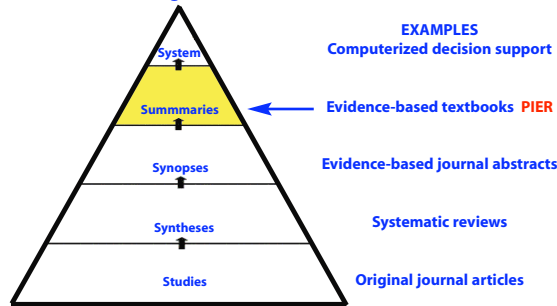


American College of Physicians

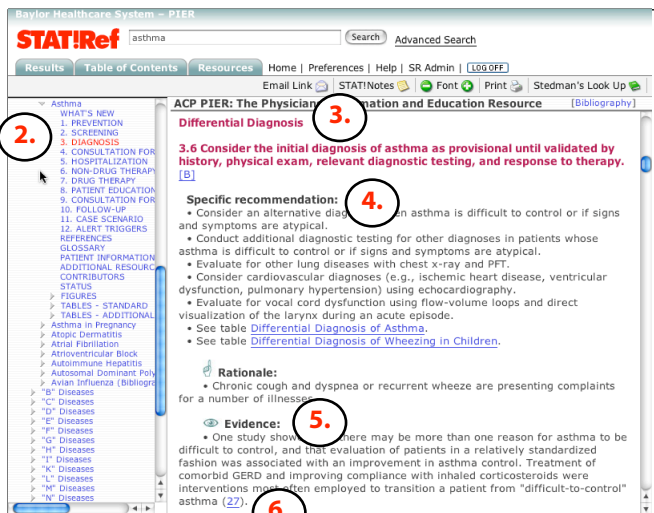
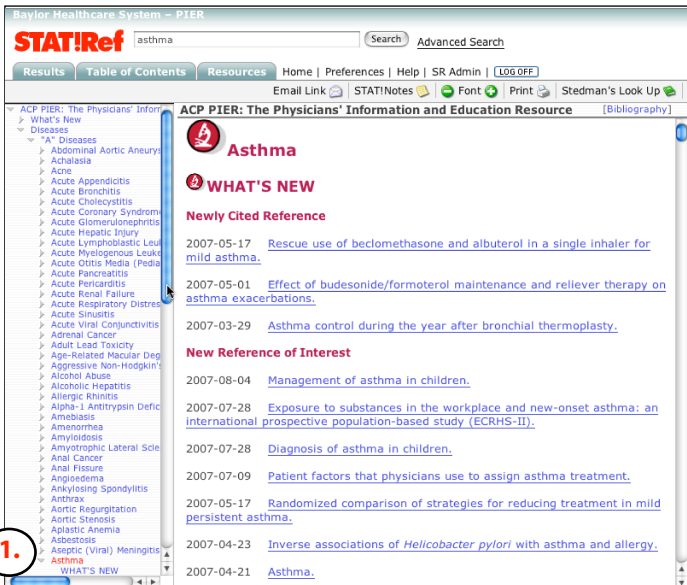
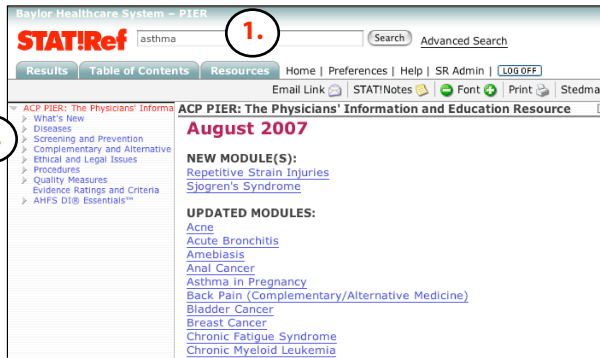
**pier**  
Physicians' Information  
and Education Resource

The "5S" Levels of Organization of Evidence From Health Care Research



"... we add a layer to the model, namely clinical topic summaries of evidence about all pertinent management options for a health condition, such as those included in *Clinical Evidence* and PIER. If a current topic summary exists, it would summarize the relevant *synopses, syntheses, or studies* about several aspects of a health condition. Thus, a current *summary* 'trumps' an individual *synopsis, synthesis, or study* or a collection of these."

