**Design of Experimental Study**

The Hospital Administration at hospital X wants to test the hypothesis that hospitalized patients have better outcomes when taken care of by hospitalists (physicians in charge of only hospitalized patients) versus residents with back-up of the attending physicians. If the hypothesis is correct, the hospital will change their procedures to improve outcome and decrease costs for medications, drug reactions, and give better quality care. To test the hypothesis, the Hospital Administration must design a study that can stand up to scrutiny. To test the above hypothesis it is decided to design a study involving patients being hospitalized with acute stroke.

Acute stroke is caused by ischemia (deficient blood flow, e.g. caused by thrombosis [a blood clot]) or hemorrhage (bleeding), and requires rapid evaluation because treatments like thrombolysis (the breaking up of a thrombus) is time-sensitive. About 87% of all strokes are ischemic strokes, and the rest is hemorrhagic strokes. Each year about 800,000 people in the US have a stroke, and almost 130,000 people die from it. That is about 5% of all deaths.

Several different study designs are suggested:

1. A study that explore the risk of mortality and paresis/paralysis in patients diagnosed in the hospital with acute ischemic stroke, according to whether they have been taken care of by a hospitalist or a resident with back-up of an attending physician. Acute ischemic stroke patients who were admitted to the hospital during a given time period are identified and separated into two categories: Those treated by a hospitalist and those treated by a resident. Records are examined to determine who died before being discharged and the degree of paresis or paralysis at discharge among those who survived. The two groups are then compared with respect to in-hospital mortality and degree of paresis/paralysis at discharge. All analyses are controlled for age, sex and socioeconomic status (SES).
2. A study in which patients who were admitted to the hospital with acute stroke are followed forward in time to determine stroke outcomes (mortality, paresis, paralysis, and the Barthel ADL index) according to whether they are treated by a hospitalist or a resident with back-up of the attending physician.
3. A study where both the exposure and outcome have already occurred. Using hospital records, patients admitted to the hospital with acute stroke are followed forward in time for stroke outcome (mortality, paresis and paralysis) according to whether they were treated by a hospitalist or a resident with back-up of the attending physician.
4. A study where patients admitted to the hospital with acute stroke are assigned, with equal probability, to care by a hospitalist or a resident with back-up of the attending physician. Mortality, paresis, paralysis and the Barthel ADL index are registered and compared between the two groups.
5. A study where patients who report having experienced acute stroke are examined by a neurology specialist (who registers paresis, paralysis and the Barthel ADL index), and at the same time fill in a questionnaire about their stroke, hospitalization, and experience with the hospitalist or resident.

In all study designs where collection of data are required, the potential study subjects sign an informed consent form of participation in the study, including informing them that they can withdraw from the study at any time without any consequences for their treatment. Study subjects includes both genders, with age range of 45-75 years. Data is collected on age, sex, socioeconomic status group, disease history, family history of disease, results of clinical and neurological examinations and, where applicable, tests during hospitalization for acute stroke such as, blood tests, electrocardiogram, and brain imaging (e.g. ultrasonography/Doppler, CT and MRI). In addition Barthel ADL index where applicable, description of paresis, paralysis or other functional limitations.

From the designs above, please select the one best answer.

1. Please match each of the following questions with the appropriate lettered statements below.
   1. A study where patients who report having experienced acute stroke

are examined by a neurology specialist (who registers paresis, paralysis and the Barthel ADL index), and at the same time fill in a questionnaire about their stroke, hospitalization, and experience with the hospitalist or resident.

* 1. A study that explore the risk of mortality and paresis/paralysis in

patients diagnosed in the hospital with acute ischemic stroke, according to whether they have been taken care of by a hospitalist or a resident with back-up of an attending physician. Acute ischemic stroke patients who were admitted to the hospital during a given time period are identified and separated into two categories: Those treated by a hospitalist and those treated by a resident. Records are examined to determine who died before being discharged and the degree of paresis or paralysis at discharge among those who survived. The two groups are then compared with respect to in-hospital mortality and degree of paresis/paralysis at discharge. All analyses are controlled for age, sex and socioeconomic status (SES).

* 1. A study where patients admitted to the hospital with acute stroke

are assigned, with equal probability, to care by a hospitalist or a resident with back-up of the attending physician. Mortality, paresis, paralysis and the Barthel ADL index are registered and compared between the two groups.

* 1. A study where both the exposure and the outcome have already

occurred. Using hospital records, patients admitted to the hospital with acute stroke are followed forward in time for stroke outcome (mortality, paresis and paralysis) according to whether they were treated by a hospitalist or a resident with back-up of the attending physician.

* 1. Astudy in which patients who were admitted to the hospital with

acute stroke are followed forward in time to determine stroke outcomes (mortality, paresis, paralysis, and the Barthel ADL index) according to whether they are treated by a hospitalist or a resident with back-up of the attending physician.

