Multijurisdictional Norovirus Outbreak Associated with Commercially Distributed Ice Cream, Minnesota, 2016

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The Chain of Regulatory Responsibility
MDA’s Role in Outbreak Investigations

- Identifying SMEs
- Conducting traceback
- Conducting facility investigations
- Testing of food product or environmental samples
- Taking actions to protect public health
  - Embargo
  - Recall request
  - Consumer advisory
  - Corrective action plans
- Providing coordination for response activities
  - Minnesota Rapid Response Team (MN RRT)
**What is a Rapid Response Team (RRT)?**

- FDA-funded program initiated in 2008
- National response network
- MN RRT is involved in:
  - Foodborne illness outbreak
  - Contamination events
  - Natural disasters
  - Many moving parts / programs involved
  - Assistance in event management
  - Program needs that stretch beyond “routine”
• Routine surveillance, studies, other projects

• Outbreak investigations
  – Coordinate between jurisdictions and agencies (e.g., Centers for Disease Control and Prevention, environmental health, MDA)
  – Case interviews
  – Analysis and statistical support
  – Public health response
• The MDA RRT is physically located in the same building as MDH epidemiology

• Cultivated strong relationship on *Salmonella, STEC, Listeria* commercial product outbreaks
Background

• MDH/MDA collaboration on norovirus investigations is infrequent
• A food item regulated by MDA is seldom identified as the source of a norovirus outbreak
• Most common?
  – “Cake checks”
  – Commissary kitchens (manufacturers)
  – Private events “catered” by grocery stores
• Used existing collaboration experience to work quickly/effectively on a “novel pathogen” for RRT
• Norovirus is the most common cause of acute gastrointestinal illness in the United States

• In Minnesota, norovirus is the etiology for ~60% of foodborne outbreaks

• Foodborne norovirus outbreaks usually caused by contamination at time of preparation
Almost all norovirus outbreaks identified through the Minnesota Department of Health (MDH) foodborne and waterborne illness hotline

- Centralized complaint system
- Illness reports collected and assessed at state level
- Investigations initiated with state or local environmental health jurisdictions
August 8, 2016

- Received complaint
  - Gastrointestinal illness among 2 of 3 meal companions
  - Only common exposure: August 4 meal at Restaurant A
  - Incubation periods 29.5 and 32 hours
Outbreak Investigation – Restaurant A

• Investigation initiated at Restaurant A
  – Lead agencies
    ▪ Hennepin County Human Services and Public Health Department, Epidemiology
    ▪ Minneapolis Health Department, Environmental Health
  – Norovirus interventions
    ▪ Restaurant clean/sanitize, education (hand hygiene, exclusions)
    ▪ Food worker interviews
  – Patron interviews (case finding, case-control study)
Investigation Results – Restaurant A

• Two cases identified
  – Vegetarian tacos; Brand X raspberry chocolate chip ice cream

• Five controls interviewed
  – Variety of other menu items; no ice cream

• Five of 85 employees with vomiting/diarrhea
  – Illness onsets July 27 – August 6
    ▪ Patron meal date: August 4

One employee: eats Brand X raspberry chocolate chip ice cream during most shifts
August 15, 2016

• MDH foodborne illness hotline received another complaint
  – Gastrointestinal illness among 3 of 20 meal companions
  – Only common exposure: August 11 visit to Brand X Ice Cream’s Franklin retail location
  – All cases ate raspberry chocolate chip ice cream
    ▪ Well individuals ate a variety of other flavors
August 17, 2016

- Hennepin County Epidemiology received a complaint from a local country club
  - Gastrointestinal illness among attendees of a catered birthday event on August 13
    - Country club did not serve Brand X ice cream
    - Symptoms/duration = norovirus; incubation periods too short
  - The group also ate together August 12 at a private home
    - For dessert: Brand X ice cream
# Private Party Case-Control Study Results

<table>
<thead>
<tr>
<th>Brand X Ice Cream Flavor</th>
<th>Cases</th>
<th>Controls</th>
<th>Odds Ratio</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/n</td>
<td>n/n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vanilla</td>
<td>1/5</td>
<td>1/10</td>
<td>2.25</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>(20%)</td>
<td>(10%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chocolate</td>
<td>3/5</td>
<td>1/10</td>
<td>13.5</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>(60%)</td>
<td>(10%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raspberry Chocolate Chip</td>
<td>5/5</td>
<td>2/9</td>
<td>--</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>(100%)</td>
<td>(22%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Norovirus Gastroenteritis Cases Associated with Brand X Ice Cream, by Meal Date

Meal Date
August 2016

Number of Cases

- Retail – Upton
- Restaurant A
- Private Party
- Retail – Franklin
- Retail – Upton
- Laboratory-confirmed
Stool Results – GII.17 Kawasaki

