

FREQUENTLY ASKED QUESTIONS

Who are the intended users of this questionnaire?

This questionnaire is intended for use by local health department officials who conduct epidemiologic investigations of foodborne disease outbreaks in their jurisdictions.

What is the intended use of the questionnaire?

The questionnaire is meant to facilitate the collection of detailed data on symptoms, food exposures, demographic factors, and host susceptibility factors (such as underlying illness, medications) from individuals who have potentially been exposed to contaminated foods in the context of a foodborne disease outbreak.

Why was the questionnaire developed?

There is a need for dose-response data for use in quantitative microbial risk assessment. Quantitative microbial risk assessment is a systematic method of gathering information that may be used to evaluate federal agency regulatory policies for food safety. Dose-response data describe the relationship between exposure to a pathogen (dose) and the frequency and severity of adverse health outcomes (response) in a given population. Foodborne disease outbreaks present an opportunity for investigators to collect this kind of data.

The questionnaire provides a template for dose-response data collection in the context of a foodborne disease outbreak. In addition to their application to risk assessment, dose-response data may serve local health departments in more immediate ways: they can provide powerful evidence to support the existence of a cause and effect relationship between a particular food item and illness¹, and for outbreaks in which more than one food item is initially suspect, dose-response data may be used to implicate more precisely a particular vehicle of transmission.²

The questionnaire was developed with the support of Cooperative Agreement FD-00431 between the U.S. Food and Drug Administration and the National Center for Food Safety and Technology.

1. Gray SF, Evans MR. Dose-response in an outbreak of non-bacterial food poisoning traced to a mixed seafood cocktail. *Epidemiol Infect.* 1993;110(3):583-90.
2. Mintz ED, Carter ML, Hadler JL, Wassell JT, Zingeser JA, Tauxe RV. Dose-response effects in an outbreak of *Salmonella enteritidis*. *Epidemiol Infect.* 1994;112(1):13-9.

How does the questionnaire differ from those used in other outbreak investigations?

Qualitatively, the questionnaire may not differ greatly from those used in routine investigations; in all foodborne disease outbreak investigations, data are collected in order to determine the etiologic agents, vehicles of transmission, and

lapses in food safety that allowed the contamination to occur. Quantitatively, though, the questionnaire facilitates the collection of more detailed data with respect to illness severity, amount of each food consumed, and host factors that may affect susceptibility. ([see comparison table](#))

When should local health departments consider using the questionnaire?

Not all foodborne disease outbreaks occur with conditions that are suitable for the collection of epidemiologic dose-response data.

First, an incident must meet the definition of an "outbreak". A foodborne disease outbreak should be suspected and investigated when a cluster of illnesses is detected (through citizen complaint, clinician report, disease surveillance, etc.) and the following are true:

- Ill individuals develop a similar, acute illness (usually gastrointestinal).
- Two or more individuals are involved.
- The individuals reside in separate households and have no exposures in common (other than foods consumed) that could explain the illness.

Initially, efforts must be made to confirm the diagnosis and find additional cases, and thus determine whether an outbreak has occurred (or is occurring). The questionnaire is intended for use in the questioning of individuals considered at risk of having consumed contaminated food(s) when the following four criteria are met:

- A bacterial pathogen is suspected, based on symptoms and incubation periods.
- The outbreak is suspected to be associated with a point-source or a single event, and the at-risk population that is well-defined (i.e. a list of exposed persons can be obtained, and a retrospective cohort study design, rather than a case-control, is appropriate).
- The number of individuals at risk of having consumed contaminated food(s) is estimated to be more than 20.
- The initial stage of the investigation narrows the number of suspected food vehicles to a number less than 35.

For incidents in which these criteria are not met, local health departments may choose to implement data collection protocols they have for routine outbreak investigations.

For the purposes of quantitative microbial risk assessment, what is the key microbiological data that would need to be collected in the investigation of a foodborne disease outbreak?

To best describe a dose-response relationship in a foodborne disease outbreak, it would be optimal to have data that approximate the amount of the pathogen that was consumed by each exposed individual. Therefore, in addition to quantifying the amount of contaminated food consumed by exposed individuals, a *quantitation of the level of contamination in this food at the time of consumption* is also necessary.

How should the questionnaire be administered?

The questionnaire is designed to be administered by telephone interviewers trained in communicable disease investigation. After revising the template to incorporate the details of the outbreak under investigation, the questionnaire should be photocopied and given to interviewers as a paper document. Responses should be recorded on the paper copy, as the questionnaire template is not intended for use as an on-screen computer document.

The recipients of the calls made by the telephone interviewers are individuals who have been identified as having potentially been exposed to contaminated foods. Their names and phone numbers are provided by event organizers in some cases, or in other cases, are obtained via questioning of other exposed persons.

Note that the questionnaire format is not appropriate for self-administration (i.e. a survey that is mailed or handed-out to exposed persons).