Chapter 1

Introduction to the Methods Guide for Medical Test Reviews

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Abstract

Evaluation of medical tests presents challenges distinct from those involved in the evaluation of therapies; in particular, the very great importance of context and the dearth of comprehensive RCTs aimed at comparing the clinical outcomes of different tests and test strategies. Available guidance provides some suggestions: (1) Use the PICOTS typology for clarifying the context relevant to the review, and (2) Use an organizing framework for classifying the types of medical test evaluation studies and their relationship to potential key questions. However, there is a diversity of recommendations for reviewers of medical tests and a proliferation of concepts, terms, and methods. As a contribution to the field, this *Methods Guide for Medical Test Reviews* seeks to provide practical guidance to achieving the goal of clarity, consistency, tractability, and usefulness.

Introduction

With the growing number, complexity, and cost of medical tests, which tests can reliably be expected to improve health outcomes, and under what circumstances? As reflected in the increasing number of requests for systematic reviews of medical tests under the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) Program, patients, clinicians, and policymakers have a profound need for guidance on this question.

Systematic reviews developed under the EPC Program (sometimes labeled "evidence reports" or "technology assessments") are expected to be technically excellent and practically useful. The challenge for EPC investigators is to complete such reviews with limited time and resources—a daunting prospect, particularly in the face of the near-exponential growth in the number of published studies related to medical tests (A MEDLINE® search using the keyword "test.mp" demonstrates a doubling of the number of citations approximately every 10 years since 1960). How can EPC investigators respond to this challenge with reviews that are timely, accessible, and practical, and that provide insight into where there have been (or should be) advances in the field of systematic review of medical tests?

This *Methods Guide for Medical Test Reviews* (referred to hereafter as the *Medical Test Methods Guide*), produced by researchers in AHRQ's EPC Program, is intended to be a practical guide for those who prepare and use systematic reviews of medical tests; as such, it complements AHRQ's *Methods Guide for Effectiveness and Comparative Effectiveness* Reviews[1] (hereafter referred to as the *General Methods Guide*).[1] Not only has the *Medical Test Methods Guide* been motivated by the increasing need for comprehensive reviews of medical tests; it has also been

created in recognition of features of medical tests and the evaluation literature that present unique problems for systematic reviewers. In particular, medical tests are used in—and are highly dependent on—a complex context. This context includes, among other factors, preexisting conditions, results of other tests, skill and knowledge of providers, availability of therapeutic resources, and so on. In this complex environment, researchers have tended to focus on narrow questions, such as the ability of a test to conform to technical specifications, to accurately classify patients into diagnostic or prognostic categories, or to influence thought or actions by clinicians and patients. Rarely are medical tests evaluated in randomized controlled trials with representative patient populations and comprehensive measures of patient-relevant outcomes. As a result, the reviewer must put together the evidence in puzzle-like fashion.

In addition to encouraging a high standard for excellence, usefulness, and efficiency in systematic reviews, this *Medical Test Methods Guide* is designed to promote consistency in how specific issues are addressed across the various systematic reviews produced by investigators. Even though consistency in approach may not always guarantee that a particular task in review development is done in an ideal way, it is certainly the case that inconsistency in approach increases the effort and energy needed to read, digest, and apply the results of systematic reviews of medical tests.

Development of the *Medical Test Methods Guide*

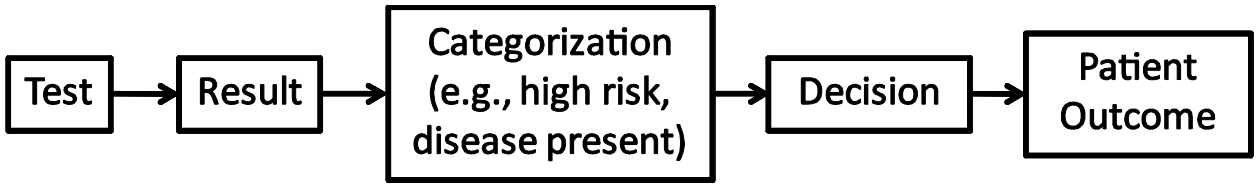
In developing this *Medical Test Methods Guide*, we sought to apply theory and empirical evidence, supplemented by personal experience and judgment, and to maintain consistency as much as possible with the principles described in AHRQ's *General Methods Guide*. We were guided by two fundamental tenets: (1) Evaluation of the value of a medical test must always be linked to the context of use; and (2) systematic reviews of medical test studies are ultimately aimed at informing the use of those tests to improve the health outcomes of patients, in part by guiding clinicians to make rational decisions and judgments.

