

**2012 UPDATED CHAPTER K:
BASING INFORMATION ON COMPREHENSIVE, CRITICALLY APPRAISED, AND
UP-TO-DATE SYNTHESSES OF THE SCIENTIFIC EVIDENCE
(Original Title: Basing Information on Up-to-Date Scientific Evidence)**

**SECTION 1:
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Note

The original title for this dimension (“Basing Information on Up-to-Date Scientific Evidence”) is now considered inadequate. The original title implied that the single criterion subsumed within this quality dimension would be that, when a decision aid is presenting scientific evidence, only recent publications needed to be cited. However, given the theoretical justification for presenting scientific information (see Section 3, below), it is no longer sufficient to cite some evidence. Rather, the onus is on the decision aid developer to ensure the aid is based on the pertinent body of evidence, systematically identified and rigorously summarized.

Therefore, this updated dimension chapter has been re-titled, and presents entirely new sections regarding definition, theoretical rationale, evidence base, and references.

The original dimension chapter is included here as an Appendix.

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SECTION 2: CHAPTER SUMMARY

What is this quality dimension?

Decision aids should be based on comprehensive, critically appraised, and up-to-date scientific evidence. “Comprehensive” refers to the extent to which decision aid developers have thoroughly considered all the pertinent scientific evidence addressing each aspect they chose to present in their decision aid. The best approach to do so is to use systematic reviews that have avoided selection bias, carefully and reproducibly assessed the quality of the incorporated reviewed studies (i.e., the studies’ protection from error and bias), summarized the estimated pertinent effects (ideally quantitatively in a meta-analysis), indicated the extent to which these estimates are trustworthy, and assessed the extent to which selective reporting and publication bias may have corrupted this body of evidence. Decision aid developers should indicate—using symbols, numbers, or phrases—the degree of confidence attributed to that information, given the quality of the scientific evidence upon which it is based. The dates when the relevant systematic reviews were used by decision aid developers should be reported and should be sufficiently recent given the pace of progress in the particular field. Developers should report a version date, and, when pertinent, a “better by” or “expiration date” to communicate to decision aid users about the speed of evidence accrual in the field and the optimal timing of future updates.

What is the theoretical rationale for including this quality dimension?

Ethical (informed patient choice), quality (patient-centered care), and scientific (evidence-based medicine) justifications make it imperative that decision aids be based on comprehensive, critically appraised, and up-to-date scientific evidence. To be completely and honestly informed so that autonomy can be exercised requires patients to access unbiased information based on a high-quality synthesis of the available evidence. Patient-centered care requires patients to actively participate in decision making and to be provided with the information and support they need to make informed choices. Evidence-based medicine calls for recognizing both that confident decision making requires confidence in the estimates of effect and that these estimates alone cannot drive decisions. Therefore, the information presented in patient decision aids should include not only evidence-based estimates of the effects of the various relevant options, but also an indication of the extent to which these estimates can be trusted. This will help patients consider this information in light of their context and values and preferences, in order to make a decision that fits their goals and circumstances.

What is the evidence to support including or excluding this quality dimension?

Half of current decision aids appear to use systematic reviews and another quarter use practice guidelines, both of which are of variable quality. Very few used the GRADE system to describe the quality of the evidence. About 5% offered an expiration date and an update policy.

**SECTION 3:
DEFINITION (CONCEPTUAL/OPERATIONAL) OF THIS QUALITY DIMENSION**

a) **Original Definition**

No explicit definition of this quality dimension was provided in the original chapter.

b) **Updated Definition**

“Information”

As noted in Chapter B (“**Providing Information about Options**”), patient decision aids present the individual patient with a summary of the patient’s current health situation, descriptions of the protocols involved in the various relevant options, and descriptions – and the likelihoods - of those options’ effects on the outcomes of most importance to patients.

“Scientific Evidence”

In the context of patients’ decision aids, this term refers to a body of empirical observations about the options and their consequences. These observations should be conducted using the scientific method, and will have, to different extents, protections against systematic and random error.

