DIFFICULT CONCEPTS MADE SIMPLE

How to choose and critically evaluate an article in evidence-based urology

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"Evidence-based medicine" is a catch phrase commonly used in academic medicine. Its penetration into the surgical world has become more apparent in recent years. The goal of this short editorial is to give guidance to the novice reader in understanding the basics of evidence-based medicine. In addition, I hope to share with you some useful references and strategies detailing which manuscripts are worth reading, as well as how to critique them. Finally, some direction is provided for possible resources when in search of evidence driven data.

At its core, evidence-based medicine (EBM) accepts an inherent uncertainty in medicine, and requires that you the physician have the ability to critically evaluate and assimilate new medical knowledge. This new emerging knowledge is then added to clinical experience thereby providing the best care for patients.[1] Although the basic premise has been around since before the 1800s, the currently accepted concept and validation of its application is relatively new. Epidemiologist, Archie Cochrane, published the book Effectiveness and Efficiency: Random Reflections on Health Services. Nuffield Provincial Hospitals Trust, London in 1972. Several centers worldwide are involved with teaching and promoting EBM in healthcare. One such center founded in 1995 in Oxford, England is the Centre for Evidence-Based Medicine.

Unfortunately, the assimilation of emerging data has become challenging. The number of peer-reviewed urologic journals has steadily increased in the past 20 years. There are now well over 10 peer-reviewed urologic journals written in the English language. Most are monthly publications, typically with greater than 25 manuscripts per issue. In addition, several "throw away" publications arrive to your office or home unsolicited. As a clinician, one is faced with the daunting task of filtering through piles of journals to determine which may be worth reading.

Which journal is worth reading? The potential significance of a journal may be assessed using a variety of parameters. One methodology for assessing a journal's significance is the Impact Factor (IF). Dr. Eugene Garfield, founder of the Institute for Scientific Information®, created the journal IF nearly 50 years ago. In its current form, the IF is calculated by Thomson Scientific, a large worldwide publisher based in the United States. Rankings for numerous disciplines are then published in Journal Citation Reports® every 3 years. At the most basic level, the IF is the frequency which an average article in a particular journal is cited over a period of time. Although inherently useful, the impact factor may be artificially manipulated so as to potentially improve rankings. For example, citations included in letters to the editor or editorial commentary may serve to increase citations. Although an interesting calculation, I don't find using the IF of a journal helpful in deciding the impact of any one particular article.

Analogous to the IF used to rank journals, several grading systems of levels of evidence are now accepted for individual manuscripts. Grading or ranking of manuscripts is significant because several factors may affect the quality of the data. One such ranking system categorizes articles from the highest rank of Level 1a to a lower rank of 5, Table 1. As seen in Table 1, randomized clinical trials achieve a higher level of evidence than do case series. Randomization for example, eliminates some inherent confounding variables between groups such as age, gender, and tumor size. Blinding of participants, physicians, and assessors similarly helps decrease bias and confounding, although this usually is not practical with surgical trials. When judging the quality of any given article or the data it

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TABLE 1. Levels of evidence. Adapted from Oxford Centre for Evidence-Based Medicine, www.cebm.net

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1a Systematic reviews (such as meta-analysis) of randomized controlled trials (with homogeneity)

1b Individual randomized controlled trials (with narrow confidence interval)

1c All or none randomized controlled trials

2a Systematic reviews of cohort studies (with homogeneity)

2b Individual cohort study or low quality randomized controlled trials (< 80% follow-up)

2c 'Outcomes' research; ecological studies

3a Systematic review of case-control studies (with homogeneity)

3b Individual case-control study

4   Case-series (and poor quality cohort and case-control studies)

5   Expert opinion without explicit critical appraisal, or based on physiology, bench research or 'first principles'

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is based upon, the higher the level of evidence that supports the conclusions, the more reliable are those conclusions. A complement to levels of evidence exists with an alternative "grade of recommendation" system. Grades of recommendation (A through D) are particularly useful for guideline developers. The grading system not only takes into account the levels of evidence, but allows the guideline developers to use their judgment as to the significance of the recommendation being made.[2]

While knowledge about impact factors and the level of evidence are helpful, a primary challenge that exists is deciding whether or not a particular article is worth reading. Authors at McMaster University in Hamilton, Ontario have written several excellent articles using a stepwise approach to deal with this dilemma.[3-7] Although some of these publications are nearly 30 years old, they still hold extreme utility. Most are freely available for download at http://www.pubmedcentral.nih.gov. As the flow chart in Figure 1 demonstrates, the reader is encouraged to start by studying the *title* of the manuscript to assess potential interest. Next, the reader is encouraged to scan the *author list* and consider the authors' track record of prior publications. The reader should then view the *conclusion* in the abstract. Assuming the conclusion is true the reader then determines the article's value. The *site* where the study was conducted should also be considered so as to assess the validity of extrapolation of the findings to the readers practice. Specific recommendations are then made for assessment based on the reader's intent.