The first tenet stands in contradiction to the common assumption that medical test results are neutral reporters of reality, independent of context. The notion that tests are "signal detectors" with invariant performance characteristics (i.e., sensitivity and specificity), likely reflects the way that the Bayes rule has been introduced to the medical community—as a pedagogical tool for transmitting the insight that a test for a condition must be interpreted in light of the likelihood of the condition before the test was performed (prior probability). Such teaching assumes that the performance characteristics of a medical test (like those of electronic receivers and similar devices) are constant over all relevant situations. There are clearly circumstances where this is true enough for practical purposes. However, the possibility that it may not be true across all relevant applications highlights the importance of context, which can affect not only sensitivity and specificity but also the clinical implications of a particular test result. Thus, throughout this document the authors return to the theme of clarifying the context in which the test under evaluation is to be used.

The second tenet is that medical tests (and therefore assessments of those tests) are about improving patient outcomes, often by guiding clinicians' judgments. Unfortunately, the vast majority of published literature on medical tests does not address the clinical impact of tests, focusing instead on test development and test performance characteristics. Indeed, test performance characteristics have been treated as sufficient criteria of test value (i.e., if the performance characteristics are good, then the test should be promoted). However, performance characteristics may not in fact be sufficient: a test with sensitivity and specificity in the high 90-

percent range may not improve the likelihood of a good patient outcome if the prevalence of the underlying condition or risk is low, or if the treatment options are of marginal efficacy or high risk. This *Medical Test Methods Guide* promotes the centrality of patient outcomes by recommending that one of the first steps in a review must be to establish a link between the use of a test and the outcomes patients and clinicians care about. This link can also be expounded through the use of visual representations such as the causal chain diagram, illustrated in a simplified form in Figure 1–1.

Figure 1–1. Causal chain diagram



In rare but ideal cases, a test is evaluated in a comprehensive clinical trial in which every relevant outcome is assessed in a representative group of patients in typical practice settings. More often, however, a systematic review may appropriately focus on only one link in this chain, as when the test is being compared with an established test known to improve outcomes. Ideally, the entire chain should be considered and evidence regarding each link assembled, evaluated, and synthesized.

Unique Challenges of Medical Tests

Of the many tools available to clinicians caring for patients, medical tests are among the most commonly employed. (Note that here "medical tests" is used as an umbrella term, to denote any test used in a health care context, irrespective of type—e.g., chemistry, genetic, radiological—or role—e.g., screening, diagnosis, or prognosis.) Tests can be used to screen for the likelihood of a disorder currently or in the future, or to diagnose the actual presence of disease. Medical tests may also be used to assess immediate or future response to treatment, including the probability of desirable or undesirable consequences. While medical tests are often thought of as something performed in the laboratory or radiology suite, the term also encompasses the traditional patient history and physical examination, as well as scored questionnaires intended, for example, for screening or to assess likely prognosis or response to therapy.

Assessing the impact of a treatment is generally more straightforward than assessing the impact of a medical test. This is the case primarily because most treatments lead directly to the intended result (or to adverse effects), whereas there may be several steps between the performance of a test and the outcome of clinical importance.[2] One consequence of this indirect relationship is that medical tests tend to be evaluated in isolation, in terms of their ability to discern an analyte or a particular anatomic condition, rather than in terms of their impact on overall health outcomes.[3]

In light of these challenges, the question we address directly in this *Medical Test Methods Guide* is: "How do we evaluate medical tests in a way that is clear (i.e., involves a process that can be reproduced), consistent (i.e., similar across reports), tractable (i.e., capable of being performed within resource constraints), and useful (i.e., addresses the information needs of the report recipients)?"

