Evidence-Based Medicine

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1. Introduction to Evidence-Based Medicine

Evidence-based medicine (EBM) today represents the confluence of **three major movements** that all originated in the early nineties. Although the principles of EBM have been widely endorsed in the urological community, many barriers impede evidence-based clinical practice.[1] These include the **low quality of evidence** provided by many studies in urology and poor reporting practices[2,3,4,5,6,7] and the **lack of familiarity with EBM** knowledge and skills, which this chapter in the AUA Core Curriculum seeks to address.

1.1 Critical Appraisal

Associated with the names of David Sackett and Gordon Guyatt at McMaster University, it emphasizes **the need for every clinician to have the knowledge and skills to critically appraise evidence from clinical research**.[8] David Sackett provided what continues to be the most commonly cited definition of EBM, which reads that EBM is "…**application of the current best evidence to care of an individual patient**". The definition further reads that EBM means "…**the integration of best evidence from clinical research with the patients' values and preferences**". Gordon Guyatt subsequently coined the term "Evidence-Based Medicine" and initiated the Users' Guide to the Medical Literature that reviews the core concepts of EBM.

1.2 Systematic Reviews

The second major movement emphasizes the **importance of drawing together the entire body of evidence for a given clinical question in a systematic way** per Sir Archie Cochrane who founded the Cochrane Collaboration. The logo of the Cochrane Collaboration represents a forest plot of multiple inconclusive clinical trials on the antenatal use of systematic steroids of mothers who were about to deliver premature infants at risk for pulmonary dysfunction due to lung immaturity. Whereas each individual trial was indeterminate, the aggregated body of evidence provided clear support for the use of steroids in this setting and changed clinical practice.

1.3 Clinical Practice Guidelines

This originated in the United States and was motivated by **observations of major variability in the**

type and intensity of patient care delivered across the country, that remained even when accounting for patient age and other differences. Since that time, clinical practice guidelines have become part of the portfolio of all major professional organizations to provide guidance at the point of care about what management options are most appropriate in a given clinical setting and also provide the background for quality of care measures.

2. Guiding Principles of EBM

The two guiding principles of EBM are **hierarchy of evidence** and **evidence alone never being enough**.

2.1 Hierarchy of Evidence

This relates to the fact that some studies are better suited than others to address a given clinical question. The initial consideration is **study design**. For example, a well-designed randomized controlled trial has the potential to provide the highest quality evidence for questions of therapy or prevention; the experimental design begins with two or more groups with similar prognosis (through **randomization and allocation concealment**) and then controls for all differences except the intervention of interest (through **blinding, completeness of follow-up and intent-to-treat analysis**). This design permits the strongest causal inference we can achieve in clinical medicine, if the trial is well designed and well reported. Meanwhile, other study designs are more appropriate for other types of questions. For example, both for questions of diagnosis and prognosis, prospective cohort studies provide high quality evidence.

Although the "**levels of evidence**"[9] have been popularized by the **Oxford Center for Evidence Based Medicine** that place a strong emphasis on study design, there is increasing recognition that additional factors beyond study design impact our **confidence in the results (effect size)** of a given study as reflected in the rating systems used by the GRADE Working Group, the United States Preventive Services Task Force and the American Urological Association (AUA). As a result, poorly performed randomized controlled trials may be downgraded, whereas select observational studies may be upgraded, with regards to the quality of evidence they provide.

See references **8, 10**

2.2 Evidence Alone Is Never Enough

In contrast to two common misconceptions (i) that EBM solely considers evidence from randomized controlled trials and (ii) there is a automatism that should prompt clinicians to choose a certain management approach when found to be effective in a randomized controlled trial, **EBM has from its early beginnings has emphasized the importance of the patient's values and preferences as well as the individual circumstances including the provider's expertise and experience**. The classic example of the Users' Guide to the Medical Literature in fact relates to urology: A patient with terminal cancer with acute renal failure due to bilateral ureteral obstruction may elect to forego percutaneous nephrostomy tube placement and die of uremia despite strong evidence that this

procedure is likely to improve her renal function and prolong survival. **This informed choice that a well-informed patient makes is entirely consistent with an evidence-based practice**.

