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Determining the Value of Diagnostic and Screening Tests

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Rapid advances in medical technology frequently lead to the development of new diagnostic procedures whose value should be determined before they are used widely. These values can be measured in terms of health and money. Health values relate to the accurate identification and successful treatment of disease; financial values relate to the husbanding of monetary resources expended for health services.

Fundamentals of Decision Making

A number of methods have been used to evaluate diagnostic procedures. The two used most frequently are: the decision matrix and the receiver operating characteristic (ROC) curve.

The Decision Matrix. This relates results of a diagnostic test with a binary outcome (normal, abnormal) to clinical or pathologic findings, also with a binary outcome. Five ratios can be derived from this table and are used to characterize such binary tests:

1. The true-positive (TP) ratio is the proportion of positive tests in all patients with disease—the sensitivity of the test.
2. The false-positive (FP) ratio is the proportion of positive tests in all patients without disease.
3. The true-negative (TN) ratio is the proportion of negative tests in all patients without disease and is the specificity of the test.
4. The false-negative (FN) ratio is the proportion of negative tests in all patients with disease.
5. The likelihood ratio (L) of a test is the ratio of the TP ratio to the FP ratio.

It is important to emphasize that these ratios describe the sensitivity and specificity of the test; they cannot be used alone to determine the significance of a positive or negative test. An extended analysis is required to determine the probability that a patient does or does not have disease, given the test result.

The ROC Curve. When tests do not have binary outcomes, but rather have a continuum of values, the true- and false-positive ratios vary with the value selected as the cutoff point. Routine chemistry examinations and radioimmunoassays are examples of such tests. We can graphically visualize the effect of changes in the cutoff point on test sensitivity by using a ROC curve, a plot of the true-positive ratio against the false-positive ratio for varying cutoff points.

General Considerations

Health Values. Health values associated with diagnostic tests are best understood through a simplified model of the diagnostic and therapeutic process. In this model, a patient with a symptom complex or a syndrome enters the diagnostic process. At the first decision point, a diagnostic test is either performed or not performed. In the former case, the first chance point depicts the results of this test in terms of the amount of information achieved. The test can provide new information (+), no information (0), or misleading information (−). This stage of the diagnostic process provides the first point at which we can measure the value of a diagnostic test and satisfy those who would claim that the ultimate test of a diagnostic procedure is its ability to sort patients with regard to specific diseases.

After diagnostic testing, treatment is instituted and the results of treatment are depicted at the second and final chance point. These outcomes represent a continuum of states, ranging from perfect health (cure) to death. The second point provides the second opportunity for measuring the value of a diagnostic procedure and satisfies more operationally-oriented physicians who claim that the ultimate test of a diagnosis is the extent to which it can save lives, restore health, or alleviate suffering. If the test is not performed, treatment is instituted on the basis of available information with the same continuum of outcomes.

Financial Values. The financial aspects of the diagnostic and therapeutic process can also be considered. In broad terms, the financial value of a test lies in its ability, if truly negative, to eliminate costs associated with unnecessary diagnostic procedures and therapeutic regimens or, if truly positive, to eliminate financial costs caused by the progression of untreated disease. These benefits are difficult to measure directly. Therefore, three other financial measures are frequently used in evaluating diagnostic tests: (a) the total cost of diagnosis and therapy once the test is introduced; (b) the average cost of achieving a given unit of health by use of the test; and (c) the marginal cost of achieving one additional unit of health by one procedure over another.

The elementary principles and the clinical examples reviewed in this article have been presented in order to provide a systematic approach to the measurement of the health and financial values of diagnostic and therapeutic intervention. It is clear that measurement of these values is becoming increasingly important as new and untested procedures and instruments are introduced. Hopefully, with knowledge of these values, the resources allocated for medical care can be optimally utilized. ■