To answer this question, we might refer to the literature on evaluation of therapies. Arguably, the most robust empirical demonstration of the utility of a medical test is a properly designed randomized controlled trial (RCT)[4–7] that compares patient management outcomes of the test to the outcomes of one or more alternative strategies. In practice, such trials are not routinely performed because they are often deemed unattainable.

Recurrent Themes in the Test Evaluation Literature

In recognition of the unique challenges to evaluation presented by medical tests, a body of test evaluation literature has emerged over the past six decades. Two recurrent themes emerge from this literature. The first is the recognition that a medical test used to discriminate between the presence or absence of a specific clinical condition can be likened to an electronic signal detector.[8–10] This has opened the way to applying signal detection theory, including the notions of sensitivity, specificity, and the application of the Bayes rule, to calculate disease probabilities for positive or negative test results.[8–10]

The second theme reflected in the historical record is that medical test evaluation studies tend to fall along a continuum related to the breadth of the study objectives—from assessing a test's ability to conform to technical specifications, to the test's ability to accurately classify patients into disease states or prognostic levels, to the impact of the test on thought, action, or outcome. Various frameworks have been developed to describe the different outcomes of the study. Table 1–1 below consolidates these terms, with relevant examples, into four basic categories. Further descriptions of the various frameworks are included in the following sections.

Table 1–1. Different objectives of medical test evaluation studies

Study Objective	Terms Used	Examples
Ability of a test to conform to technical specifications	Technical efficacy	Technical quality of a radiological image
	Analytic validity	Accuracy of a chemical assay for the target analyte Concordance of a commercial genetic test with the true genotype
Ability of a test to classify a patient into a disease/phenotype or prognosis category	Diagnostic accuracy efficacy Clinical validity Test accuracy Test performance Performance characteristics Operating characteristics	Sensitivity and specificity Positive and negative likelihood ratios Positive and negative predictive value Test yield Receiver operating characteristic (ROC) curve
Ability of a test to direct clinical management and improve patient outcomes	Diagnostic thinking efficacy Therapeutic efficacy Patient outcome efficacy Clinical utility	Impact on mortality or morbidity Impact on clinician judgment about diagnosis/prognosis Impact on choice of managment
Ability of a test to benefit society as a whole	Societal efficacy	Incremental cost-effectiveness

Analytic Frameworks

While the preceding discussion provides a way to classify test evaluation studies according to their objectives, it does not offer the reviewer an explicit strategy for summarizing an often complex literature in a logical way in order to respond to key questions. In 1988, Battista and Fletcher applied "causal pathways" for the United States Preventive Services Task Force (USPSTF) in the study of evaluating preventive services, as a test for understanding and

evaluating the strength of support for the use of a preventive measure.[11] Such a framework is useful in maintaining an orderly process, clarifying questions, and organizing evidence into relevant categories. This value has been reiterated in other recommendations for reviewers.[12–14] In 1991, Woolf described a conceptual model that he termed the "Evidence Model,"[15] and in 1994, he described this same model as the "analytic framework."[16]

These points were reiterated in the most recent Procedure Manual for the USPSTF:

> The purpose of analytic frameworks is to present clearly in graphical format the specific questions that need to be answered by the literature review in order to convince the USPSTF that the proposed preventive service is effective and safe (as measured by outcomes that the USPSTF considers important). The specific questions are depicted graphically by linkages that relate interventions and outcomes. These linkages serve the dual purpose of identifying questions to help structure the literature review and of providing an "evidence map" after the review for the purpose of identifying gaps and weaknesses in the evidence.[17]

Two key components of the analytic framework are: (1) a typology for describing the context in which the test is to be used, and (2) some form of visual representation of the relationship between the application of the test or treatment and the outcomes of importance for decisionmaking. Visual display of essential information for defining key questions will also explicitly define the population, intervention, comparator and outcomes, which makes analytic frameworks consistent with the current standard approach to classifying contexts, the PICOTS typology, which is further described below. (For more information on PICOTS, see Chapter 2.)