See reference **8**

3. How to Practice EBM

The practice of EBM is represented by the **5 "As"** which stand for: [8]

3.1 Ask

This refers to the need for clinicians to recognize that they have frequent information needs in order to treat patients according to the current best evidence and the importance of being able to formulate this information need into an answerable clinical question.

3.2 Acquire

This refers to the activity of going to suitable information sources, which are increasingly web-based, to find the current best evidence.

3.3 Appraise

Any study used to guide medical management should be scrutinized as to whether it is valid, whether the results are clinically significant and whether it applies to the care of a given patient.

3.4 Apply

This steps refers to the process of **shared medical decision-making** in explicit acknowledgement of the patient's values, preferences and individual circumstances.

3.5 Assess

Evidence-based practitioners should reflect upon on how well they "journey" through the evidence cycle (how often do they search for up-to-date information, what evidence-based resources do they utilize) in order to improve their performance with the goal of improving patient care.

4. How To Formulate An Answerable Question

An important distinction is that which exists between **background and foreground information**. Background information relates to question such as "what is prostate cancer?", "what causes prostate cancer?" or "what is the incidence of prostate cancer?". While important questions, these do not fall under the purview of EBM, which focuses on information needs to guide the management for individuals or groups of patients (**a foreground question**). These questions should be framed in the **PICO format**, which in the case of questions of therapy/prevention stands for[11]: (i) **Patient** (ii) **Intervention** (iii) **Comparison** (iv) **Outcome**.

For example, if interested in the therapeutic effects of adjuvant radiation therapy for patients who have undergone radical prostatectomy, one might frame the following clinical question: In patients at

risk for disease recurrence after radical prostatectomy **(P)**, how does treatment with adjuvant radiation **(I)** compare to an observation approach **(C)** with regards to disease-specific survival **(O).** Note that questions of therapy (in contrast to those of prognosis) always have a comparator and that the main interest lies in the incremental benefit (or harm), **the so-called effect size**. In addition, the outcome that is part of the PICO question should be a patient-important rather than surrogate outcome.

5. How To Search Effectively

Having realized the need for current best evidence to guide patient management, and having framed this information need into a focused clinical question in PICO format, it is important to choose the right information resource.[11] Medical information resources can be broadly categorized into **primary (original research studies)** and **secondary resources (systematic reviews, evidence-based synopses, clinical practice guidelines)**. Secondary resources are distinct from the primary resources as they incorporate some degree of formal critical appraisal validity and clinical importance, thereby saving the reader time spent making those assessments themselves. When at all possible, **urologists should draw on secondary resources of evidence rather than individual studies** to make sure that they apply the current best evidence to the care of their patients.

6. How To Appraise A Study: The Users' Guide Framework

While alternate frameworks for critical appraisal exist, the most widely used is that popularized by the User's Guide to the Medical Literature [12] that suggests that every consumer of the medical literature ask the following three questions of each study he/she encounters (i) **are the results valid?** (ii) **what are the results?** and (iii) **do the results apply to my patient?** Each of these three questions is independently important and study results should not be applied to patient care if not all three questions are addressed satisfactorily.

6.1 Are The Results Valid?

Validity refers to the extent that a given study provides an accurate representation of "the truth in the universe" meaning that we can believe the results to be true. **Validity is also defined as the absence of bias**, which refers to a systematic deviation from the truth in one direction or the other (patient survival from a new chemotherapy is less in reality than in a biased clinical trial). In the context of studies that seek to establish that a new treatment modality is better than an established treatment, the direction of bias is typically in the direction of an exaggerated treatment effect, meaning that a study may suggest that a treatment works when it really doesn't or that it has a large effect when it really is only minimal effective. Below we will discuss methodological safeguards against bias that are relevant to different types of study questions to prevent this from occurring.

