

Designing an  
epidemiologic study  
to test the hypothesis  
on multi-state e.coli  
out...



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## 1. How would you define controls for this study?

A control in this study is defined as part of the experiment that is analyzed after the exposure information that was collected for the 7 days before the interview and for the 7 days before the onset of illness in the matching case and to analyze whether the system behaves as it should despite of the E. coli outbreak in the system. This is done by using sequential digit dialing technique where two control subjects were to be matched to each case subject by age group(0-<2 years, 2-<5 years, 5-<12 years, 12-<18 years, 18-<60 years, and 60+ years) and gender. Age groups were less than 2 year, 2 to5 years, 5 to 12 years, 12 to 18 years, 18 to 60 years and 60 years and older.

Age and sex based samples of matched controls was selected through systematic, sequential-digit telephone dialing. Usually in experiments that use sequential-digit dialing technique to record the case-subjects and controls history by matching their age group and gender as male or female, sometimes postal or zip code and telephone exchange code can also be taken into account to maintain the subject's history. With this technique using telephone number / zip postal code, the 2 control subjects may have the same telephone area code and 3-digit prefix as the case subject. For selection, in a sequential-digit dialing technique using telephone code 1 digit should be subtracted or added to the last 4 digits of a case subject's phone number until 2 prospective control subjects were known.

However sequential-digit dialing technique using age and gender for recording the subjects in the case study can be effectively done using codes.

A potential control subject who can be of the same age group and sex as the  
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case subject can be recorded using codes and taken in to the case study only after a careful examination of any illness and symptoms during the 7 days before the interview and for the 7 days before the onset of illness caused by E. coli.

2. Do you agree with the investigators' decision to match on age group and gender? Why or why not?

I don't agree with the investigators decision to match only age group and gender because the investigator should take into account of the Epidemiology of the E. coli outbreak in human beings. It may be spread through Fecal - borne transmissions usually by fecal-oral route, Food-borne transmission especially in cases observed with intake of E. coli type O 15: H7 traced contaminated meat. E. coli may be caused through Endogenous infection observed as Urinary Tract Infection (UTI) in female frequently associated with sexual activities.

Therefore apart from age and gender investigations, the investigator should take into account the demographics, socioeconomic status, age-specific activities like sexual activities, work history, eating habits and household characteristics. The household characteristic includes physical space, number of persons in the household, cleanliness, and symptoms in other persons in the past 14 days for controls or in the 7 days before disease caused among case-patients exposed / not exposed to E. coli.

3. What methods might be used to identify controls? What are the advantages and disadvantages of each method?

- Sequential digit dialing technique : It's an effective method where the case and the controls can be differentiated with numerical digits and usually postal or zip code and telephone exchange numbers can be considered.

Advantages: Recording a patients history can be simplified by feeding the numbers into the database and maintain a file with numbers. It will easy to search the patient's history and reduces time and labor.

Disadvantages: Identifying case and control subjects using sequential digit dialing technique with low socioeconomic status is a drawback because they often do not have telephone service; however, because only case subjects who could be contacted by telephone can be encouraged to participate in the case study, case subjects and control subjects should be probably comparable in that regard.

- Laboratory Diagnosis: This technique can be done by collecting specimens from the cases and control. If the investigator takes into account the epidemiology of the case study for E. coli outbreak among the subjects then the samples like serum, urine can be collected and examined. If the case / control are found with any other lesions or symptoms, then pus from wound can be diagnosed under laboratory conditions. There are many methods to identify the E. coli in the sample. It is usually identified using Microscopy - Gram Negative staining, Culture of the samples in Microbiology labs, Biochemical reactions of E. coli and various other tests like Agglutination test, bacterial count in bacteriuria, etc.

Advantages: The results obtained in laboratory conditions are always accurate and reliable. The exact type of infection can be diagnosed and recorded.

Disadvantages: All the samples should be collected only fresh and under sterile conditions in labs and most of the time the case / control subjects vacillate to provide their samples for such case studies. It is costly to spend in laboratories and time consuming to get the results of the study as early as possible.

4. Over what time period would you examine exposures to possible risk factors for cases? For controls?

The 7 days time period is the actually span of time the case study is done and recorded, so within the 7 day period the case subject should be examined at least for every 24 hours because of the fact that E. coli takes very little time for multiplication in the host. It takes 17 – 20 minutes for doubling of the bacteria and so it is recommended to examine the case subjects and controls every 24 hours time to record the occurrence of E. coli in their system.

There may be many risk factors that may contribute to the outbreak of E. coli infection among the case / control subjects. Most common factors that can be taken into account is subjects in the case study who consume stale or spoilt meat that is contaminated with E. coli, subjects who have taken fecal contaminated foods or drank fecal contaminated water may be prone to have the E. coli outbreak in their system, even subjects who follow offensive cleanliness habits, especially woman involvement in sexual activities, and

those who work in unhygienic conditions are prone for the E. coli outbreak in their system. The other factors like household characteristics that include physical space, number of persons in the household history, locality and socio-economic conditions may also contribute to the outburst of E. coli infection among the control subjects.