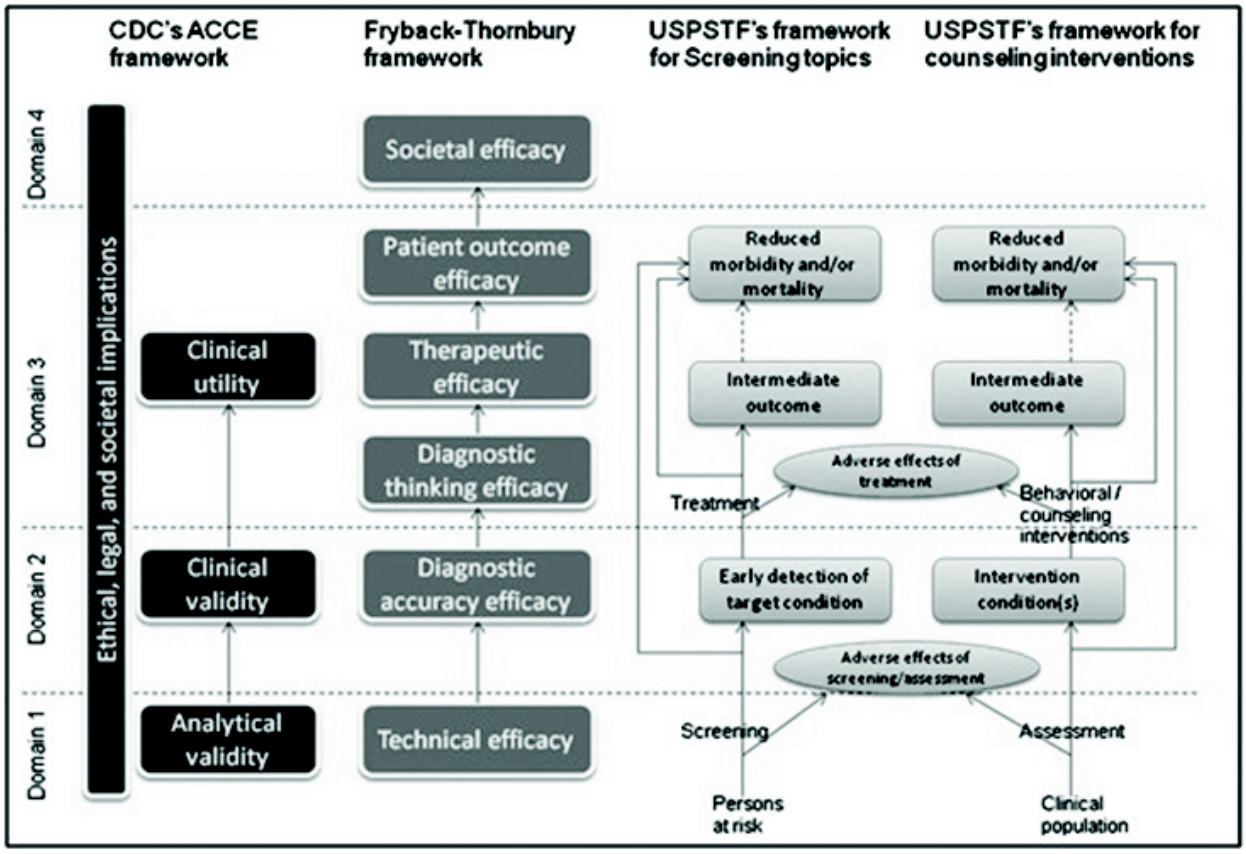
In addition to using the analytic framework in reviews to support clinical practice guidelines and the USPSTF, the AHRQ EPC Program has promoted the use of analytic frameworks in systematic reviews of effectiveness or comparative effectiveness of non-test interventions.[1] Although not specifically recommending a visual representation of the framework, the Cochrane Collaboration also organizes key questions using a similar framework.[18]