“Comprehensive”

By comprehensive, we do not mean the scope and range of the information presented in the decision aid. For this criterion, “comprehensive” refers to the extent to which decision aid developers have thoroughly considered all the pertinent scientific evidence addressing each aspect they chose to present in their decision aid.

“Critically Appraised”

This means that decision aid developers will use evidence derived from systematic reviews that a) avoid selection bias; b) carefully and reproducibly assess the quality of the incorporated reviewed studies (i.e., the studies’ protection from error and bias); c) summarize the estimated pertinent effects (ideally quantitatively in a meta-analysis); d) indicate the extent to which these estimates are trustworthy; and e) assess the extent to which selective reporting and publication bias may corrupt the body of evidence.

Then developers present this synthesized evidence in the decision aid itself. [For definitions, theoretical rationales, evidence, and emerging issues about particular presentation formats, see Chapters B (“**Providing Information about Options**”), C (“**Presenting Probabilities**”), E (“**Using Personal Stories**”), I (**Balancing the Presentation of Options**), and J (“**Addressing Health Literacy**”).]

Whatever the presentation format, note that decision aid developers clearly state that the aid is offering the “best available” synthesized information, and indicate—using symbols, numbers, or phrases—the degree of confidence attributed to that information, given the quality of the scientific evidence upon which it is based.

“Up-to-Date”

The dates when the relevant systematic reviews were searched for, compiled, critically appraised, and synthesized by decision aid developers are reported and are sufficiently recent given the pace of progress in the particular field. This implies that decision aid developers should develop a sense of the speed with which evidence that matters accrues in their area of work, and implement an update policy. Developers should report a version date, and, when pertinent, a “better by” or “expiration date” to communicate to decision aid users about the speed of evidence accrual in the field and the optimal timing of future updates.

c) Emerging Issues/Research Areas in Definition

1. What are the duties of decision aid developers in relation to evidence accrual?

As stated, the new standard goes much beyond citation of published literature, the prior standard. The new standard requires high-quality synthesis of the available evidence about the issues the decision aid developers seek to present in their aid.

Decision aid developers could make use of existing syntheses they find to be of high methodological quality and reasonably recent. This suggests that developers should be able to judge the quality of these reviews. Some tools exist to assist with this work¹. If high quality syntheses were not available, then developers need to conduct their own reviews or commission their conduct to credible parties. In these cases, decision aid users would need to critically review the synthesis, which implies that the review must be fully reported and placed in the public domain and subject to peer review.

This process is similar to that followed by rigorous guideline developers and would require methodological research to further understand how it affects the process and costs of decision aid development and how it affects the aids’ credibility and value as a tool to translate this evidence into practice. In particular, can and should decision aid developers prevent the dissemination of corrupt evidence through their decision aids?

2. What triggers an update?

Besides specifying a regular update policy for a decision aid, its developers also need to specify a literature-monitoring policy, since, for example, clinical trials may occasionally generate actionable data, which, in turn, should trigger an update of the decision aid. Of note, our emphasis on systematic syntheses of evidence requires that when a new data point emerges it be subject to synthesis along with the previous body of evidence. Thus new evidence should not directly update the aid, but rather an updated synthesis should update the aid. How might decision aid developers build these monitoring policies? What should trigger an update for new

evidence of benefit? Of harm? When is the evidence stable enough that updates can be further spaced? Is this likely to change by area of work, by intervention, by outcome?

SECTION 4: THEORETICAL RATIONALE FOR INCLUSION OF THIS QUALITY DIMENSION

a) Original Theoretical Rationale

The original rationale for this quality dimension referred to patients' and health professionals' *expectations* that the information presented in a decision aid will be accurate, derived from high-quality sources, directly applicable to the patients and practitioners using the decision aid, tailored to individual patients' characteristics, and regularly revised as new evidence accumulates.

b) Updated Theoretical Rationale

The updated rationale for basing information on comprehensive, critically appraised, and up-to-date scientific evidence is basically consistent with the original rationale.