6.2 What Are The Results?

As the second step, the Users' Guide encourages clinicians to gain a **full understanding of the study results in terms of the effect size measures being presented**. We broadly distinguish

between relative (relative risk, hazard ratios) and absolute effect size measures (absolute risk reduction, number needed-to-treat or number). While both groups of outcome measures have their role in evidence-based clinical practice, **relative effect size measures are often times deceiving** and **absolute effect size measures are the most important** to individual patient decision-making. It is therefore important for urologists to be able to derive absolute effect size measures from relative effect size measures. [13] Part of fully understanding a given result is appreciating the degree of precision by which it was measured. In contrast to accuracy, **precision refers to degree to which a study is affected by chance variation or random error**. **Precision can be assessed by the width of the confidence interval** surrounding an effect size and is most dependent on study size and the frequency of outcome events. The narrower a confidence interval around a given effect size, the less influence of chance we worry about to explain the result; however, it does not help us to determine whether the result is likely true or not, which refers to validity and the absence of bias.

See reference **14**

6.3 Are The Results Applicable To My Patient?

Equally important as the dimensions of validity and clinical impact is the applicability of the results to the care of the patient whom you are counseling. Considerations include the extent to which the patient meets the eligibility criteria of the study from which the best evidence is derived and whether there is a compelling reason to believe that the results may not be applicable to him/her. The second consideration is whether the study assessed all patient-important outcomes. It is common for clinical studies to rely on surrogate outcomes which are not directly relevant to patients but have some association with the outcome we do care about, for example PSA levels in patients with recurrent prostate cancer and the outcome of disease-specific survival. While these outcomes may be useful in the absence of direct information about the patient-important outcome, it is important to note that they introduce additional uncertainty. In addition, there are potential adverse effects and costs to consider and weigh against the anticipated benefits. Finally, the clinician should weigh the patient's values and beliefs about the treatment under consideration and the feasibility of the intervention. For example, the potential merits of an organ-sparing cystectomy in a female patient may be entirely irrelevant to a patient who is not sexually active and does not intend to be. Different types of clinical questions are best answered by different study designs that call for an adaptation of the Users' Guide framework for critical appraisal. [8]

See reference **8, 15**

7. Questions Of Therapeutic Effectiveness And Prevention

Table 1. Critical Appraisal Criteria For A Study Of Therapy (Randomized Controlled Trials)

Are the results valid?

1. Did the 2 groups begin the study with a similar prognosis?
    1. Did the investigators take into account the learning curve?
    2. Were the patients randomized?
    3. Was the randomization concealed?
    4. Were patients stratified?
    5. Were all patients' data analyzed in the group to which they were randomized?
    6. Were patients in the 2 groups similar with respect to known prognostic factors?

2. Did the 2 groups retain a similar prognosis after the study started?
    1. Were patients aware of group allocation?
    2. Were surgeons aware of group allocation?
    3. Were outcome assessors aware of group allocation?
    4. Was the follow-up complete?

What are the results?

1. How large was the treatment effect?
2. How precise was the estimate of the treatment effect?

Can I apply the results to patient care?

1. Were the study patients similar to my patient?
2. Were all clinically important outcomes considered?
3. Are the likely treatment benefits worth the potential harm and costs?

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Questions that relate to therapy and prevention are among the most commonly asked questions by urologists and are best addressed through randomized controlled trials. [16] These have the potential of providing the highest quality evidence if they are well done and transparently reported. The validity of such trials rests on the extent to which the following methodological safeguards against bias have been addressed. Failure to use these measures potentially leads to the introduction of bias, frequently resulting in an overestimate of the effectiveness of the intervention. The Users' Guide to the Urological Literate provides a set of criteria to critical appraise an individual study of a therapeutic intervention (**Table 1**).[16]

7.1 Randomization

Refers to the generation of groups through a random process (computer generated sequence) that are comparable at baseline for both known and unknown prognostic variables.

