Burtis, et al: Tietz Fundamentals of Clinical Chemistry, 6th Edition

Test Bank

Chapter 1: Principles of Clinical Chemistry and Evidence-Based Laboratory Medicine

MULTIPLE CHOICE

1. During diagnostic accuracy studies in evidence-based laboratory medicine, a laboratory test being studied, for example, produces results that are compared with the "gold standard" of testing, which would be the currently used assay or assay system. The test of interest is referred to as
   A. index test.
   B. reference standard.
   C. outcome study.
   D. practice test.

   ANS: A
   An index test is the method being assessed, and the results of the index test are compared with the reference standard, which is the current best practice, or method, used to obtain results.

   DIF: 1 REF: Pages 1, 4 OBJ: 5

2. In reading a research article, you determine that the study design was flawed because there was no control group. This is an example of a weakness in
   A. internal reliability.
   B. internal validity.
   C. external reliability.
   D. external validity.

   ANS: B
   Problems in the design of a study are considered to be poor internal validity and will produce systematic error because the estimates of diagnostic accuracy differ from those one would have obtained using an optimal design for the study.

   DIF: 2 REF: Pages 1, 4 OBJ: 6

3. When developing clinical practice guidelines, what is the critical first step?
   A. Requesting input from health insurance companies and government officials
   B. Preparing a cost analysis based on patient needs
   C. Determining the intended group that will be directly involved with implementation
   D. Selecting and refining the topic upon which the investigation will center

   ANS: D

Selection and refinement of the topic needing investigation must be accomplished before target groups are chosen and primary evidence is assessed. Scope, topic, and clinical area must all be addressed within the abilities of the group initiating guideline development.

DIF: 2 REF: Page 13 OBJ: 13

4. Another way that "bias" can be defined is as _____ error.
   A. random
   B. systematic
   C. analytical
   D. clinical

   ANS: B
   Bias is systematic error that occurs when there is constant overestimation or underestimation of a measured value.

   DIF: 1 REF: Pages 1, 4 OBJ: 5

5. Internal validity is
   A. the degree to which the variables in the study apply to all individuals in the study.
   B. the degree to which the results of your sample can be inferred to the general population outside of your study.
   C. equal to consistency.
   D. is the calculation of mean and variance from repeated measures.

   ANS: A
   Internal validity is the degree to which the results of a study can be trusted for the population of patients in the study.

   DIF: 1 REF: Pages 1, 4 OBJ: 6

6. A new hormone analyzer is received in the lab. By assaying a control sample 50 times and assessing the mean and variance of the results, you are checking the _____of the instrument.
   A. sensitivity
   B. accuracy
   C. validity
   D. reliability

   ANS: D
   Reliability is related to consistency, whereas accuracy and sensitivity are related to validity. Checking a sample 50 times determines how consistent the analyzer is when producing results for the same sample.

   DIF: 2 REF: Page 2 OBJ: 5 | 6

7. A research study was prepared to assess the diagnostic accuracy of a therapeutic drug monitoring assay for HMG-CoA reductase inhibitors (statins). The study was flawed with poor design. Which of the following statements are correct?
   A. Random error decreased
   B. Systematic error decreased
   C. Systematic error increased
   D. A and B are both correct.

   ANS: C
   Poor internal validity caused by poor study design produces systematic error.

   DIF: 2 REF: Page 4 OBJ: 5 | 6

8. Determine if the following study design is a randomized control trial or a case-control study: Analysis of leptin in breast milk of obese versus nonobese breast-feeding mothers.
   A. Randomized control trial
   B. Case-control study

   ANS: B
   Randomized control studies typically examine a single randomly selected sample, who are then further randomly assigned to either the treatment group (index) or the control group (reference). Case-control studies examine two groups, one of which already has the disease in question (cases) and one that does not (controls).

   DIF: 3 REF: Pages 9, 15 OBJ: 9

9. Determine if the following study design is a randomized control trial or a case-control study: Analysis of the effect of ingestion of one aspirin daily on the platelet count in men over the age of 60.
   A. Randomized control trial
   B. Case-control study

   ANS: A
   Randomized control studies typically examine a single randomly selected sample, who are then further randomly assigned to either the treatment group (index) or the control group (reference). Case-control studies examine two groups, one of which already has the disease in question (cases) and one that does not (controls).

   DIF: 3 REF: Pages 9, 15 OBJ: 9

10. Determine if the following study design is a randomized control trial or a case-control study: Study of the effects of vitamin C ingestion on serum iron concentration in a group of 30-year-old women.
    A. Randomized control trial
    B. Case-control study

    ANS: A

Randomized control studies typically examine a single randomly selected sample, who are then further randomly assigned to either the treatment group (index) or the control group (reference). Case-control studies examine two groups, one of which already has the disease in question (cases) and one that does not (controls).

DIF: 3 REF: Pages 9, 15 OBJ: 9

11. Determine if the following study design is a randomized control trial or a case-control study: Assessment of mercury levels in a group of children that live near a toxic waste dump versus a group of children who live in an urban area.
A. Randomized control trial
B. Case-control study

ANS: B
Randomized control studies typically examine a single randomly selected sample, who are then further randomly assigned to either the treatment group (index) or the control group (reference). Case-control studies examine two groups, one of which already has the disease in question (cases) and one that does not (controls).