However, in this revised chapter we push the rationale further, by:

- i.) Proposing several underlying justifications for the existence of these patients' / professionals' expectations in the first place; and
- ii.) Expanding on the approaches to rating the quality of evidence about the effects of a therapeutic option.

i. Underlying Justifications

Informed Patient Choice

One key principle driving the development of patient decision aids is the ethical argument for informing patients about their health care choices. Respect for patient autonomy is a governing principle of medical ethics² and is generally understood to refer to an individual's ability to make and carry out informed health care decisions based on unbiased and thoughtful deliberation. The American Board of Internal Medicine, the American College of Physicians, and the European Federation of Internal Medicine state in their charter on medical professionalism that "[p]hysicians must be honest with their patients...and ensure that patients are completely and honestly informed before the patient has consented to treatment and after treatment has occurred."³ To be 'completely and honestly informed' so that autonomy can be exercised requires access to unbiased information that is based on a high-quality synthesis of the available evidence that is relevant to the patient's clinical situation and acknowledges where uncertainty exists because of the quality or quantity of that evidence. When used as part of a shared decision making process, high-quality patient decision aids that are based on the best available clinical evidence support clinicians in fulfilling their ethical obligation to promote autonomy by ensuring that patients are fully informed about their health care choices.

Patient-Centered Care

The growing emphasis on patient-centered care is another driving force behind the development of patient decision aids. Principles of patient-centered care require that patients actively participate in decision making and be provided with the information and support they need to make informed choices. Work by the Picker Institute and others has identified respect for the patient's values and preferences and access to clear, *high-quality information* and education to be among the important characteristics of patient-centered care.⁴ Patient decision aids support the practice of patient-centered care by ensuring that patients' preferences are informed and based on accurate expectations; this requires in turn that the tools be based in high-quality evidence that, when possible, is relevant to patients' individual risk profiles.

Evidence-Based Medicine

Over the last 20 years, evidence-based medicine (EBM) has strongly influenced the practice of medicine⁵ as it had required use of the best available evidence alongside clinical expertise to formulate recommendations to patients that were pertinent to their context and sensitive to their values and preferences. To this extent, EBM follows two principles.

The first principle recognizes that not all observations and experiments are similarly protected from random and systematic error. The degree of protection from error offers confidence in the estimates of effect. Therefore, in the interests of fostering EBM, the information presented in patients' decision aids should include not only evidence-based estimates of the effects of the various relevant options, but also an indication of the extent to which this evidence is protected from error (i.e., is trustworthy).

The second principle holds that the evidence alone is never sufficient to fully inform a clinical decision. The evidence will be considered during the transactions between the treating clinician with a particular level of expertise and the patient with unique goals, values, and preferences; furthermore, the evidence will be applied in a particular biological, psychological, and sociocultural context. Therefore, in the interests of fostering EBM, the information presented in patients' decision aids needs to be directly applicable to the patients and practitioners using the decision aid, and tailored to individual patients' characteristics.

Ethical (informed patient choice), quality (patient-centered care), and scientific (evidence-based medicine) justifications make it imperative that decision aids be based on comprehensive, critically appraised, and up-to-date scientific evidence.

ii. Some Approaches to Rating Quality of Evidence

It is important to note that decision aid developers may want to include information based on different forms of evidence. Natural history and prognostic information, for instance, often requires the developer to use large and long observational studies. Adverse effects, particularly those that are rare, may be better characterized in case reports, and their linkage to exposures ascertained through case-control studies. The original chapter echoed the notion of a hierarchy of evidence about each of these questions and considered rating approaches⁶. Since then, an important international consensus emerged in the guidelines movement about how to assess the

quality of evidence in support of a recommended course of action: the GRADE approach. While we will now focus on this approach, we recognize that other approaches to grading the evidence exist, but they have substantial shortcomings that this method obviates. Furthermore, consistency in rating evidence from guideline to decision aid may facilitate the development of decision aids in conjunction with clinical practice guidelines efforts.

