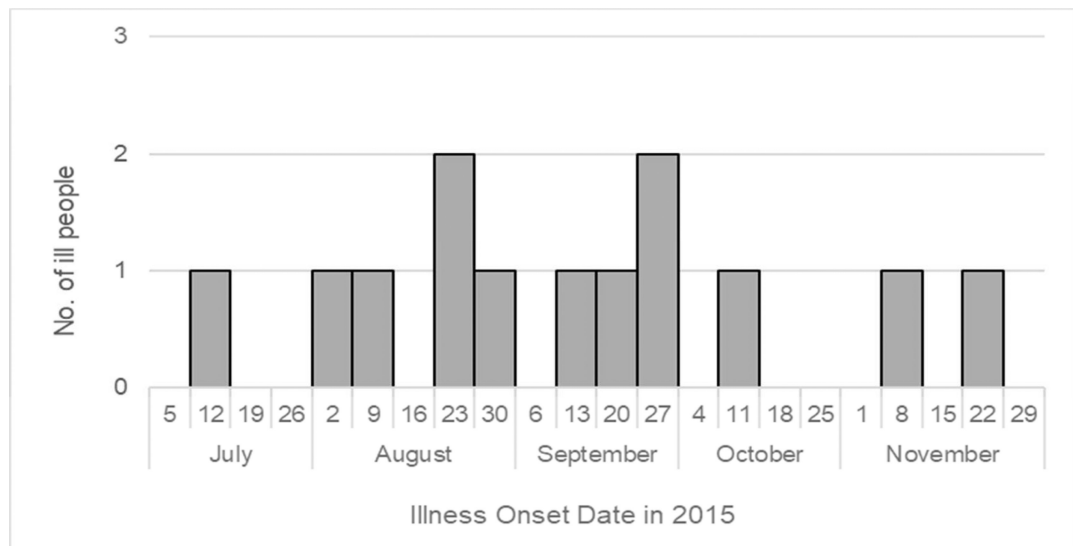
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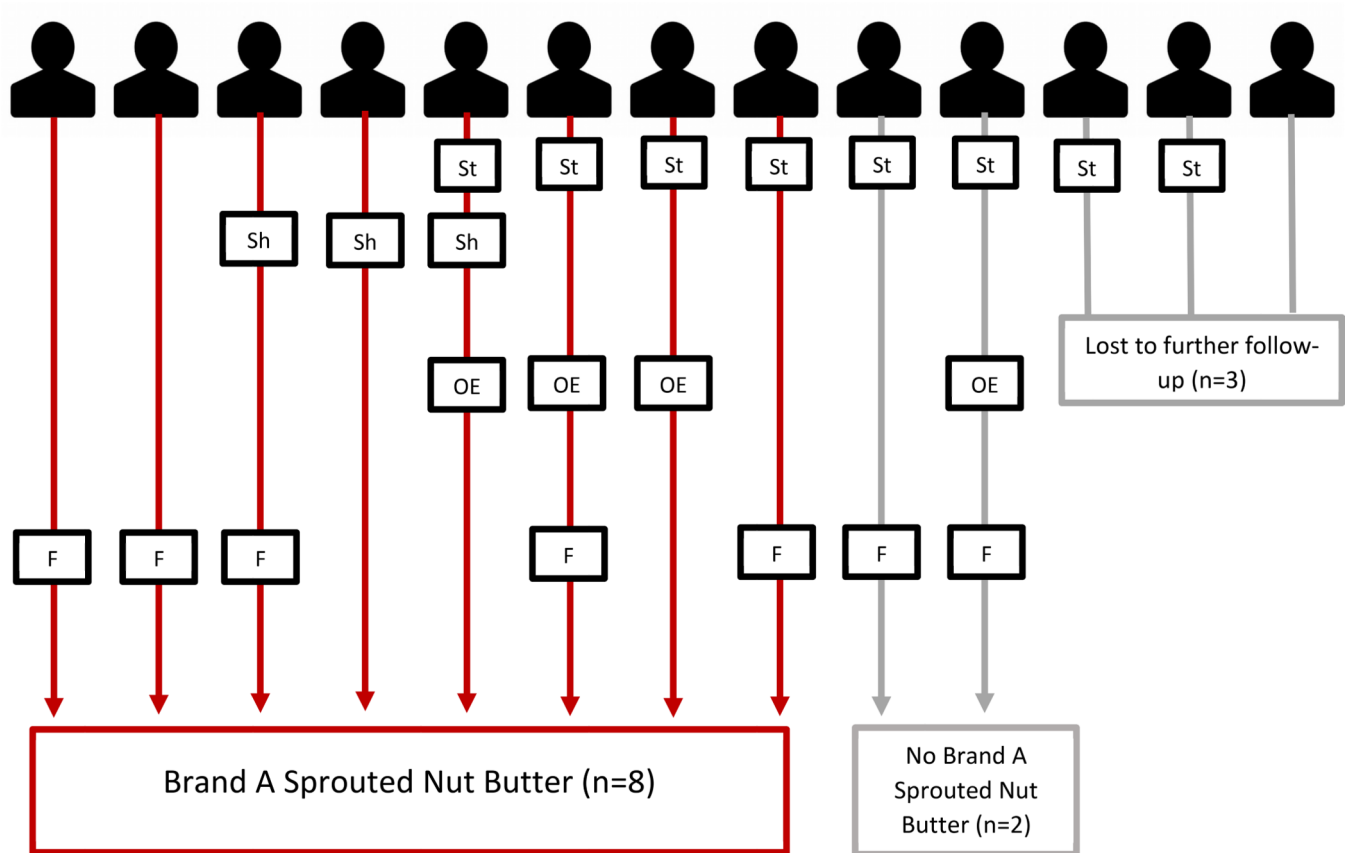
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**Figure 1.**  
People infected with the outbreak strains of *Salmonella* Paratyphi B var. L(+) tartrate (+), by state of residence, 2015, (n=13)



**Figure 2.**  
People infected with the outbreak strains of *Salmonella* Paratyphi B var. L(+) tartrate (+), by date of illness onset, 2015 (n=13)



St = State questionnaire, Sh = shotgun questionnaire, OE = open-ended interview, F = focused questionnaire

**Figure 3.**

Hypothesis generation and hypothesis testing questionnaires administered, and Brand A raw sprouted nut butter exposure, by ill person