

Mini-protocol for analytical investigations in the context of an outbreak

Insert name of primary investigator here

<i>Identification of the outbreak</i>	
<u>Diagnosis:</u>	<u>Confirmed:</u> 1. Yes: Method: 2. No
<u>Date of reporting:</u>	<u>Location:</u>
<u>Number of cases to date:</u>	
<i>Background - justification</i>	
<ul style="list-style-type: none"> Describe the outbreak: Diagnosis, mode of reporting, number of cases and case fatality ratio. Describe how the time, place and person information as well as other elements allowed raising hypotheses about the source of infection. Spell out the suspected mode(s) of transmission and / or source(s) for the outbreak 	
<i>Objectives</i>	
<ul style="list-style-type: none"> Spell out objectives of the analytical investigation. In most cases, it will be about testing a hypothesis regarding suspected mode(s) of transmission and/or source(s) of the outbreak. 	
<i>Proposed methods</i>	
<u>Null hypothesis</u>	
<ul style="list-style-type: none"> Spell out the null hypothesis that will be tested with this investigation. 	
<u>Design</u>	
<ul style="list-style-type: none"> Describe the type of design (e.g., survey, case-control, cohort) in one short bullet. If case control, specify if matching is needed and why. 	
<u>Population</u>	
<ul style="list-style-type: none"> Specify the population in which the investigation will be conducted (State, district, population size) 	
<u>Case definition</u>	
<ul style="list-style-type: none"> Spell out the case definition that will be used. 	
<u>Case ascertainment</u>	
<ul style="list-style-type: none"> Explain the strategy to look for cases to be included (in the case of a case control approach). 	
<u>Recruitment of controls (for case control studies)</u>	
<ul style="list-style-type: none"> Explain the recruitment strategy for controls and the matching criteria (if applicable). 	
<u>Data collection</u>	
<ul style="list-style-type: none"> Explain shortly (1) what data will be collected {major categories: For example: Demographic characteristics, socio-economic status, exposure to the suspected food, other risk factors} and (2) the data collection methods. Develop the questionnaire after consensus has been reached on this concept paper. 	
<u>Analysis plan</u>	
<ul style="list-style-type: none"> Summarize the type of analysis (e.g., descriptive, analytical, stratified, multivariate) that will be carried out. Mention laboratory analysis if part of the investigations. 	
<u>Sample size</u>	
<ul style="list-style-type: none"> Briefly mention the sample size and the main assumptions used to calculate it. This should contain enough information for the reader to redo the calculations and double-check the estimate. 	
<i>Expected benefit</i>	
<ul style="list-style-type: none"> Describe the expected outcome: How this investigation will influence prevention and control activities for the problem in question in the area where the project will be conducted. 	