The GRADE Approach

GRADE (Grading of Recommendations Assessment, Development and Evaluation) is the most comprehensive approach developed for the purposes of formulating clinical practice guidelines⁷. It could be particularly helpful for decision aid developers, as an approach to explaining to patients the extent to which one can have confidence in the pertinent estimates of an option's effects.

We will summarize the GRADE approach to grading evidence of effectiveness here, but developers should review the extensive published guidance (www.gradeworkinggroup.org).

A key feature of this approach is that the assessment of quality applies to the body of evidence (not just to the individual study). This includes: a) the likelihood of bias (from the absence of protective features such as concealed randomization, blinding of pertinent groups, and analysis of participants as randomized)⁸; b) the likelihood of reporting or publication bias⁹, leading to inconsistency in results across studies¹⁰; c) any imprecision in the estimates of effect (e.g., wide confidence intervals)¹¹; and d) the degree of indirectness (in which the results do not directly apply to the pertinent patients, the comparisons are inadequate, or the studies measure a surrogate of limited validity)¹².

Randomized trials start as high quality evidence and “lose points” as they accumulate problems. Observational studies start as low quality evidence, and “lose points” in a similar manner, but could rise in scored quality when they show strong evidence of a dose-response relationship or when the magnitude of the association of interest is very large¹³. Importantly, the quality of evidence supporting the association of treatment with outcomes often differs by outcome. Higher quality evidence may exist for benefits than for harms, for example.

c. Emerging Issues/Research Areas in Theoretical Rationale

1. Relevant Information

In the original chapter for this dimension, the authors paid attention to ensuring that the evidence used to inform a decision was pertinent to the patients who are the intended audience of the tool. The extent to which evidence is pertinent is subject to much judgment. Most subgroup analysis yield findings with limited trustworthiness (e.g., subgroup effects that cannot be confirmed or are very imprecise), such that it is sometimes advisable to use estimates from the general population¹⁴. The challenge of applying evidence from somewhat different patients, interventions, or outcomes to the situation of interest falls under the general rubric of *indirectness*¹². The degree with which these differences are likely to make a difference, the extent of indirectness, reduces the confidence that the estimates of effect are correct and this could be reflected in the decision aid. Efforts to improve the volume and quality of comparative

effectiveness research may enhance the evidence base for decision aids, because this research requires direct comparisons that matter to clinical stakeholders – that is, measuring the effect of interventions on patient important outcomes.

2. Tailored Estimates

Decision aids often need to present absolute risk estimates that relate to the individual characteristics of the patient of interest (see Chapter C, “Presenting Probabilities”). Prognostic calculators offer the opportunity to tailor such risk estimates. Given the importance of these estimates, decision aid developers must report which calculator they are using and provide an assessment of its validity, a matter that often requires independent evaluation from the population from which the formula was derived, as well as comparisons with competing risk estimators.¹⁵

3. Will Linking Information to Evidence-Based Practice Guidelines Foster Decision Aid Uptake?

A key issue with decision aids is their underuse in practice, despite increasing evidence of their effectiveness and surging policy support in some regions. Thus, efforts to explicitly link their design and content to clinical policy and workflow may facilitate their adoption. This supports in part our approach of linking the development and content of decision aids to state-of-the-art approaches to the development and content of evidence-based practice guidelines.

The “ideal” situation indicating the potential usefulness of a patient decision aid is one in which there is high-quality evidence linking options to outcomes, but the options are closely matched, and the choice of the “best” course of action will depend mostly on the patient’s values and preferences. Guideline developers following GRADE usually will offer a weak or conditional suggestion in those circumstances. A suggestion based on high-quality evidence would require the incorporation of patient values and preferences for implementation, that is, would benefit from a decision aid. This linkage between guidelines and decision aids may affect development and uptake of decision aids. An obvious advantage from using the same approach for grading the quality of evidence in guidelines and in decision aids is that decision aid developers can use the evidence supporting current high-quality guidelines as their source for up-to-date evidence. Furthermore, implementation of the guidelines, i.e., quality improvement efforts, could then be linked to the implementation of decision aids for weak or conditional suggestions.