DIF: 3 REF: Pages 9, 15 OBJ: 9

12. In a randomized control trial, the use of a new vaccine was observed to reduce the number *Chlamydia trachomatis* infections in a population of college-aged women. This is referred to as a(n)
A. clinical audit.
B. systematic review.
C. patient outcome.
D. internal validator.

ANS: C
Outcomes may be defined as results of medical interventions in terms of health or cost. "Patient outcomes" are results that are perceptible to the patient.

DIF: 2 REF: Pages 1, 6-7 OBJ: 9

13. Continuing with the question above, a physician asks if the results from the therapeutic drug assay will predict the patient's eventual health outcome. A study to determine this is referred to as a
A. patient outcome study.
B. case-control study.
C. systematic review.
D. prognostic value study.

ANS: D
Studies of the prognostic value of a test ask the question, "Can the test be used to predict an outcome?"

DIF: 1 REF: Page 8 OBJ: 8 | 9

14. Meta-analysis
    A. is a statistical technique that compares results from various studies.
    B. is an extensive and explicit strategy to find all studies (published or unpublished) regarding a single assay.
    C. includes the quality and the quantity of the health outcome.
    D. is a tool to facilitate implementation of lessons from primary studies and systematic reviews.

    ANS: A
    Meta-analysis compares assay results obtained from different studies and synthesizes them by use of statistical techniques.

    DIF: 1 REF: Page 11 OBJ: 10

15. Which one of the following *is not* a component of a clinical audit?
    A. Solving problems associated with a process or outcome
    B. Monitoring workload in the context of controlling demand
    C. Evaluation of the costs of alternative approaches that produce the same outcome
    D. Monitoring the introduction of a new test and/or changes in practice

    ANS: C
    Cost minimization assessment is a methodology of economic evaluation.

    DIF: 1 REF: Pages 13, 16 OBJ: 13 | 14

16. Following a systematic review, case-control studies, clinical audit, and a cost evaluation, an assay for assessment of growth hormone level as a predictor of bone cancer has been recommended by a group of orthopedic surgeons to be performed in your chemistry laboratory. What is the next step before implementation of the assay?
    A. Evaluating the costs of alternative methods to produce similar outcomes
    B. Developing a clinical practice guideline for implementation of the assay
    C. Performing a meta-analysis
    D. Beginning a second round of randomized control trials

    ANS: B
    For the findings from evidence-based medicine studies to be finally applied, clinical practice guidelines must be developed to facilitate implementation of what was learned from primary studies and systematic reviews.

    DIF: 3 REF: Pages 13-14 OBJ: 13 | 14

17. Regarding the preceding question, what if anything is inappropriate about the group that is wishing to develop guidelines for clinical practice and a recommendation to implement the bone cancer assay?
    A. This group would likely not have the expertise needed to suggest implementation and develop a guideline.
    B. This specialty group of physicians might be motivated to implement this test to

produce income for the group practice.
C. The systematic review, research studies, and statistical analysis would be beyond the scope of this group of physicians.
D. There is nothing inappropriate about this group because they are experts in the field.

ANS: B
When guidelines are developed by a professional group (such as specialist physicians), the recommendations may be suspected of promoting the welfare of that professional group.

DIF: 3 REF: Page 15 OBJ: 13

18. STARD
A. relates to the four components of economic evaluation in an evidence-based laboratory medicine study.
B. is the assessment of the value of a test analysis for those individuals who are tested.
C. is a set of guidelines assembled to put into practice the findings of an evidence-based laboratory medicine study.
D. includes a listing of items that need to be included in reports of studies of diagnostic accuracy.

ANS: D
Standards for Reporting of Diagnostic Accuracy (STARD) is an initiative that intends to improve reporting the results of diagnostic accuracy studies. The STARD document includes a checklist of items to be included in diagnostic accuracy studies and a diagram of study design and participant action.

DIF: 2 REF: Pages 2, 6 OBJ: 7

19. QALY
A. is associated with a quality systematic review of literature.
B. assesses the quality of a diagnostic accuracy study.
C. is an outcome expressed in cost-of-intervention analysis.
D. relates to the implementation of the findings of a clinical audit.

ANS: C
A cost-utility analysis of an economic evaluation examines the quality of the life-years gained. While the cost of the intervention is assessed in monetary terms, the outcomes are expressed in quality adjusted life years (QALY).

DIF: 2 REF: Page 12 OBJ: 11

20. If the evidence overwhelmingly points toward the introduction of a new laboratory analysis and practice, yet physicians fail to incorporate the new test into their clinical practice, what component of evidence-based laboratory medicine will reveal this?
A. Clinical audit

B. Economic evaluation
C. Systematic review
D. Clinical practice guidelines

ANS: A
In applying the principles of evidence-based laboratory medicine to everyday practice, there must be adherence to the recommendations made by those involved in formulating new clinical practice guidelines. This commitment is monitored by the clinical audit, particularly the audit of adherence to best practice.

DIF: 2 REF: Page 17 OBJ: 14 | 15