7.2 Allocation Concealment

The investigators should determine patient enrollment without potential foreknowledge of the study arm that a patient has been allocated to. **Alternating allocation, non-opaque envelopes and open randomization lists are all examples in which allocation concealment is compromised** and bias may therefore exist.

7.3 Blinding

Blinding refers to the lack of awareness of what group a patient is assigned to. **Blinding guards against placebo effects, co-interventions and biased outcome assessment.** Groups of individuals that ideally should be blinded in a clinical trial (and to the extent possible in observational studies as well) include the **patient, the study personnel interacting with the patient, the data collectors, the outcome assessors, the data analysts and the members of the data monitoring committee** .

7.4 Intention-To-Treat Analysis

Especially when treatment options vary considerably (such as, radical prostatectomy versus radiation therapy for clinically localized prostate cancer) a subset of patients may not receive the intervention they were allocated to or even cross over to the other treatment group. In this setting, there is widely held consensus that the preferred approach that yields the more conservative estimate of effect is to **analyze that patients in the groups they were randomized to**, irrespective of what actually happened; this approach is referred to as the intention-to-treat method. **This preserves the comparability of groups for important baseline characteristics** that was achieved through randomization and allocation concealment. The alternative approach is referred to as the "per protocol" or "treatment received" approach and has mainly explorative purposes.

See Reference **17**

7.5 Completeness Of Follow-Up

Study subjects in whom the outcome can ultimately not be determined are labeled as lost to follow-up. The loss of study patients not only affects the statistical power of a study and thereby the precision of the results, but more importantly represents a potential source of bias. The underlying issue is that loss to follow-up is oftentimes not a random event, but occurs in patients that have a different prognosis, thereby biasing the results. Readers should therefore take mental note of the proportion of patients in each group that were lost to follow-up; if the number of patients lost-to-follow-up is large, sensitivity analyses using best and worst case scenario assumptions can assess the potential impact on the results.

For most clinical questions in urology, there is no RCT evidence to guide decision-making. Consistent with the principle of EBM to search for the current best evidence, decision-making should therefore be based on whatever evidence does exist, be it prospective or retrospective cohort studies, case-control studies or even non-comparative case series. However, it is important to realize that these studies are at higher risk for deviations from the truth, which including selection bias and confounding. Therefore, our confidence in the results of observational studies for questions of therapy and prevention is usually lower than is it for well-designed RCTs.

See reference **18**

8. Questions of Diagnostic Test Accuracy

Table 2. Critical Appraisal Criteria For A Study Of Diagnosis

Are the results valid?
1. Was there an independent, blind comparison with a reference standard? 2. Did the patient sample include an appropriate spectrum of patients to whom the diagnostic test will be applied in clinical practice? 3. Did the results of the test being evaluated influence the decision to perform the reference standard? 4. Were the methods for performing the test described in sufficient detail to permit replication?
What are the results?
1. Are LRs for the test results presented or data necessary for their calculation provided? 2. How precise are the LRs?
Can I apply the results to patient care?
1. Will the reproducibility of the test results and its interpretation be satisfactory in my setting? 2. Are the results applicable to my patient population? 3. Will the results change my management? 4. Will patients be better off as a result of the test?
View Image.

While the hallmarks of high quality randomized controlled trials are fairly well understood, this is not the case for studies designed to establish the accuracy of a new diagnostic test.[19] For questions of diagnostic accuracy, the ideal study design is a prospective cohort study, in which a cohort of consecutive representative patients undergoes both the index test of interest and an established and trusted reference standard. Important validity criteria are as follows (**Table 2**).[19]

8.1 Did The Investigators Face Diagnostic Uncertainty?

Investigators should enroll patients in whom it is not known whether they do or do not have the target condition that is being tested for. At times, investigators compare test performance on a group of patients with the disease versus a group of patients who do not have the disease. One issue with this approach is that tends to reduce the spectrum of disease in which the test is being evaluated to those that clearly have or do not have the disease, there eliminating the “shades of grey” in whom the diagnosis may be harder to establish; this would result in an overestimation of test accuracy.