SECTION 5: EVIDENCE BASE UNDERLYING THIS QUALITY DIMENSION

a) Original Evidence Base

The original evidence base about providing up-to-date scientific evidence in patients’ decision aids cited the 2003 Cochrane Collaboration’s review of 29 patient decision aids tested in 34 RCTs in which patients were facing actual choices¹⁶.

b) Updated Evidence Base

To evaluate the current practice of including evidence in decision aids, we examined the Ottawa Decision Aid Inventory. Out of 257 decision aids included in the inventory, 134 provided references to scientific evidence used, when they were last updated (N=135), and whether they were available on the Internet (N=134). In a random sample of those decision aids (N = 20), stratified to correct for differences between providers, ten aids used a high quality systematic review/meta-analysis (AMSTAR score range 2-11 on a scale of 1-11), and five aids were based on practice guidelines (AGREE II score range 1-6 on a scale 1-7). Two decision aids used data from multiple sources of original research, whereas two used only a narrative review or an expert's opinion or a single piece of original research as source for evidence. Four decision aids did not explicitly cite, hence we could not locate and evaluate, the evidence they used. One of the 20 aids explicitly stated an expiration date and an update policy, whereas eight refer to a policy statement of the complete contents of the provider-website (as part of a site notice on the website but not as part of the aid itself). Three used the GRADE system in their presentation to clarify the quality of the evidence to the user.

c. Emerging Issues/Research Areas in the Evidence Base

1. How Often Should Systematic Reviews be Up-dated?

The frequency with which systematic reviews should be updated – and by extension products derived from these – is still subject to research question. A comprehensive technical review commissioned by the Agency for Healthcare Research and Quality published in 2007¹⁷ found that the median time for the emergence of a signal that a review should be updated (e.g., substantial new evidence of effectiveness or harm, new alternatives, revelations about the nature of the old evidence) was 5.5 years; yet about 25% of the reviews could benefit from updating within 2 years of publication. The authors were not able to identify predictors of more urgent review and suggested yearly surveillance of systematic reviews.

2. Effects of Quality & Up-Dating on Use in Practice

Given that the uptake in practice of decision aids remains limited, there is no strong evidence that decision aids supported by high quality and updated summaries of the body of evidence would be more likely to be taken up in practice. There is no *a priori* reason to believe that the quality of the process of evidence synthesis and their adaptation into evidence-based decision aids will lead to better decisional processes and outcomes.

3. When There are Discrepancies

A key aspect worthy of surveillance is the fate of decision aids developed based on the best available evidence, but which disagree in their presentation with extant guidelines and with the quality-of-care parameters derived from these guidelines. These discrepancies can appear because decision aids may use more recently updated summaries of evidence, or because the recommendations apply to a different context or resulted from panels with distorted values (e.g.,

pharmaceutical lobbying). In one example, this apparent divergence led to difficulties in the use of the decision aid and to nonuse¹⁸.

4. Communicating Quality of Evidence

Communicating the confidence decision aids developers have around the estimates of the benefits and harms associated with the selected options would help decision aids users make sense of the magnitude and trustworthiness of the estimates. The communication of this confidence in the evidence should be done in a way that is simple and understandable, yet remains precise, without adding cognitive burden on decision aid users.

There is limited empirical work on how to communicate quality of evidence to stakeholders in general, let alone decision aids users. A systematic review of information in decision aids reported that very few decision aids developers had addressed or incorporated quality of evidence in their tool.¹⁹ The ways by which these developers were representing quality of the evidence varied greatly, from icons (i.e., bronze-gold medals), to verbal labels (i.e., high, moderate, low), and numeric intervals, and have yielded mixed results.¹⁹

The GRADE approach for guidelines offers a simple way to report on quality of evidence, using categories^{20 21}. An obvious advantage gained from using the same approach for grading the quality of evidence in guidelines and in decision aids is that decision aid developers could use the evidence supporting current high-quality guidelines as their source for up-to-date evidence.