If you have decided to read the publication, how do you systematically critique the manuscript beyond just assigning a level of evidence? I have found that a systematic approach aids in this endeavor significantly. Such a methodical approach is easily taught to residents in training. According to one approach, the three key questions to ask about a study include: 1) are the results valid 2) what are the results and 3) how do the results/conclusions apply to patient care.[8] Another reliable outline I find useful is described by Theodore Colton, Table 2. The aim/objectives of the article should be clearly noted in the introductory paragraph. The reader is encouraged to ask if the objective was actually worth investigating. In the methods section, the reader focuses on the study design (prospective or retrospective). Was the study design appropriate to answer the aims of the investigation? The sample population examined in the study should be chosen in a way which allows the results of the study to remain valid. In the methods/results section, the reader evaluates the data and the statistical analysis. Critical analysis does require basic knowledge about biostatistics and study design. Several excellent books exist for those interested in this topic. Finally, the conclusions should be evaluated in terms of being justified by the findings in the paper.

Given the time constraints of a busy clinician, what evidence-based references exist and are readily available? A bibliographic search on PubMed http://www.ncbi.nlm.nih.gov/entrez/ may yield too many articles to review given limited time. The filters on this free search engine are too crude to significantly tailor the search. To reduce the burden, expert panels have performed systematic reviews, commonly known as pre-appraised data. An example may be the practice guidelines available from the American Urological Association http://auanet.org/guidelines/ or the European Urological Association http://www.uroweb.org/ Although these expert guidelines are useful, at times conclusions impacting clinical practice may not be reached given the lack of high levels of evidence. Other
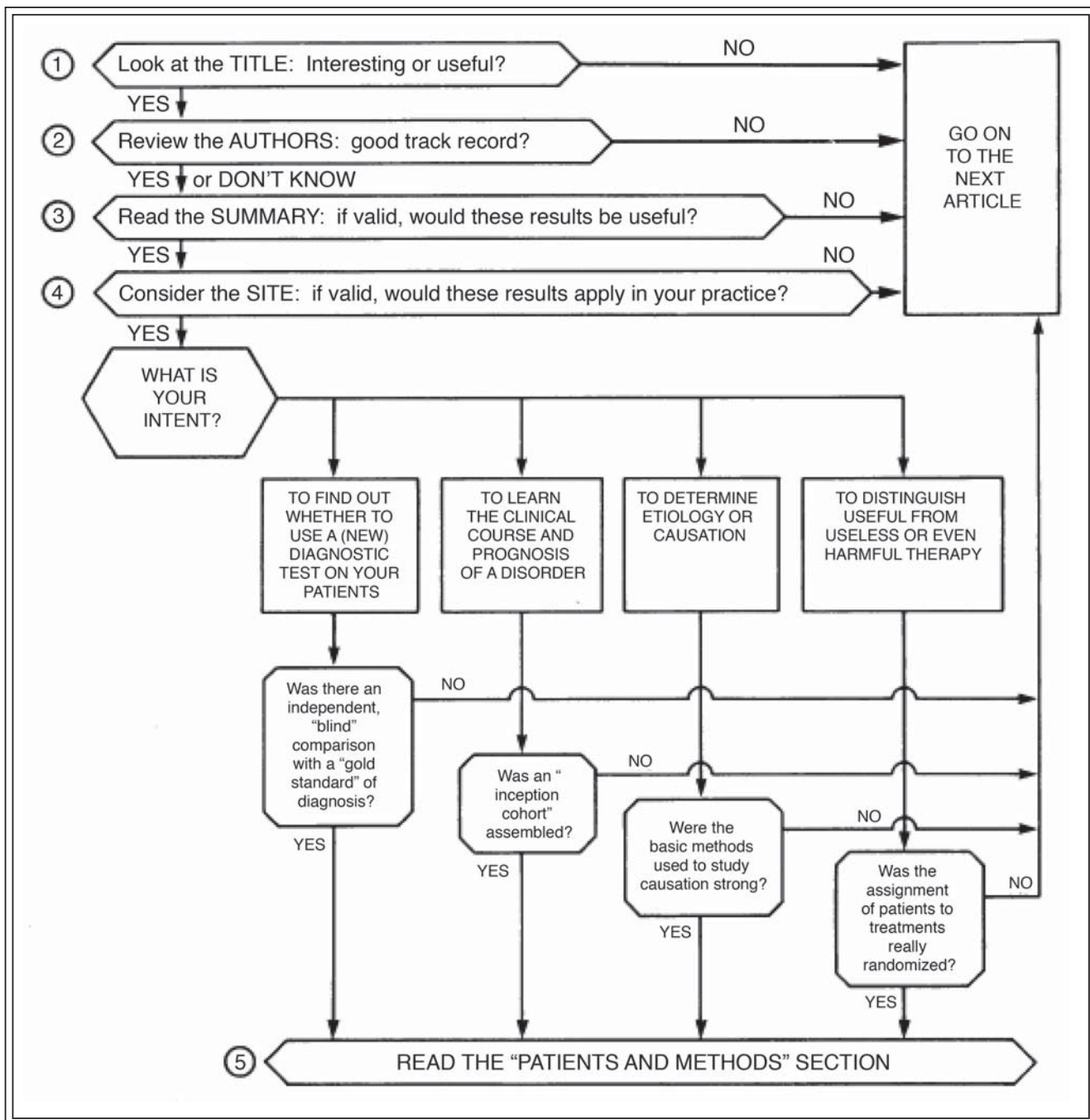
Figure 1. The first steps in how to read articles in clinical journals. Reprinted from, CMAJ 1-Mar-81;124, Page(s) 555-590 by permission of the publisher. © 1981 Canadian Medical Association