8.2 Did The Investigators Compare The “Index” Test To An Appropriate, Independent Reference Standard?

The reference standard that is used to establish whether a patient does or does not have the disease should be accepted as definite. For example, when assessing the diagnostic accuracy of TRUS biopsy to identify prostate cancer, radical prostatectomy specimen would be appropriate.

8.3 Were Those Interpreting The Test And Reference Standard Blind To The Other Results?

When interested in the ability of a new test to determine the presence or absence of a disease or condition, the person responsible for performing and interpreting the index test should not any knowledge of the results of the reference standard. For example, when interested in the ability of PET imaging to accurately diagnose lymph node involvement in muscle-invasive bladder cancer, PET interpretation should occur prior to pathological reporting of the lymph node status.

8.4 Did Investigators Perform The Same Reference Standard In All Patients Regardless Of The Results Of The Test Under Investigation?

This criterion maps to an issue called **verification bias**. Sometimes investigators forego testing of a subset of patients, in particular those of low risk, which tends to overestimate the diagnostic accuracy of the test by omission of the patients that would have been false negative. For example, if interested in the diagnostic accuracy of biopsy in patients with small renal masses, all patients should undergo subsequent partial nephrectomy to confirm pathology, even those in whom the biopsy is negative.

The results of diagnostic accuracy studies are reported as sensitivities and specificities, as well as positive and negative predictive values. It is important to realize that the latter two are dependent on the prevalence of the disease and therefore will change depending on the patient population being studied. Since investigations will preferentially study new tests in high-risk populations, there is a tendency to overestimate diagnostic accuracy. An extremely helpful measure that can be derived

from sensitivity and specificity are **likelihood ratios**,[20] which indicate how much more common a given test result is in patients with the condition of interest compared to that same test result in patients that do not have the condition of interest. Using a an estimate of the probability that a given patient has a given condition (for example, a ureteral stone), the so-called pre-test probability one can apply the likelihood of a positive or negative test result (for example that of a CT scan) and arrive at a so-called post-test probability. Calculating likelihood ratios is very helpful in determining the strength of a given test to shift probability. Consideration should be given to performing a test if neither a positive or negative result will shift probability sufficiently to either rule in (and trigger treatment) or rule out (and negate need for further testing), respectively. **Tests with likelihood ratios ≥ 10 or ≤ 0.1 result in substantial changes in probabilities and are therefore the most definitive** (**Table**). Likelihood ratios can be applied by multiplying them with the pre-test odds to obtain the post-test odds. Since this is cumbersome and odds are difficult to interpret, **Fagan nomograms** and online calculators that allow direct entry of pre-test probabilities are more practical.

9. Questions of Prognosis

Table 3. Critical Appraisal Criteria for a Study of Prognosis

Are the results valid?
1. Was there a representative sample of patients? 2. Were the patients sufficiently homogenous with respect to prognostic risk? 3. Was follow-up sufficiently complete? 4. Were objective and unbiased outcome criteria used?
What are the results?
1. How likely are the outcomes to occur over time? 2. How precise are the estimates of likelihood?
Can I apply the results to patient care?
1. Were the study patients and their management similar to your own? 2. Was follow-up sufficiently long? 3. Can you use the results to determine the management to your patients?
View Image.

Studies of prognosis answer the question about the probability of a given outcome (like death) of patients with certain characteristics or risk factors (like age or cancer stage). [21] They have an important role in helping patients predict what to expect and also to determine the baseline risk of a given even to determine whether treatment is indicated or not. Validity criteria are as follows (**Table 3**)[21]:

9.1 Was The Sample Of Patients Representative?

Study results are biased if they systematically over or underestimate the likelihood of an outcome; this will happen if the patients studied is different than the general patient population. For example, patients that present to an urologist for complaints for evaluation of a urinary tract infection represent a select group of patients with a higher likelihood of significant underlying pathology compared to those presenting to the office of a primary care physician.

