Evidence-Based Medicine

What is an Evidence-Based, Value-Based Health Care System? (Part 1)

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The two biggest issues facing health care organizations in the United States today are the rising cost of health care and maintaining or improving the quality of the care they deliver.

It is estimated that 20-30 percent of all prescriptions, visits, procedures and hospitalizations in the United States fall into the categories of overuse, underuse (including non-use) and misuse of what the best available evidence tells us should be applied to provide quality care.1

With a national annual expenditure of $1.6 trillion dollars for health care, this represents waste of over $300 billion dollars annually—and often results in patient harms, including death. That means for every million dollars spent on health care in the United States more than an estimated $200,000 is likely to be wasted and is potentially causing patient harms.

The significant variation in medical practice and its impact on wasteful spending across the country are well-documented and it appears that regions with higher spending do not provide better quality of care.2

In fact, Medicare areas with the highest spending appear to have worse outcomes in some preventive care areas.3 Moreover, a high incidence of underuse of evidence-based care practices has been found in high-cost regions of the country, suggesting that greater spending does not improve the use of evidence-based recommendations.4

Overall, it appears that adults in the United States are receiving only 55 percent of recommended preventive care, 54 percent of recommended acute care and 56 percent of chronic care recommendations.5 There are a number of reasons for this staggering amount of inappropriate care, but “uncertainty” appears to be a major contributing factor.6

The probabilistic nature of health care and the lack of needed information at the time of decision making by clinicians and patients results in significant amounts of inappropriate care.

Systemic approach to quality improvement

What can you do to correct this?

Physician leaders and their administrative colleagues must provide the necessary attention and resources to evidence- and value-based quality improvement efforts to achieve improved health and health care outcomes within organizations.

An evidence- and value-based approach to quality improvement requires a systematic review and synthesis of the evidence regarding benefits, harms, risks, costs, alternatives and uncertainties of health care interventions as well as an assessment of the trade-offs between effectiveness, cost, the patient’s perspective and the organization’s priorities (e.g., considerations of the significant impacts of making clinical change, such as impacts on marketing, public relations and legal issues).

A systematic approach to quality improvement is based on valid, useful and usable information and brings together leadership, culture, structures, processes, skills and the tools required to improve health care and health outcomes. Historically, however, obtaining valid, useful and usable information has not been easy for most organizations.

Each week more than 10,000 articles are entered into the National Library of Medicine—many of these articles are case series, studies of poor quality or studies of inappropriate design and are likely to be misleading to readers not familiar with the basic principles for determining validity through critical appraisal.
Unfortunately, most clinicians, clinical pharmacists and others involved in health care decision-making have not received even modestly successful training in critical appraisal of the medical literature. Therefore, most health care professionals are not capable of determining the validity or usefulness of most published literature.

In a simple three-question quiz regarding the basics of critical appraisal that we have administered to hundreds of physicians and other health care professionals, we found that roughly 75 percent lacked even the most basic skills of critical appraisal—a deficit that directly and regularly adversely impacts patient care and outcomes.

A recent example of how research can be misleading concerns hormone replacement therapy (HRT) in post-menopausal women with coronary artery disease. Over the past several decades there have been numerous observational studies in which women who chose to take HRT after menopause were compared to women who chose not to take hormone replacement therapy.

These observational studies reported a 40 percent to 70 percent decreased incidence of coronary artery disease in women with pre-existing coronary heart disease—even in one of the best studies of this type.7

However, only well-done randomized, controlled trials allow drawing conclusions regarding cause and effect. Yet based on these observational studies, physicians recommended HRT to women at high risk for coronary events and advised them that their risks of coronary heart disease would be decreased with HRT.

When valid randomized controlled trials were performed,8,9 it became clear that there were no cardiovascular benefits. In fact, there are potential harms from taking HRT, such as the increased risks of breast cancer and Alzheimer’s dementia.10

### Quality goals for organizations

The Institute of Medicine defined quality of care as the “degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”11

A reasonable set of goals based on this definition includes:

- Making our care patient-centered
- Knowing what is and what isn’t appropriate health care for our patients
- Identifying and closing gaps between current clinical practice and optimal practice
- Diminishing clinical uncertainty
- Continuously improving the care we deliver
- Considering quality and cost outcomes (value) together along with other organizational considerations.

### Table: Phases for Achieving Quality Goals

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<th>Phase 1:</th>
<th>Readiness</th>
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<td>Readying your organization for evidence-based medicine (EBM)</td>
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<th>Phase 2:</th>
<th>Clinical Improvement Project Identification</th>
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<td>How to go about deciding what and how to improve</td>
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<th>Phase 3:</th>
<th>Clinical Content</th>
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<td>How to decide on the clinical content for your improvement project—what does the evidence say?</td>
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<th>Phase 4:</th>
<th>Impact Assessment to Achieve the Evidence-based Value Proposition</th>
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<td>Now that you know the evidence, anticipate the impacts of change for your organization.</td>
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<th>Phase 5:</th>
<th>Create, support and sustain change</th>
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<td>Now that you know what you want to do, how do you create desired change and keep it going?</td>
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<th>Phase 6:</th>
<th>Update and improve</th>
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<td>Cycle back through Phases 1-5</td>
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How might an organization accomplish these goals? We believe the key is to organize the necessary work for quality improvement into manageable and sequential phases, with logical pass/fail points. This approach is efficient and represents a systematic way to yield quality information upon which to base health care decisions.