systematic reviews on select topics exist for example, the Cochrane Collaboration, which serves to systematically review literature and provide concise summaries (http:// www.cochrane.org/reviews/index.htm). This website is probably one of the best and most concise reviews on a given topic. For example, searching the Cochrane database for prostate cancer screening yields an excellent review on the subject. Unfortunately, the database is geared more towards primary care non-surgical fields, although this may change in the future. Specific to urological oncologic care, I have found the National Comprehensive Cancer Network (NCCN) guidelines, http://www.nccn.org to be the most user friendly. The guidelines are clearly provided in both algorithmic as well as written formats.

TABLE 2. **Colton's outline for critique of a medical report. Adapted from: Colton T. Statistics in medicine. Boston: Little Brown and Company, 1995.**

I. Object or hypothesis
    A. What are the objectives of the study or the questions to be answered?
    B. What is the population to which the investigators intend to refer their findings?

II. Design of the investigation
    A. Was the study an experiment, planned observation, or an analysis of records?
    B. How was the sample selected? Are there possible sources of selection bias which would make the sample atypical or non-representative? If so, what provision was made to deal with this bias?
    C. What is the nature of the control group or standard of comparison?

III. Measurements
    A. Are there clear definitions of terms used, including diagnostic criteria, measurements made, and criteria of outcome?
    B. Was the method of classification or of measurement consistent for all subjects and relevant to the objectives of the investigation? Are there possible biases in measurement and, if so, what provisions were made to deal with them?
    C. Are the observations reliable and reproducible?

IV. Analysis
    A. Are the data worthy of statistical analysis? If so, are the methods of statistical analysis appropriate to the source and nature of the data and is the analysis correctly performed and interpreted?
    B. Is there sufficient analysis to determine whether "significant differences" may in fact be due to lack of comparability of the groups in sex or age distribution, in clinical characteristics, or in other relevant variables?

V. Conclusions
    A. Which conclusions are justified by the findings? Which are not?
    B. Are the conclusions relevant to the questions posed by the investigators?
    C. Are there possible explanations for the data that have not been discussed or considered by the authors that should be considered in analyzing the data presented?

VI. Presentation of findings
    A. Are the findings presented clearly, objectively, and in sufficient detail to enable the reader to judge them for himself/herself?
    B. Are the findings internally consistent, i.e., do the numbers add up properly, can the different tables be reconciled, etc.?

For readers interested in other reviews on the topic of evidence-based medicine, I highly recommend one of the post-graduate courses at the American Urological Association meeting. The presenters discuss several of the above references presented in this article in detail. You may alternatively visit one of several excellent websites focusing on evidence-based medicine (http://clinicalevidence.bmj.com/ceweb/index.jsp). I hope that this short commentary will help guide the reader toward references aimed at helping choose what manuscripts to read and how to read them in this evidence-based medical world.

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