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**APPENDIX:
ORIGINAL CHAPTER K**

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Original Rationale

Use of Accurate Information

There is an expectation by patients and health professionals that patient decision aids are based on the most accurate information available. For a particular clinical decision, the patient decision aid should use the best available evidence to describe all the relevant health care options and their associated outcomes (benefits and risks). Ideally, the patient decision aid's evidence should be based on data from a systematic review(s), in which the published and unpublished literature is systematically searched for the highest quality studies, then summarized, if applicable, using meta-analyses. Normally, practice guidelines will carefully outline the quality of evidence of the benefits of different health care options. Ideally, the harms associated with the health care options described in the patient decision aid should also be supported by the highest quality of evidence available. On occasion, patient decision aid developers will have to perform their own systematic reviews to adequately identify the best available option/outcome evidence. In this situation, details of these reviews should be described in the patient decision aid's background material.

Source for Accurate Information

The quality of the information used in the patient decision aid has implications for the level of certainty placed on that information; patients have a right to know the limitations of the evidence supporting the effectiveness of different options. The best available option/outcome evidence should be characterized in terms of its quality, so that users (patients and practitioners) can appreciate the level of uncertainty regarding the likelihood that a particular screening/treatment option causes a particular therapeutic/harmful outcome. There are many rating systems for quality of evidence, ranging from high grade (usually a metaanalysis or randomized trial) to relatively low grade (often a cohort study or a case series) (Oxman et al., 2005). For example, data from a non randomized comparison cohort study regarding the efficacy of treatment is likely to be less certain than data from a large randomized trial.

- For studies of treatments, the highest quality of evidence regarding effectiveness comes from rigorous meta-analyses or large randomized trials.

- Observational studies (e.g. cohort studies or case control studies) are less likely to provide high quality evidence about the relationship between a particular screening/treatment option and a therapeutic effect.
- Descriptive studies, including case series, provide lower quality evidence about the relationship between an option and an outcome.
- With respect to the incidence of adverse effects, observational and descriptive studies may provide as good or better evidence than data from randomized trials.

Relevance of Evidence

Information describing the therapeutic effectiveness of different treatment options in the patient decision aid should be directly applicable to the patients and practitioners who use it. This pertains not only to the population who will use the instrument, but also, in particular, to the intervention being described. For example, a patient decision aid describing the benefits and harms of adjuvant chemotherapy in women with breast cancer should be based on data from randomized trials or systematic reviews involving patients of similar age and stage of disease as the women who will be using the patient decision aid.

Tailored Information to Individual Characteristics

When outcome probabilities are tailored to the clinical risk for different patient populations, evidence for the different risk groups or the risk assessment tool employed in the patient decision aid should be provided. Such evidence might include data from those studies and any secondary validation studies.

Regular Updating of Evidence

Information supporting different health care options can quickly become out-dated. Ideally, evidence supporting the information contained in the patient decision aid should be regularly updated at least every two to three years and preferably on a yearly basis. The process used for the update (i.e. whether a systemic review was performed) should be described. By providing a statement regarding the update policy, patients and practitioners can form their own opinions about the degree of confidence to be placed in the patient decision aid's information.

Original Evidence

RCTs Involving Patients Facing Actual Choices

Of 29 individual patient decision aids, evaluated in 34 RCTs included in the Cochrane review, 19 were available for review of their content (O'Connor et al., 2003). Of these,

- 13 of 19 (68%) of DAs provided specific citation either within the patient decision aid (3 of 13) or in a separate resource (10 of 13).
- 5 of 19 (26%) described the quality of the evidence with 3 patient decision aids that were

based on clinical practice guidelines

- 3 of 19 (16%) described the uncertainty in the evidence presented within the patient decision aid.

Two studies described how different risk groups used in the patient decision aid were identified.

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