Complainant – Upton retail
Complainant – Franklin retail
Complainant – Private party
Complainant – Private party
Complainant – Restaurant A
Employee – Restaurant A
Complainant – Upton retail
Complainant – Upton retail
Complainant – Franklin retail

GII_17B_13BH1_TW13
GII_17A_Katrina-17_US05

1 nucleotide difference
August 16, 2016

- Raspberry chocolate chip ice cream ingredients:
  - Vanilla base mix, chocolate chips, frozen raspberries, sugar, stabilizer
  - No kill step for raspberries

- Preparation involved no direct food worker handling

- All 16 employees interviewed by Team Diarrhea
  - No illnesses reported
Norovirus Gastroenteritis Cases Associated with Ice Cream, by Meal Date

<table>
<thead>
<tr>
<th>Meal Date</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>1</td>
</tr>
<tr>
<td>22</td>
<td>2</td>
</tr>
<tr>
<td>23</td>
<td>3</td>
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<tr>
<td>24</td>
<td>4</td>
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<tr>
<td>25</td>
<td>5</td>
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<td>26</td>
<td>6</td>
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<td>27</td>
<td>7</td>
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<td>28</td>
<td>8</td>
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<tr>
<td>29</td>
<td>9</td>
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<tr>
<td>30</td>
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<td>1</td>
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<td>8</td>
<td>18</td>
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<td>19</td>
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<td>19</td>
<td>29</td>
</tr>
<tr>
<td>20</td>
<td>30</td>
</tr>
</tbody>
</table>

http://www.amcharts.com/visited_countries/
<table>
<thead>
<tr>
<th>Meal Date</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td></td>
</tr>
<tr>
<td>21 22 23 24 25 26 27 28 29 30 31</td>
<td>1</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19</td>
<td>6</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19</td>
<td>7</td>
</tr>
</tbody>
</table>

- **Raspberry shipment of interest received at commissary**
- **Product withdrawal initiated**
Brand X Ice Cream Product Withdrawal & Consumer Notification Decision

Retail (2.5 gallon tubs)
• Distributed to Brand X’s two retail locations and other venues (restaurants)
  – By August 19, 146 tubs returned to commissary

Patron Homes (pints)
• Brand X retail locations sell pints scooped at counter
  – Sales information: 348 pints of all flavors sold July 1 to August 15
  – Raspberry chocolate chip 3rd most popular flavor
Sample Collection for Testing at FDA Center for Food Safety and Applied Nutrition (CFSAN) Laboratory

Six bags of frozen raspberries

- Ten 2.5 gallon containers
- Chile (n=2) from Serbia and China (n=2)
Sample Analysis and Timeline

• Samples shipped to FDA CFSAN on September 28, 2016

• Challenges:
  − Size of shipment
  − Timing
  − Use of dry ice
    ▪ Insulated boxes
    ▪ Labeling requirements
    ▪ How much dry ice?

• Raspberry samples set up by CFSAN on October 10, 2016
# Product Testing Results

**FDA CFSAN & Office of Regulatory Science Laboratories**

<table>
<thead>
<tr>
<th>Product</th>
<th>Amount Tested</th>
<th>Norovirus Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vanilla Ice Cream</td>
<td>2 pints</td>
<td>pending</td>
</tr>
<tr>
<td>Chocolate Ice Cream</td>
<td>2 pints</td>
<td>pending</td>
</tr>
<tr>
<td>Raspberry Chocolate Chip Ice Cream</td>
<td>10 x 2.5 gallons</td>
<td>presumptive positives</td>
</tr>
<tr>
<td>Frozen Raspberries</td>
<td>Chile: 2 bags, Serbia: 2 bags, China: 5 bags</td>
<td>negative, negative, positive</td>
</tr>
</tbody>
</table>
Raspberry Sequences

Region B

ME2016012738
ME2016012799
ME2016012168
ME2016012834
ME2016012842
Seq1 raspberries
Seq2 raspberries

Human Specimen  GII.17 Kawasaki
Human Specimen  GII.17 Kawasaki
Human Specimen  GII.17 Kawasaki
Human Specimen  GII.17 Kawasaki
Human Specimen  GII.17 Kawasaki
Human Specimen  GII.17 Kawasaki
Raspberries      GII.17 Kawasaki
Raspberries      GII.17 Kawasaki
Conclusions

• Outbreak of norovirus associated with ice cream produced using contaminated frozen raspberries, sourced from China
• Ice cream manufacturer has initiated a kill step for frozen raspberries
Discussion

• Frozen berries: vehicle for hepatitis A virus, norovirus (Europe)

• This is the first norovirus outbreak due to imported frozen berries in United States

• Outbreak was tough to find
  – Outbreak-detection systems venue-focused, not sensitive to commercially distributed vehicles

• Norovirus outbreaks due to commercially distributed foods likely more common

• Several system components were essential to detecting and solving
Detection of Norovirus Outbreaks due to Commercially Distributed Products