9.2 Were The Patients Sufficiently Homogenous With Regards To Prognostic Risk?

Most disease entities have recognized factors that affect prognosis such as the TNM system for malignancies. While feasible, it makes little sense to ignore these prognostic factors, assess prognosis across all TNM stages and average the results. Such information would likely overestimate or underestimate the prognosis of individual patients that have many or few risk factors, respectively. It is therefore important to assess to what extent investigators have accounted for all prognostic factors that we know about.

9.3 Was Follow-Up Sufficiently Complete?

Whereas journal club discussions will frequently focus on the length of follow-up, completeness of follow-up is an equally important issue that is commonly ignored. [18] There is empirical data to demonstrate that loss-to-follow-up in randomized controlled trials and observational studies alike is not a random event, but affects patients that have a differential prognosis. For example, if a prognostic study of a cancer treatment relies on an active effort by the patient to contact the researchers to update them of his condition, then prognosis may be systematically overestimated because patients who are doing poorly may be less inclined to put in the time and effort to contact the research team.

9.4 Were Outcome Criteria Objective And Unbiased?

Outcome measures may be objective and easily measured such as death, whereas others may require judgment or effort to measure, such as quality of life or functional impairment. Ideally, target outcomes chosen by a study should be clearly specified and objective in nature. When outcomes are inherently subjective like death from a specific cause, then they should take additional precautions to provide assurance that measurement occurs in an unbiased manner.

10. Questions of Harm

Most, if not all therapeutic interventions have the potential for adverse events or complications.[22] This potential for unintended harm to patients should find equal consideration on the decision-making process as the likelihood of benefit, which is the reason why adverse events need to be captured and reported in clinical trials no differently than therapeutic benefits. However, reporting of side-effects in RCTs is often limited by virtue of poor reporting practices,[3] relatively small number of patients enrolled, concerns over representativeness of trial populations (trials will commonly selected for more healthy patients and exclude high risk populations such as the pregnant women or the elderly) as well their short time horizon. Alternative observational study designs, in particular cohort and case-control studies have an important role in establishing both short-term and long-term safety of both drugs and surgical devices (**Table 4**).[22]

Table 4. Critical Appraisal Criteria for a Study of Harm (Observational Studies)

Are the results valid?

1. In a cohort study, aside from the exposure of interest, did the exposed and control groups start and finish
    1. Were patients similar for known prognostic factors (or did statistical adjustment level the playing field)
    2. Were the circumstances and methods for detecting the outcome similar?
    3. Was follow-up sufficiently complete?

2. In a case-control study, did the cases and control group have the same risk (chance) for being exposed in the past?
    1. Were cases and controls similar with respect to the indication or circumstances that lead to exposure?
    2. Were the circumstances and methods for determining exposure similar for cases and controls?

What are the results?

1. How strong is the association between exposure and outcome?
2. How precise was the estimate of the risk?

Can I apply the results to patient care?

1. Were the patients similar to the patients in my practice
2. Was follow-up sufficiently long?
3. Is the exposure similar to what might occur in my patient?
4. What is the (absolute) magnitude of the risk?
5. Are there any benefits that are known to be associated with exposure?

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11. Systematic Reviews

Systematic reviews have an important role in guiding evidence-based clinical practice by applying a well-defined and transparent process to comprehensively search, appraise and summarize an entire body of evidence to address a focused clinical question. [23] Aside from their importance to individual patient decision-making, they are critical to the development of clinical practice guidelines. We distinguish them from narrative review, where most if not all features of a systematic review are absent (**Table 5**).[23] Most review articles and book chapters found in the urological literature do not represent systematic reviews. It is also understood that the validity of a systematic review hinges both on the underlying studies that are being summarized and the methodological quality used to conduct the review. Common shortcomings of systematic reviews published in the literature are failure to conduct a systematic literature search that includes the so called “grey” literature of unpublished studies which may result in publication bias and failure to rate the quality of the studies being summarized. [24] The Cochrane Collaboration has pioneered most of the standards currently use to appraise systematic reviews and also provides one of the best resources for finding high quality systematic reviews through the **Cochrane Database of Systematic Reviews and the Database of Reviews of Effectiveness (DARE).**[25]

