Evidologists, medical information scientists & evidence-based clinical improvement (EBCQI) experts. Delfini—

- Evaluates medical evidence
- Trains others in EBCQI including critical appraisal of the medical literature
- Facilitates EBCQI projects including clinical guidelines
Patients Deserve Right Care

Reliable + useful information
—combined with good communications—
resulting in decisions and actions that meet each patient’s unique personal requirements

“personal health care problems, special circumstances, values and preferences—
all of which go into informing a patient’s health care needs + wants”
The Health Care Journey

1. Information input/output

2. Decision

3. Action

4. Outcome
We Look to Medical Research for Interventions to Inform us

If I take this pill, what might happen to me?

Determine cause & effect (causality) +

Assess likelihood of effects (probability)
The Great Big Health Care Misinformation Problem

- Review of 60,352 studies reported that only 7 percent passed criteria of high quality methods and clinical relevancy. [McKibbon]
- Fewer than 5 percent passed a validity screening for a highly respected evidence-based journal. [Glasziou] Etc.
- Lots of variation in quality everywhere including Cochrane and others with good reputation.
- One study found 18 to 68% of abstracts in 6 top-tier medical journals contained information not verifiable in the body of the text—NEJM, JAMA, BMJ, Annals of Internal Medicine, Lancet, CMAJ. [Pitkin]
Patient Safety, Overuse, Waste & Missed Opportunities for Right Care: Typically Overlooked Are These...

Often published studies—even of best repute—are of uncertain reliability and clinical usefulness.

Typically, clinicians
1. Are not aware of this problem.
2. Can’t tell good studies from bad.
3. Want to Diagnosis + Do.
4. Fail in communicating key information that patients need to make informed decisions.

This can hurt patients + costs us all...

Typically, patients expect something done and trusts their doctors.

Dr. Knows Best

Training Gaps

Rx
Failures to Understand Medical Science Basics

• Many health care professionals don’t know how to quickly assess a trial for reliability and clinical usefulness—and yet mastering the basics is not difficult

• Approximately 70% doctors, clinical pharmacists and other health care professionals fail Delfini’s critical appraisal training pre-test—"failure" being defined as missing 2 or 3 of the 3 questions
We Are All At Risk For A Bad Outcome
In a Typical Journey

1. Information absent or misleading

2. No consent or decision is not informed

3. Action leads to

4. Bad outcome
Waste, Harms and Missed Opportunities for Right Care

• Overuse and misuse of medical interventions results in thousands of preventable deaths and massive waste each year

• Up to 30% of our approximate 3 trillion dollar healthcare expenditures is wasted, and much of this waste is due to inappropriate care

Source: Institute of Medicine (name changed to National Academy of Medicine in 2015)
58,000 US Lives Were Lost in the Vietnam War...

Contrast that with the estimated >123,000 preventable deaths from two common treatments which we believe would not have been prescribed if doctors understood basics of evaluating medical evidence and shared the evidence with patients. Hundreds of thousands of prescriptions for these drugs would probably not have been written.
Adverse Events, Deaths and Wasted Resources

- There are many stories where the use of an intervention preceded valid evidence documenting no benefit or harms > benefits
  - Rofecoxib
  - Bevacizumab for advanced breast cancer
  - Epidural steroids for chronic low back pain
  - Encainide and Flecainide
  - Off-label use recombinant factor VIIa for bleeding
  - Rosiglitazone for type II diabetes
  - Pulmonary artery catheters
  - Episiotomy
  - Brain bypass surgery
  - High dose chemoRx and bone marrow transplant breast cancer
  - Lung volume reduction surgery
  - Arthroscopic meniscal knee surgery
  - Many, many new drugs approved by the FDA
  - We could on and on with this list...
Critical Appraisal of the Medical Literature Is Required

• Assuring that our medical interventions result in greater benefit than harm requires a proven method for evaluating diagnostic and therapeutic interventions.

• Evidence-based medicine (EBM) provides that method through critical appraisal of all medical evidence before allowing medical evidence to inform health care decisions.

• More than 2,000 medical research papers are published each day, and the majority of these studies report unreliable results or results which are not useful.