Organizations can structure their quality improvement work into six phases—readiness, project identification, clinical content, impact assessment, creating/sustaining change, and updating/improvement (Table 1).

In phase 1, organizations establish an evidence- and value-based framework for clinical quality improvement work. This requires attention to creating a system that successfully ensures the availability of needed skills and creates the structures, processes and tools to facilitate posing answerable questions, acquiring source material, and appraising and utilizing the best available evidence for health care decision making.

Although the initial work involves an evidence-based focus on quality, the system should also address cost and other important factors such as legal, marketing and public relations issues.

The system components include:

- EBM and value principles
- Leadership roles
- Resources
- Structures such as pharmacy and therapeutics committees, technology assessment committees, guidelines and pathways groups and other quality improvement work groups
- Processes and aids to processes such as criteria, templates for requesting review and summarizing committee deliberations and determinations, and implementation and measurement plans

### Table 1: The 5 “A”s of Evidence-based Medicine

| Ask & Acquire | Identify significant gaps and uncertainties; identify possible projects for consideration
|              | Pass/fail further development of rejected projects
|              | Search for the best available project content
|              | Pass/fail projects depending upon lack of content available

| Appraise     | Assess the amount of work needed to make the practice change
|              | Pass/fail if unable to acquire or develop the content
|              | Unless the information is based on a “trusted source,” critically appraise content for validity — and ensure the content is up to date
|              | Pass/fail invalid information
|              | Examine results of valid content and assess usefulness
|              | Pass/fail information that is not useful or usable
|              | Summarize and synthesize the evidence
|              | Assess the potential impacts of practice change
|              | Pass/fail project if you cannot meaningfully narrow or close a significant gap

| Apply        | Create information, decision and action aids — these can be for clinicians, patients, leaders, other health care staff, etc.
|              | Implement the project

| Appraise     | Measure success of implementation and report

| AAAA Again-cycle through the first four “A”s to update information and continuously improve care |
• Staff roles
• Skills
• Tools

A useful framework for achieving quality is to apply the essential elements and steps based on the five “A”s of evidence-based medicine: Ask, Acquire, Appraise, Apply and “A”s Again.12

Organizations can apply the five “A”s framework by integrating it into the six phases described above. As shown in Table 2 and Figure 1, the five “A”s can be utilized to create an evidence-based medicine (EBM) system where—if the sequential steps, combined with key pass/fail points, are followed—the result is an efficient, reliable method to provide the best available evidence to decision makers at all organizational levels—leaders, clinicians and other health care professionals such as those participating in various health care committees and quality improvement teams—and patients.

The five “A”s are easy to remember and use to efficiently plan an organization’s evidence-based quality improvement work.

We agree with the Institute of Medicine that to provide quality health care each organization should have at the heart of their quality improvement system the solid core of evidence-based medicine.

We recommend that this commitment be part of the organization’s mission statement. Other key elements include:

• A “value” plan—A new name and concept for “quality plan” to recognize and incorporate the need to consider economic and non-economic factors to provide true value.

• A business plan organized upon the evidence-based value model.

• Committed leadership—Leaders must understand and utilize the methods of EBM and the value model in order to effectively improve outcomes. Leaders must teach, encourage, demonstrate and persuade as well as establish norms, incentives and systems that have EBM at the center.

• An evidence-based culture—The principles, methods and tools of EBM must thrive in the committees, work groups and daily lives of health care professionals.

• Training—Staff should be trained in the necessary skills for carrying out evidence-based work and conducting appropriate analyses.

• Aligned incentives—Incentives should promote the net view of the evidence-based value model and not inadvertently foil efforts to achieve value. For example, costs must be viewed in terms of full organizational impact, not just departmentally. Net gains and losses in the areas of desired health outcomes, costs, satisfaction and other issues such as marketing, public relations and legal issues should be considered.

• Aligned work components—EBM should be the organizing principle and be at the heart of all organizational work. Considerations of cost and quality should be evident in the decisions and actions taken by health care professionals.

• Resources—Sufficient resources are required to support the effective and efficient use of EBM processes and tools to improve outcomes.

A final step in readying an organization for evidence-based quality improvement is chartering committees and work groups and providing adequate training to support the individuals doing the quality improvement work.

**Key committees**

Oversight—At the highest level is an oversight group which we have termed the Value Oversight
Council. This important group provides oversight and guidance for clinical quality, service quality, cost and regulatory functions. The Value Oversight Council charters new work (using criteria), prioritizes projects, makes resource allocation decisions and reviews the work of quality improvement (QI) work groups.

Pharmacy and Therapeutics (P & T) Committee—Provides evidence-based assessments of new medications, makes formulary decisions regarding effectiveness (and frequently value), assesses cost impact and creates information, decision and action aids regarding drug products and therapies. The P & T committee should make decisions based on explicit criteria. It may also be chartered to decide or recommend coverage. Decisions regarding issues such as generic substitution, therapeutic substitution and reference pricing can make huge impacts on quality and cost within an organization.

Medical Technology Assessment Committee—Provides evidence-based assessments of medical technologies, frequently compared to alternatives, and makes recommendations for coverage.

Other Work Groups and Teams—Examples include clinical practice guideline teams, QI improvement teams, EBM working groups and journal clubs. Each of these groups determine gaps between optimal clinical practice, as defined by the best available published scientific evidence, along with the organization’s current clinical practice, and carry out steps to close quality and cost gaps.

In the next article we will expand upon the five “A’s” of EBM and provide details of the next phases of the evidence and value approach to achieving organizational quality and value goals.

References:


