Clinical Epidemiology

Lab 3

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Practice

9.1. A randomized controlled trial compares two drugs in common use for the treatment of asthma. Three hundred patients were entered into the trial, and eligibility criteria were broad. No effort was made to blind patients to their treatment group after enrollment. Except for the study drugs, care was decided by each individual physician and patient. The outcome measure was a brief questionnaire assessing asthma-related quality of life. Which of the following best describes this trial?

A. Practical clinical trial
B. Large simple trial
C. Efficacy trial
D. Equivalence trial
E. Non-inferiority trial

9.2. A randomized controlled trial compared angioplasty with fibrinolysis for the treatment of acute myocardial infarction. The authors state that "analysis was by intention to treat." Which of the following is an advantage of this approach?

A. It describes the effects of treatments that patients have actually received.
B. It is unlikely to underestimate treatment effect.
C. It is not affected by patients dropping out of the study.
D. It describes the consequences of offering treatments regardless of whether they are actually taken.
E. It describes whether treatment can work under ideal circumstances.

9.3. In a randomized trial, patients with meningitis who were treated with corticosteroids had lower rates of death, hearing loss, and neurologic sequelae. Which of the following is a randomized comparison?

A. The subset of patients who, at the time of randomization, were severely affected by the disease
B. Patients who experienced other treatments versus those who did not
C. Patients who remained in the trial versus those who dropped out after randomization
D. Patients who responded to the drug versus those who did not
E. Patients who took the drug compared with those who did not

9.4. A patient asks for your advice about whether to begin an exercise program to reduce his risk of sudden death. You look for randomized controlled trials but find only observational studies of this question. Some are cohort studies comparing sudden death rates in exercisers with rates of sudden death in sedentary people; others are case-control studies comparing exercise patterns in people who had experienced sudden death and matched controls. Which of the following is *not* an advantage of observational studies of treatments like these over randomized controlled trials?

A. Reported effects are for patients who have actually experienced the intervention.
B. It may be possible to carry out these studies by using existing data that was collected for other purposes.
C. The results can be generalized to more ordinary, real world settings.
D. Treatment groups would have had a similar prognosis except for treatment itself.
E. A large sample size is easier to achieve.

9.5. In a randomized controlled trial of a program to reduce lower extremity problems in patients with diabetes mellitus, patients were excluded if they were younger than age 40, were diagnosed before becoming 30 years old, took specific medication for hyperglycemia, had other serious illness or disability, or were not compliant with prescribed treatment during a run-in period. Which of the following is an advantage of this approach?

A. It makes it possible to do an intention-to-treat analysis.
B. It avoids selection bias.
C. It improves the generalizability of the study.
D. It makes an effectiveness trial possible.
E. It improves the internal validity of the study.

9.6. Which of the following is *not* accomplished by an intention-to-treat analysis?

A. A comparison of the effects of actually taking the experimental treatments
B. A comparison of the effects of offering the experimental treatments
C. A randomized comparison of treatment effects

9.7. You are reading a report of a randomized controlled trial and wonder whether stratified randomization, which the trial used, was likely to improve internal validity. For which of the following is stratified randomization particularly helpful?

A. The study includes many patients.
B. One of the baseline variables is strongly related to prognosis.
C. Assignment to treatment group is not blinded.
D. Many patients are expected to drop out.
E. An intention-to-treat analysis is planned.

9.8. A randomized controlled trial is analyzed according the treatment each patient actually received. Which of the following best describes this approach to analysis?

A. Superiority
B. Intention-to-treat
C. Explanatory
D. Phase I
E. Open-label

9.9. In a randomized controlled trial, a beta-blocking drug is found to be more effective than placebo for stage fright. Patients taking the beta-blocker tended to have a lower pulse rate and to feel more lethargic, which are known effects of this drug. For which of the following is blinding possible?

A. The patients' physicians
B. The investigators who assigned patients to treatment groups
C. The patients in the trial
D. The investigators who assess outcome

9.10. Which of the following best describes "equipoise" as the rationale for a randomized trial of two drugs?

A. The drugs are known to be equally effective.
B. One of the drugs is known to be more toxic.
C. Neither drug is known to be more effective than the other.
D. Although one drug is more effective, the other drug is easier to take with fewer side effects.

9.11. Antibiotic A is the established treatment for community-acquired pneumonia, but it is expensive and has many side effects. A new drug, antibiotic B, has just been developed for community-acquired pneumonia and is less expensive and has fewer side effects, but its efficacy, relative to drug A, is not well established. Which of the following would be the best kind of trial for evaluating drug B?

A. Superiority
B. Cross-over
C. Cluster
D. Non-inferiority
E. Equivalence

9.12. In a randomized controlled trial of two drugs for coronary artery disease, the primary outcome is a composite of acute myocardial infarction, severe angina pectoris, and cardiac death. Which of the following is the main advantage of this approach?

A. There are more outcomes events than there would be for any of the individual outcomes.
B. All outcomes are equally affected by the interventions.
C. The trial has more generalizability.
D. Each of the individual outcomes is important in its own right.
E. If one outcome is infrequent, others make up for it.

9.13. In a randomized controlled trial comparing two approaches to managing children with bronchiolitis, baseline characteristics of the 200 children in the trial are somewhat different in the two randomly allocated groups. Which of the following might explain this finding?

A. "Bad luck" in randomization
B. A breakdown in allocation concealment
C. Both
D. Neither

9.14. Which of the following is usually learned from a Phase III drug trial?

A. The relationship between dose and efficacy
B. Rates of uncommon side effects
C. Efficacy or effectiveness
D. The dose range that is well tolerated

9.15. Which of the following is the main advantage of randomized controlled trials over observational studies of treatment effects?

A. Fewer ethical challenges
B. Prevention of confounding
C. Resemble usual care
D. Quicker answer
E. Less expensive