1. A retrospective cohort study design
2. A prospective cohort study design
3. A case-control study design
4. A cross-sectional study design
5. A randomized controlled trial (RCT) design
6. The study design marked **B** in the description above (page 1) is also called:
   1. A case-comparison study
   2. A retrospective study
   3. An incidence study
   4. A migrant study
7. The study design marked **A** in the description above (page 1) is also called:
   1. A longitudinal study
   2. A backward-looking study
   3. A prospective study
   4. An ecologic study
8. The study design marked **E** in the description above (page 2) is also called:
   1. A correlation study
   2. An incidence study
   3. A prevalence study
   4. A follow-up study
   5. a and c
   6. b and d
9. The study design marked **D** in the description above (page 2):
   1. Uses before/after measurements in the same individual
   2. Is very prone to distorted results because of the Hawthorne effect
   3. Is prone to wrong results because of natural variation in the outcome
   4. Is a controlled trial
10. Reasons for using a randomized controlled trial design in this case are all of the following, **EXCEPT**:
    1. There are no ethical concerns with this kind of study
    2. Each patient has equal chance of being treated by a hospitalist or a resident with back-up of attending physician
    3. Known and unknown factors that could relate to the prognosis are evenly distributed between intervention and control groups
    4. Reduced information bias because baseline information is gathered at the start of the study
    5. Absolute risk measures (Cumulative Incidences) for the outcomes are available to calculate relative risk and attributable risk
11. Reasons for using a cohort study design in this case are all of the following, **EXCEPT**:
    1. Reduced information bias because baseline information is gathered at the start of the study
    2. Absolute risk measures (Cumulative Incidences) for the outcomes are available to calculate relative risk and attributable risk
    3. Biases are virtually non-existent in cohort studies
    4. Correct time sequence of exposure and outcome
    5. Very good data quality because they are gathered before the outcome
12. Reasons for using a case-control study design in this case are all of the following, **EXCEPT**:
    1. Can use existing records from the hospital
    2. Small sample size needed because we start with the cases
    3. Short time frame because data are already available
    4. Less costly than cohort and experimental study designs
    5. Absolute risk measures (Cumulative Incidences) for the outcomes are available to calculate relative risk and attributable risk
13. What study design would you expect the Hospital Administration to use to test the hypothesis that hospitalized patients have better outcomes when taken care of by hospitalists versus residents with back-up of attending physician? Why?
    1. A prospective cohort study design, because it has very good data quality, and often have limited risk of biases.
    2. A retrospective cohort study design, because it probably has god data quality, is inexpensive and can be completed in a short time while having limited risk of biases, and no recruitment is necessary.
    3. A randomized controlled study design, because it is the gold standard in research, is done under controlled conditions, with very little risk of biases.
    4. A case-control study design, because it is often the least costly and can be completed in a short period of time.
    5. A cross-sectional study design, because all the data are assembled at one point in time, e.g. by using a questionnaire, and it takes a short time to complete.
14. The target study population are people at risk for acute stroke, and should include all of the following, **EXCEPT:**
    1. Blacks, whites, and Hispanics.
    2. Both genders
    3. Incident and prevalent cases
    4. Age range 45-75 years
    5. Hypertensives
    6. Diabetics
15. Patients with the following diseases are excluded from the study, **EXCEPT**:
    1. Atrial fibrillation
    2. Terminal cancer
    3. Serious infectious diseases
    4. Psychosis
    5. Other serious diseases that makes participation difficult
16. All of the following clinical data must have been collected, **EXCEPT**:
    1. Clinical examination (heart, extremities, etc.)
    2. Neurological examination
    3. Imaging study of the brain (CT/MRI)
    4. Electrocardiogram (ECG)
    5. Hearing test
    6. Blood tests
17. Follow-up of a cohort may be of importance to explore the long-term effects of exposure to hospitalists vs. residents by patients with acute stroke. In a retrospective cohort study follow-up requires all of the following, **EXCEPT**:
    1. Follow-up requires that a sufficiently large proportion of the original cohort be identified and assembled to have sufficient power in the study
    2. Follow-up requires new evaluation instruments to keep up with the technological development
    3. The cohort exposure data should be fairly recent to make findings relevant today
    4. The first hospitalization for acute stroke should be a fairly recent event to avoid that the outcome is affected by new hospitalization(s) and treatment(s)
    5. Follow-up requires evaluation instruments sufficiently precise to assure necessary power for the study
18. In all of the suggested study designs used for understanding the cause-and-effect relationship between caretaker and outcome, all of the following outcomes are assessed, **EXCEPT**:
    1. Mortality
    2. Paresis
    3. Paralysis
    4. Barthel ADL index
19. Strength of the suggested designs are all of the following, **EXCEPT**:
    1. Case-control designs are used to evaluate many causal factors in the same study
    2. Cross-sectional designs is fast and cheap
    3. Retrospective cohort studies are used to evaluate rare outcomes
    4. Randomized controlled trials balances prognostic factors
    5. Prospective cohort designs are used to evaluate several outcomes of the same exposure
20. Weaknesses of the suggested designs are all of the following, **EXCEPT**:
    1. Randomized controlled trials are fast to do, are cheap and not plagued by non-compliance
    2. Prospective cohort studies may encounter change in exposure during the follow-up
    3. Case-control studies do not produce incidence data
    4. Cross-sectional studies produce prevalence data
    5. Retrospective cohort studies are plagued by non-response and tracing problems