1. Centralized complaint system
   - Link complaints from multiple jurisdictions
2. Rapid and thorough investigation of all norovirus outbreaks
   - Analytical studies, timely sequencing
3. Strong relationships and communication among investigators
   - All levels of outbreak response
4. Iterative investigation process
   - Restaurant A employees re-interviewed
   - Private party attendees re-interviewed
Lessons Learned

• Used previously-existing relationships between RRT and Epi for a strong response to a novel outbreak type
• Fostered communication for investigations involving several agencies
• Good example of importance of investigating all norovirus outbreaks
• Consider shipment challenges early in the sampling process
• Are frozen berries a high-risk food?
Norovirus Frozen Berry Outbreaks


Berries - Advice to boil imported frozen berries (May 2015)

Warning issued over frozen berries following virus outbreak

The FSAI has reminded people to boil all frozen berries before consumption.
Norovirus Frozen Berry Outbreaks

- “Largest outbreak in German history caused by imported strawberries”
- New German recommendations for institutions catering for vulnerable populations -> heat frozen berries
- January 2013, EU regulation: 5% of frozen strawberries imported from China to EU must be tested for norovirus
Norovirus Frozen Berry Outbreaks

Quebec issues warning on several raspberry products due to norovirus risk

Several bakeries, dépanneurs and grocery stores sold products at risk of contamination

Recalls and safety alerts

Gelsius brand IQF Whole Raspberries recalled due to Norovirus

Starting date: June 20, 2017
Type of communication: Recall
Alert sub-type: Notification
Subcategory: Microbiological - Other
Hazard classification: Class 1
Source of recall: Canadian Food Inspection Agency
Recalling firm: Distribution Farine (113712 Canada Inc.)
Distribution: New Brunswick, Ontario, Quebec
Extent of the product distribution:

CFIA reference number: 11486

Affected products

Brand name: Gelsius
Common name: IQF Whole Raspberries
Size: 5 x 1 kg
Code(s) on product: D16083101

Report a Concern
Investigation Partners & Acknowledgements

MN Department of Health
Epidemiology (Joshua Rounds, Nicole Hedeen, Dana Eikmeier, Kirk Smith, Carlota Medus) ● Team Diarrhea ● Public Health Laboratory (Liz Horn, Ginette Dobbins, Elizabeth Cebelinski)

City of Minneapolis Health Department
Environmental Health

FDA
Office of Human and Animal Food Operations, Division 1 West ● Office of Regulatory Science ● CFSAN

Brand X Ice Cream Photo Credit
Brand X website http://bit.ly/1tMslG7

MN Department of Agriculture
Inspections (Lisa Ramacher) ● Laboratory (Matt Forstner)

Hennepin County Human Services and Public Health Department
Epidemiology (Carol Hooker, Erica Bagstad) ● Environmental Health

Virginia Department of Health
Laboratory ● Epidemiology

CDC
Jan Vinjé, Leslie Barclay, Aron Hall
Thank You! | Questions?

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GII.17 Kawasaki

• First reported Fall 2014 (Jiangsu, China)

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**Emergence of a New GII.17 Norovirus Variant in Patients with Acute Gastroenteritis in Jiangsu, China, September 2014 to March 2015**

Fu J1,2, Ai J1,2, Jin M3, Jiang C4, Zhang J5, Shi C6, Lin Q7, Yuan Z8, Qi X1, Bao C1, Tang F1, Zhu Y (jszyf@jscdc.cn)1

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• Was predominant strain during 2014 – 2015 season (not GII.4)

• Sequencing study (Parra et al.) shows same virus also present in U.S. during that time
  - Parallel evolution, introduction, or both
National Outbreaks

Minnesota

• GII.17 Kawasaki outbreaks with 100% similar sequences seen in previous outbreaks earlier in the year

CaliciNet

• 57 outbreaks 100% similar to outbreak sequences (April 2015 – May 2016)
• 90 outbreaks with 1 nucleotide difference (Feb 2015 - May 2016)
• 3 months between last GII.17 Kawasaki outbreak and ice cream outbreak
15 cases identified

• Female: 10 (67%)
• Median incubation: 31.5 hours (range, 21 to 45 hours)
• Median duration (n=8): 34.5 hours (range, 9 to 96 hours)
• Vomiting: 13 (87%)
• Diarrhea: 13 (87%)
• Cramps: 8 (53%)
• Fever: 5 (33%)
• Hospitalized: 1 (7%)
Heterogeneous Region C & Region BC

Region C

Region BC
Norovirus im Speise-Eis

Bis Donnerstagnachmittag waren es 157 Meldungen eines Magen-Darm-Virus, die dem Kreisgesundheitsamt gemeldet wurden. Laut dem Reutlinger Amt wurden im konsumierten Spiseeis Noroviren nachgewiesen.