

Data Management for Clinical Research – Coursera MOOC
Week 3 Quiz

Instructions:

For this quiz, we will describe to you a hypothetical clinical research scenario and provide you with partial information about the data collection plan. The quiz questions will ask you about the overall plan or about some of the missing components below. While study design and data analysis considerations are very important components of planning a study, they are outside the scope of this course and are not the focus of this assignment.

Background:

You are tasked with planning the data collection process for a study that will track children who are in their first 5 years of life (ages 0-5) who attend 4 daycare (nursery) centers in your city. Specifically, the study will look at the incidence and prevalence of febrile illness (fever) in this group throughout a 1-year period and look for correlation between their cases and characteristics that you measure that are (1) specific for the children themselves, (2) relate to global trends like seasonal disease outbreaks (e.g. flu), and (3) relate to the local environment like school location and classroom environment and potential transmission in the classroom or school building.

Data Sources:

- You will have access to a list of all the school buildings, their geographical locations, and the room numbers of the different classrooms in each school. *The plan to collect and manage this data is not the focus of this quiz.*
- At the end of the year, you will be able to obtain a roster of all the teachers, substitute teachers, and teacher assistants who worked in these facilities during the year and their daily assignments (i.e. which classroom they worked on every day of the year). *The plan to collect and manage this data is not the focus of this quiz.*
- A **baseline data collection form** that is filled once per child at the beginning of the 1-year study period and updated as needed. Each child will have one and only one record in this form.
- A **case report form (CRF)** that will be filled every time a child is sick with fever.

Additionally, here are some assumptions that are made about the setting of this study and the associated data sources:

- Children 6 months and older require only one dose of vaccine per season.
- Children will stay in the same classroom throughout this one-year study period. No new students are enrolled or assigned new classrooms during the year. No new classrooms will be built during the year of the study.
- The teachers, substitute teachers and teacher assistants can be assigned to different classes on different days
- Study personnel will periodically monitor the children's information and update the baseline data collection form as needed.

Some of the data elements that will be used for this study

What data element?	Why will it be collected?	Where will it be collected?	How will it be collected?
Age of child	Children of different ages have different susceptibility to different diseases.	XX	XX
Height of the child	To assess the overall growth of the child at baseline and at the time of the illness.	XX	A text field with the label indicating that the height is requested in cm and validated as a numerical field
Weight of the child	To assess the overall growth of the child at baseline and at the time of the illness.	Baseline form + During every illness CRF	XX
The time of the year that the case of febrile illness occurred	To assess the temporal relationship between the specific case seasonal outbreaks e.g. flu season	During every illness CRF	A date field specifying the first day of the febrile illness episode
Extent of Fever	This is one measure of the severity of the illness	During every illness CRF	Ask the study personnel to record the temperature in a text field using degrees Celsius as the unit and validated as a numerical field.
Duration of illness	This is one measure of the severity of the illness	During every illness CRF	XX
Associated symptoms	To gather indicators of relating to the nature and severity of the illness.	During every illness CRF	XX
Did they receive the flu vaccine that year?	To assess whether flu vaccination was related to the incidence of febrile illness.	Baseline form	A date field that would include the date of vaccine if the child was vaccinated and that would be left empty if the child did not receive the flu vaccine during the study
If they received a flu vaccine, how long before or after receiving the flu vaccine did the specific illness occur?	To assess whether and how flu vaccination was related to the incidence of febrile illness.	XX	XX
Other people living in the child's household	To gather information about possible transmission routes outside of the daycare setting	XX	XX