Table 5. Critical Appraisal Criteria for Review Articles

Are the recommendations valid?
1. Were all important options and outcomes considered? 2. Was an explicit and sensible process used to identify, select and combine evidence? 3. Is there a description of individuals involved in the development process? 4. Were the conflicts of interest of the guideline panel members accounted for? 5. Are the sources of evidence used in the guideline development identified? 6. What were the methods used to interpret and assess the strength of evidence? 7. Were the methods used to formulate recommendations described? 8. Has the guideline been subjected to peer review and testing? 9. Are methods for updating the guideline document described?
What are the recommendations?
1. Are practical, clinically important recommendations made? 2. How strong are the recommendations?
Will the recommendations help you in caring for your patients?
1. Is the primary objective of the guideline consistent with my patients' objectives? 2. Are the recommendations applicable to my patients?
View Image.

12. Clinical Practice Guidelines

Guidelines are becoming increasingly important to the practice of urology as witnessed by the amount of resources invested in their development by the AUA other organizations[26,27] and plans by the American Board of Urology to base some of their examination questions on the AUA guidelines. Apart from the AUA's website, The National Guidelines Clearing House and the website of the Guidelines International Network (G.I.N) provide excellent resources for identifying clinical practice guidelines that meet minimal quality standards. Similar to systematic reviews, there are well-established criteria (**Table 6**)[26] by which to critically appraise a clinical practice guideline.[26] Among these are that they should be **based on a systematic review** of the evidence, that the **quality of evidence should be rated**, that there needs to be a clear **distinction between the quality of the evidence and strength of recommendation** and that **any potential conflict of interest should be transparently managed.**

Presentations

EVIDENCE-BASED MEDICINE Presentation 1

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This article is the first in the 8 article series of the Users' Guide to the Urological Literature series and provides an introduction to the framework of evidence-based medicine.

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19 This article in the Users' Guide to the Urological Literature series explains the critical appraisal framework that is applicable to studies of diagnostic test accuracy, based on an example from the practice of urology (detection of bladder cancer). Aside from explaining important validity criteria, it introduces the value of likelihood ratios.

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21 This article in the Users' Guide to the Urological Literature series explains the critical appraisal framework that is applicable to studies of prognosis, once again using an example (salvage radiation therapy for prostate cancer) from the day-today practice of urology.

22 Levine M, Ioannidis JP, Haines A, Guyatt G. Harm (Observational Studies). Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice, Second Edition. New York: American Medical Association; 2008: 363-81.

☆ † Tseng TY, Dahm P, Poolman RW, Preminger GM, Canales BJ, Montori VM. How to use a systematic literature review and meta-analysis. J Urol 2008; 180(4): 1249-56.

23 This article in the Users' Guide to the Urological Literature series explains the critical appraisal framework that is applicable to review articles. It distinguishes systematic reviews from narrative reviews and explains their importance to guide an evidence-baed practice of urology.

24 ☆ MacDonald SL, Canfield SE, Fesperman SF, Dahm P. Assessment of the methodological quality of systematic reviews published in the urological literature from 1998 to 2008. J Urol 2010; 184(2): 648-53.

25 Hajebrahimi S, Dahm P, Buckingham J. Evidence-based urology in practice: the cochrane library. BJU Int 2009; 104(8): 1048-9.

☆ † Dahm P, Yeung LL, Gallucci M, Simone G, Schunemann HJ. How to use a clinical practice guideline. J Urol 2009; 181(2): 472-9.

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This article in the Users' Guide to the Urological Literature series explains the critical appraisal framework that is applicable to clinical practice guidelines. It explains how guideline panels can arrive at different recommendations and emphasizes the value of a unified and transparent approach for guideline development.

27 Dahm P, Chapple CR, Konety BR, et al. The future of clinical practice guidelines in urology. Eur Urol 2011; 60(1): 72-4.