MINNESOTA
Integrated Food Safety
Center of Excellence
MINNESOTA DEPARTMENT OF HEALTH • UNIVERSITY OF MINNESOTA

Subcluster Analytic Studies – Frequently Asked Questions and Barriers

In multi-state foodborne outbreaks due to commercially distributed foods, interviews of cases often detect groups of cases that report exposure to the same individual points of service such as restaurants, catered events, or cafeterias - these groups of cases are termed ***establishment subclusters*.**

Why is it so important to conduct formal analytic studies in subcluster investigations?

Multi-state outbreaks are very intensive and difficult to investigate, including interviewing cases about their entire exposure period with lengthy hypothesis-generating questionnaires, and then re-interviewing with focused questionnaires. Subclusters are so valuable because they allow the investigation to focus on the limited number of items consumed by cases at the subcluster establishment(s). Epidemiology can be an extremely powerful and rapid tool in these situations – the fact that an outbreak occurred means there should be a quantifiable difference between case and control exposures at subcluster establishments.

When should I start a subcluster investigation, i.e., how many cases should there be to start?

Time is of the essence in these investigations – the more quickly they begin the more likely the establishment will cooperate and the vehicle will be identified. You should start thinking about an investigation as soon as 2 (or more) cases name the same establishment, because more subcluster cases will frequently be identified (see the next question below) and starting with 2 cases will ensure as rapid an investigation as possible.

There are too few cases in the subcluster to conduct a meaningful analytic study, so shouldn't we just wait?

No. In most instances, more cases can be ascertained by asking all other cluster cases specifically about the subcluster establishment (as many won't remember without a specific prompt). More cases can also be ascertained by contacting patrons from the implicated meal date(s). Even studies with few cases can be critical, especially when combined with results from other subcluster investigations. The time lapse caused by waiting to begin a subcluster investigation can hinder, and ultimately kill, the investigation.

How do I convince the local health department to do this?

Stress to them that subcluster analytic studies represent the best chance to solve a multi-state outbreak, and are a best practice being emphasized by the Council to Improve Foodborne Outbreak Response. Tell them that all other investigation partners nationwide are depending on jurisdictions with subclusters. Therefore, these investigations should be a high priority. Provide all available resources to them, and relay that other entities (perhaps you, CDC, or a CoE state) are available to assist.

Ok, we're going to do it – how do I start?

First, make sure all subcluster cases have been interviewed with the establishment menu, making sure to note additions or subtractions to the menu items ordered by cases. Then, you will need to get recipe/ingredient information from the establishment. For step-by-step instructions, refer to our establishment subcluster investigation checklist and Ingredient Specific Analysis Matrix CodeBuilder.

What's the best way to get recipe/ingredient info from the establishment?

Menu-item level analytic studies are certainly valuable, but analyses also need to be done at the ingredient level. The establishment manager and chef/prep staff should be interviewed to obtain ingredient lists for menu items; it is often beneficial to have the lead epidemiologist accompany the environmental health professional to the restaurant to do this in person. If the establishment is part of a chain, its corporate office might have the information available electronically (but please verify the accuracy of that info with establishment staff). For additional guidance, review this ingredient specific analysis guidance.

How can I get patron contact info from the establishment?

You will need contact info for patrons from the implicated meal date(s). You should pursue any data sources that are available, e.g., Apps/Delivery Services/Online orders, credit card receipts, reservations. To get this info, it is often helpful

to provide establishment management a letter from investigators documenting their statutory authority to receive (and protect) the requested information. If necessary, the environmental health agency that licenses the establishment can reiterate that providing the information is required. A conversation with management explaining that their establishment has been implicated as the setting of an outbreak, and that it would be in their best interest to cooperate fully, as that will maximize the chances of identifying a specific contaminated food product that was supplied to the establishment (and who supplied it). That way, they won't be the sole business "on the hook" for any subsequent legal action. It is also often helpful to provide the script of what you will be saying to their patrons, and accept any of their requested edits that don't detract from the investigation. If all of this is unsuccessful, a press release might be necessary to solicit patrons to contact you; when an establishment learns of these plans, they will frequently acquiesce to providing the requested information in lieu of a press release.

To do an analytic study, comparison group information will be needed – how do I get this?

The lowest hanging fruit and best matched controls are well meal companions of cases, so do everything you can to interview meal companions with the same establishment menu-based questionnaire that was used for cases. If these controls are not sufficient, controls can also be ascertained via the patron contact info discussed in the previous question above (just make sure they ate on the cases' meal date, and that they did not have any symptoms afterwards). If it is not possible to recruit enough controls in these ways, restaurant sales data / transaction records / product mix reports can be used to estimate background consumption rates of menu items (and thus ingredients) – these background rates can be compared to case ingredient consumption frequencies in binomial probability models.

All or most of the cases are eating the same things (apparent co-linearity) – isn't it impossible to tease out a single vehicle in this situation?

No. This is perhaps the biggest perceived obstacle and the most common misunderstanding among investigators. Co-linearity among cases should not be viewed as an obstacle to conducting analytic studies. It is true that we often run into the situation, such as in Mexican-style restaurant subclusters, where more than 90% of cases have eaten numerous ingredients (e.g., cilantro, tomatoes, onions, jalapeno peppers). However, this is why using comparison information in the analysis is so critical – it often happens that a low % of controls ate 1 or more of the ingredients. Applying controls can clearly implicate 1 ingredient in some outbreaks. Sometimes this becomes apparent in a univariate analysis, but sometimes a multivariate analysis is required. Sometimes, 4 or 5 commonly ingredients can be narrowed down to 2, which is a tremendous help to partners who are conducting traceback investigations, or who are otherwise combining data from multiple subclusters around the country.

It is not possible to get any sort of meaningful comparison data at all – can a subcluster investigation still be useful to the national investigation?

For sure! In this circumstance, it would still be extremely helpful to document solid case ingredient consumption frequencies (by interviewing cases with the subcluster establishment menu and getting recipe/ingredient info for menu items to determine those frequencies). Even just case data, if systematically documented, can be critical when combined with data form other subclusters, including trace backs.

Conducting an analytic study in a subcluster establishment is so much work – is it really worth it?

Yes. They are a lot of work, but they are less work than interviewing and re-interviewing all cases nationally with hypothesis-generating and then more focused questionnaires, they are much more likely to identify the correct vehicle, and they will yield the answer much more quickly. Other states are depending on this work. If the resources are not available at the jurisdiction leading the investigation, please ask for the assistance that is available from other sources.

Can't we just skip the work of an analytic study and go straight to an informational trace back?

You could, but then you wouldn't be using all of the tools at your disposal. Epidemiology is a powerful tool, and only when we use it systematically and in combination with other tools, such as trace backs, can we solve multi-state outbreaks as rapidly and accurately as possible.