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Decision Making: Food Safety Applications

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Foodborne outbreak investigations are a special category of epidemiologic study. These investigations, by their nature, are not planned research studies. In addition, because there is often time pressure to determine if a problem might be ongoing and require urgent public health action, epidemiologists often need to use preliminary information as a basis for subsequent actions. Investigations often begin as a perceived increase in gastrointestinal illness without clear food-related hypotheses. They often require the use of available descriptive statistics to generate hypotheses before analytic studies are conducted to test these hypotheses. This process is usually iterative, in that it may be repeated throughout an investigation, and the epidemiologists assess the direction of the study at each step. Thus, foodborne outbreaks can be constantly evolving investigations, rather than fixed designs, and their design may change based on the analysis of incomplete data at unanticipated intervals. Historically, retrospective cohort designs are used when the at-risk population can be defined, such as at a "church" picnic (CDC, 1995); a case-control approach is used when the at-risk population cannot be unequivocally defined and/or enumerated (CDC, 2007).

Because foodborne outbreak investigations are conducted in field settings, the approach to the investigation is subject to multiple constraints and practical considerations. Compared with planned research efforts, outbreak investigations are often characterized by limited control over many aspects of a study. Limited access, small numbers, or reluctance to participate on the part of cases and controls may limit statistical power. The investigator may be unable to collect appropriate clinical specimens and/or food samples for laboratory analysis. Bias may be potentially introduced by publicity, and the social pressure to intervene may conflict with the desire for methodological rigor. Foodborne outbreak investigations may be complicated by protracted time between exposure, illness, and investigation (Hedberg et al., 2008). Data sources may be incomplete, inaccurate, or not ideally designed for the study purpose. Case-control studies, in general, and some foodborne outbreak investigations, in particular, may be especially vulnerable to information bias (Decker et al., 1986). Self-selection bias can be a problem if ill restaurant employees are reluctant to cooperate or cases "over-remember" certain food exposures. On the other hand, foodborne outbreak investigations may be increasingly less vulnerable to misclassification of cases and controls because of the increased availability of standardized molecular subtyping in public health laboratories (Swaminathan et al., 2001).

Although many textbooks emphasize ". . . that epidemiologic evidence by itself is insufficient to establish causality" (Last, 2000), the field epidemiologist must balance the risks to the community against the level of uncertainty that specific interventions are necessary and appropriate. Although criteria for causal inference have been discussed since the time of Robert Koch (Evans, 1976; Hill, 1965), implicating a food vehicle as the cause of the outbreak in the final analysis comes down to the judgment of the public health professionals conducting the investigation. As with any professional judgment, a number of criteria are used, which often include consistency with findings from previous outbreaks, knowledge of the natural history of the disease, as well as the results of an epidemiologic study (Petersen and James, 1998). Despite recognized limitations and uncertainties, the utility of epidemiology and statistics in foodborne outbreak investigations has been consistently demonstrated (USDA Food Safety and Inspection Service, 2003).

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