A Note on Terminology

With the evolution of the field, there has been a proliferation of terms used to describe identical or similar concepts in medical test evaluation. In this *Medical Test Methods Guide,* we have attempted to identify similar terms and to be consistent in our use of terminology. For example, throughout this document, we use terms for different categories of outcomes (Table 1–1) that are rooted in various conceptual frameworks for test evaluation (hereafter referred to as "organizing frameworks," although elsewhere referred to as "evaluative" or "evaluation" frameworks). There have been many different organizing frameworks; these have recently been systematically reviewed by Lijmer and colleagues.[5] Each framework uses slightly different terminology, yet each maps to similar concepts.

To illustrate this point, Figure 1–2 shows the relationship between three representative organizing frameworks: (1) The "ACCE" model of Analytic validity, Clinical validity, Clinical utility, and Ethical, legal and social implications,[19–20] (2) the Fryback and Thornbury model, one of the most widely used and well known of all the proposed organizing frameworks,[21] and (3) the USPSTF model for assessing screening and counseling interventions.[22] Since the key concepts are similar, unless another framework is especially apt for a particular review task, our principle of achieving consistency would argue for use of the USPSTF (See Chapter 2.)

Figure 1–2. A mapping across three major organizing frameworks for evaluating clinical tests



Notes: Used with permission of the ECRI Institute. The ECRI institute created this figure based on the specified evaluation frameworks. For a detailed description of each included framework, the reader is referred to the original references.[16–19] Domain 1—analytical validity; Domain 2—clinical validity; Domain 3—clinical utility; Domain 4—ethical, legal and societal implications.

PICOTS Typology

A typology that has proven extremely useful for the evaluation of therapies, and which also applies to the evaluation of medical tests, is called PICOTS. This typology—Patient population, Intervention, Comparator, Outcomes, Timing, Setting—is a tool established by systematic reviewers to describe the context in which medical interventions might be used, and is thus important for defining the key questions of a review and assessing whether a given study is applicable or not.[23]

The EPC Program, reflecting the systematic review community as a whole, occasionally uses variations of the PICOTS typology (Table 1–2). The standard, unchanging elements are the PICO, referring to the Patient population, Intervention, Comparator, and Outcomes. Timing refers to the timing of outcome assessment and thus may be incorporated as part of Outcomes or as part of Intervention. Setting may be incorporated as part of Population or Intervention, but it is often specified separately because it is easy to describe. For medical tests, the setting of the test has particular implications for bias and applicability in light of the spectrum effect. Occasionally, "S" may be used to refer to Study design. Other variations, not used in the present document, include a "D" that may refer to Duration (which is equivalent to Timing) or to study Design.

Table 1–2. The PICOTS typology as applied to interventions and medical tests.

Element	As Applied to Interventions	As Applied to Medical Tests	Comment
P	Patient population	Patient population; includes results of other/prior tests	Condition(s), disease severity and stage, comorbidities, patient demographics
I	Intervention	Index test; includes clinical role of index strategy in relation to comparator, and test-and-treat strategy in relation to clinical outcomes	Description of index test; includes administrator training, technology specifications, specific application issues Three main clinical roles in relation to comparator: replacement, add-on, triage Desciption of index test performance and interpretation; how results of index test lead to management decisions/actions
C	Comparator	Comparator test-and-treat strategy	Desciption of comparator test performance and interpretation; how results of comparator test lead to management decisions/actions
O	Outcomes	Relevant clinical outcomes; includes any intermediate outcomes of interest	Patient health outcomes; includes morbidity (including adverse effects of test and treatment), mortality, quality of life; intermediate outcomes: includes technical specifications, accuracy, decisional, therapeutic impact
T	Timing	Timing of outcome assessment	Duration of followup; single or multiple followup assessments
S	Setting	Setting of test assessment	Ambulatory settings (including primary, specialty care) and inpatient settings

Organization of This *Medical Test Methods Guide*

As noted above, this *Medical Test Methods Guide* complements AHRQ's *General Methods Guide*,[1] which focuses on methods to assess the effectiveness of treatments and other non-test interventions. The present document applies the principles used in the *General Methods Guide* to the specific issues and challenges of assessing medical tests, and highlights particular areas where the inherently different qualities of medical tests necessitate a variation of the approach used for a systematic review of treatments. We provide guidance in stepwise fashion for those conducting a systematic review.