• Critical appraisal of the medical literature is a crucial step in determining the reliability of medical evidence.
Critical Appraisal

• Critical appraisal means evaluating medical research and information utilizing medical research for likely reliability of results, looking for —
  – Threats to validity
  – Likelihood of chance effects

• Reliable results should be evaluated for meaningful clinical benefit
  – Clinical usefulness in areas that matter to patients
  – The likelihood (probability) of benefit by assessing the size of results
Does Critical Appraisal Make A Difference?

Yes!

- Low quality clinical trials compared to high quality are **likely to overestimate benefit** by up to a relative 30-50% or more.
- This would result in interventions tending to appear more effective than they are—or effective when they are not.
## Positive Predictive Values of Various Study Types

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Positive Predictive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well-done RCT</td>
<td>0.85</td>
</tr>
<tr>
<td>Meta-analysis of well-done RCTs</td>
<td>0.85</td>
</tr>
<tr>
<td>Meta-analysis of small, inconclusive RCTs</td>
<td>0.41</td>
</tr>
<tr>
<td>Well-done epidemiological (observational) study</td>
<td>0.20</td>
</tr>
<tr>
<td>Epidemiologic study with threats to validity</td>
<td>0.12</td>
</tr>
<tr>
<td>Discovery-oriented exploratory research</td>
<td>0.0010</td>
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</tbody>
</table>

Effect Size in Systematic Reviews: Comparison of Reviews That Included High Risk of Bias Studies vs Reviews Including Low Risk of Bias Trials

<table>
<thead>
<tr>
<th>Group</th>
<th>No of studies</th>
<th>Effect size (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>61</td>
<td>0.52 (0.37 to 0.66)</td>
</tr>
<tr>
<td>Unclear</td>
<td>96</td>
<td>0.52 (0.39 to 0.64)</td>
</tr>
<tr>
<td>Low</td>
<td>6</td>
<td>0.23 (-0.16 to 0.62)</td>
</tr>
<tr>
<td>All</td>
<td></td>
<td>0.52 (0.37 to 0.66)</td>
</tr>
</tbody>
</table>

High and uncertain risk of bias studies may distort results by ~relative 50%
Why Critical Appraisal Matters

WITHOUT BEING INFORMED OF VALID SCIENCE, PATIENTS CANNOT GIVE INFORMED CONSENT. RISK GREATER HARMS, MISS OPPORTUNITIES FOR RIGHT CARE SUFFER WASTE.
What Health Care Systems Need To Do

Leadership

Work Components

Culture

What Health Care Systems Need To Do
The Evidence-based Organization is a System that Identifies & Closes Gaps in Quality, Satisfaction & Cost

Reliable & Clinically Useful Evidence should inform all components...

Mission Statement, Quality Plan & Business Plan

Leadership

Work Components

Culture

EBM 5 “A”s
Ask
Acquire
Appraise
Apply
Again
The Evidence Must Be of *High* Quality

Effective *critical appraisal* is *required*

- *Everyone* involved in *health care decision-making* should understand the need for critical appraisal and possess basic *critical appraisal skills*
- *Leadership* needs to possess a general understanding as well and demonstrate a commitment to EBM and institutionalize it
  - This includes leadership at the highest level, structural leaders and opinion leaders
- Key *support staff* should possess *advanced critical appraisal knowledge*
- “A 21st century clinician who cannot critically read a study is as unprepared as one who cannot take a blood pressure or examine the cardiovascular system.” Glasziou, *BMJ*—PMID: 18815165
What Is Needed

• **Leadership** needs to support with principles, structures and resources

• **Structures** for EBM should be developed and organized around principles, standards and criteria

• **Staff** should be given effective roles, concepts, methods, processes, skills and tools

• **Appraised information** needs to be converted into useful and usable communication tools: information, decision and action aids

• **Systems** are created for sharing reliable information and answering clinical questions as needed

• Clinicians should possess skills in **engaging and communicating** with patients, including understanding how to convey evidence-based information

• Ideally, patients are **educated**
Strategies for Implementation and Closing Quality Gaps

Think “combinations” of strategies—

1. Leadership buy-in & support efforts;
2. Decision support materials for target groups;
3. Information dissemination & training;
4. Continuing education and other educational events;
5. Academic detailing (a carefully planned visit to a clinician's office during which a physician or other respected health care professional provides specific valid educational information and “leave-behinds”);
6. Systems and administrative changes;
7. Patient-centered strategies; and,
8. Measurement & feedback