R. Brian Haynes, MD, PhD  
McMaster University



1. Enter a search term(s) and click **Search**. Or browse the Disease modules in the left hand Table of Contents.
2. Choose a relevant result from the applicable module. (For Example, in the asthma search image on the left, we see several results related to asthma.)
3. View the standardized section by scrolling or directly clicking on the blue link in the left-hand Table of Contents navigation bar.
4. Find the *Specific Recommendation* within the section. Each *Specific Recommendation* includes rationale, evidence and comments.
5. Consider the Evidence Rating\*  
\* **Evidence Ratings**  
[A] The preponderance of data supporting this statement is derived from level 1 studies, which meet all of the evidence criteria for that study type.  
[B] The preponderance of data supporting this statement is derived from level 2 studies, which meet at least one of the evidence criteria for that study type.  
[C] The preponderance of data supporting this statement is derived from level 3 studies, which meet none of the evidence criteria for that study type or are derived from expert opinion, commentary or consensus.
6. Click on the Evidence footnote to find the Study Criteria\*  
\* **Study Criteria**

- [1] Studies that meet all of the evidence criteria for that study type.
- [2] Studies that meet at least one of the evidence criteria for that study type.
- [3] Studies that meet none of the evidence criteria for that study type or are derived from expert opinion, commentary or consensus.

**Editorial consultants who update the text, references and additional resources linked to the modules review all PIER modules continually. Find editorial changes in the Status section at the end of the module or at the bottom in the left-hand local Table of Contents navigation bar.**

**More frequent updates are made when warranted by the release of important new studies, drug therapies and guidelines. New modules are added monthly. New modules are listed at the top of the main PIER Table of Contents.**

## Criteria:

### **Studies of prevention or treatment must meet these additional criteria:**

- Random allocation of participants to comparison groups
- Follow-up (end-point assessment) of at least 80% of those entering the investigation
- Outcome measure of known or probable clinical importance

### **Studies of diagnosis must meet these additional criteria:**

- Inclusion of a spectrum of participants, some but not all of whom have the disorder or derangement of interest
- Objective diagnostic ("gold") standard (e.g., laboratory test not requiring interpretation) OR current clinical standard for diagnosis (e.g., a venogram for deep venous thrombosis), preferably with documentation of reproducible criteria for subjectively interpreted diagnostic standard (i.e., report of statistically significant measure of agreement beyond chance among observers)
- Each participant must receive both the new test and some form of the diagnostic standard
- Interpretation of diagnostic standard without knowledge of test result
- Interpretation of test without knowledge of diagnostic standard result

### **Studies of prognosis must meet these additional criteria:**

- Inception cohort of individuals, all initially free of the outcome of interest
- Follow-up of at least 80% of patients until the occurrence of a major study end point or to the end of the study

### **Studies of causation must meet these additional criteria:**

- Exploration of the relation between exposures and putative clinical outcomes
- Prospective data collection with clearly identified comparison groups for those at risk the outcome of interest (in descending order of preference from randomized controlled trial, quasi-randomized controlled trial, nonrandomized controlled trial, cohort studies with case-by-case matching or statistical adjustment to create comparable groups, to nested case-control studies
- Masking of observers of outcomes to exposures (criterion assumed to be met if outcome is objective, i.e., all-cause mortality, objective test)

### **Studies of quality improvement or continuing education must meet these additional criteria:**

- Random allocation of participants or units to comparison groups
- Follow-up of at least 80% of participants
- Outcome measure of known or probable clinical or educational importance

### **Studies of the economics of health care programs or interventions must meet these additional criteria:**

- The economic question addressed must be based on comparison of alternatives in real or hypothetical patients
- Alternative diagnostic or therapeutic services or quality improvement activities must be compared on the basis of both the outcomes produced (effectiveness) and resources consumed (costs)
- Evidence of effectiveness must be from a study (or studies) of real (not hypothetical) patients, which meets the above-noted criteria for diagnosis, treatment, quality improvement, or a systematic review article that also meets criteria
- Results should be presented in terms of the incremental or additional costs and outcomes of one intervention over another
- Where uncertainty exists in the estimates or imprecision in the measurement, a sensitivity analysis should be done

### **Studies of clinical prediction guides must meet these additional criteria:**

- The guide must be generated in one or more sets of real (not hypothetical) patients (training set)
- The guide must be validated in another set of real (not hypothetical) patients (test set) and must deal with treatment, diagnosis, prognosis, or causation

### **Studies of differential diagnosis must meet these additional criteria:**

- A cohort of patients who present with a similar, initially undiagnosed but reproducibly defined clinical problem
- Clinical setting, including the referral filter, is explicitly described
- Ascertainment of diagnosis for 80% of patients using a reproducible diagnostic workup strategy for all patients and follow-up until patients are diagnosed or follow-up of 1 month for acute disorders or 1 year for chronic or relapsing disorders

### **Systematic review articles must meet these additional criteria:**

- An identifiable description of the methods indicating the sources and methods for searching for articles
- Statement of the clinical topic and the inclusion and exclusion criteria for selecting articles for detailed review
- At least one article in the review must meet the above noted criteria for treatment, diagnosis, prognosis, clinical prediction, causation, quality improvement, or economics of health care.

Purpose and Procedure. [http://www.acpjc.org/shared/purpose\\_and\\_procedure.htm#criteria](http://www.acpjc.org/shared/purpose_and_procedure.htm#criteria). In: ACP Journal Club [online database]. Philadelphia, American College of Physicians-American Society of Internal Medicine, 2002.