Chapters 2 and 3 consider the tasks of developing the topic, structuring the review, developing the key questions, and defining the range of decision-relevant effects. Developing the topic and structuring the review—often termed "scoping"—are fundamental to the success of a report that assesses a medical test. Success in this context means not only that the report is deemed by the sponsor to be responsive but also that it is actually used to promote better quality care. In this *Medical Test Methods Guide,* we introduce various frameworks to help determine and organize the questions. While there is not a specific section on developing inclusion and exclusion criteria for studies, many of the considerations at this stage are highlighted in chapters 2 and 3, which describe how to determine the key questions, as well as in chapters 5 and 6, which describe how to assess the quality and applicability of studies.

Chapters 4 through 10 highlight specific issues in conducting reviews: searching, assessing quality and applicability, grading the body of evidence, and synthesizing the evidence. Searching for medical test studies (Chapter 4) requires unique strategies, which are discussed briefly. Assessing individual study quality (chapter 5) relates primarily to the degree to which the study is internally valid; that is, whether it measures what it purports to measure, in as unbiased a fashion as possible. Although much effort has been expended to rate features of studies in a way that accurately predicts which studies are more likely to reflect "the truth," this goal has proven

elusive. In Chapter 5, we note several approaches to assessing the limitations of a study of a medical test and recommend an approach.

Assessing applicability (Chapter 6) refers to determining whether the evidence identified is relevant to the clinical context of interest. Here we suggest that systematic reviewers search the literature to assess which factors are likely to affect test effectiveness. We also suggest that reviewers complement this with a discussion with stakeholders to determine which features of a study are crucial (i.e., which must be abstracted, when possible, to determine whether the evidence is relevant to a particular key question or whether the results are applicable to a particular subgroup.)

Once systematic reviewers identify and abstract the relevant literature, they may grade the body of literature as a whole (Chapter 7). One way to conceptualize this task is to consider whether the literature is sufficient to answer the key questions such that additional studies might not be necessary or would serve only to clarify details of the test's performance or utility. In Chapter 7, we discuss the challenges and applications of grading the strength of a body of test evidence.

Chapter 8 through 10 focus on the technical approach to synthesizing evidence, in particular, meta-analysis and decision modeling. Common challenges addressed include evaluating evidence when a reference standard is available (Chapter 8), and when no appropriate reference standard exists (Chapter 9). In reviewing the application of modeling in clinical test evidence reviews, we focus in chapter 10 on evaluating the circumstances under which a formal modeling exercise may be a particularly useful component of an evidence review.

Finally, in Chapters 11 and 12, we consider special issues related to the evaluation of genetic tests and prognostic tests, respectively. While both topics are represented in earlier chapters, those chapters focus on methods for evaluating tests to determine the current presence of disease, as with screening or diagnostic tests. Chapters 11 and 12 complete the guidance by addressing special considerations of assessing genetic and prognostic tests.

Summary

Evaluation of medical tests presents challenges distinct from those involved in the evaluation of therapies; in particular, the very great importance of context and the dearth of comprehensive RCTs aimed at comparing the clinical outcomes of different tests and test strategies. Available guidance provides some suggestions: (1) Use the PICOTS typology to clarify the context relevant to the review, and (2) Use an organizing framework to classify the types of medical test evaluation studies and their relationship to potential key questions. However, there is a diversity of recommendations for reviewers of medical tests and a proliferation of concepts, terms, and methods. As a contribution to the field, this *Medical Test Methods Guide* seeks to provide practical guidance to achieving the goal of clarity, consistency, tractability, and usefulness.

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