Delfini.org

Informing Health Care Decisions ™

Delfini

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

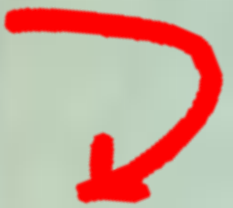
- **Evaluates medical evidence**
- **Trains others in EBCQI including critical appraisal of the medical literature**
- **Facilitates EBCQI projects including clinical guidelines**

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

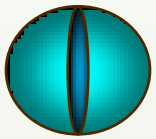
2. Decision

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**)

+

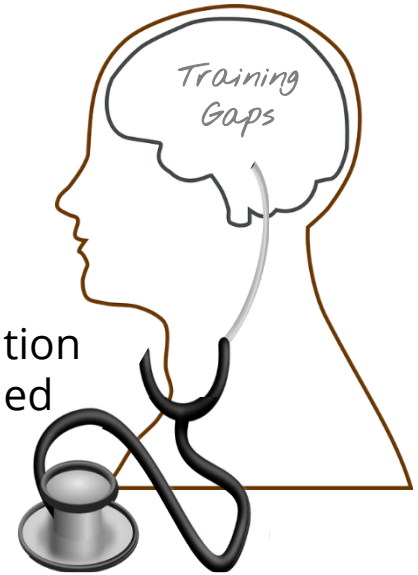
Assess likelihood of effects (**probability**)

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

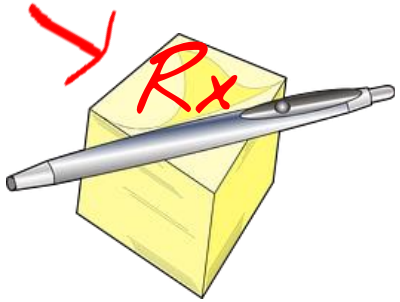


Typically, **clinicians**

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.



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

JOURNALIA MEDICUS HYPOTHETICALIA

Vol. 55, No. 2, April 1, 2014, pp 1225-1234
Delfini Group Publishing, LLC

Use of Myoceptimab, a New Smooth Muscle Surface Protein Inhibitor, for Treatment of Patients with Exercise-Related Coronary Artery Angina on Individualized Medical Therapy

Stewart MB, Streit SA, and Pingla CP. University of Delphinidae.

BACKGROUND
Optimal management of patients with multivessel coronary artery disease untreatable by percutaneous coronary intervention (PCI) is challenging. Myoceptimab is a smooth muscle cell proliferation inhibitor previously demonstrated to improve coronary arterial blood flow and provide relief from angina [refs]. This is the first RCT evaluating the efficacy of myoceptimab in patients with angina pectoris untreatable by PCI.

STUDY DESIGN
Double-blind, multicenter, randomized controlled superiority trial.

OBJECTIVE
To compare efficacy and safety of myoceptimab and placebo in patients with exercise-induced angina pectoris and multivessel coronary artery disease untreatable by PCI.

METHODS
We conducted a randomized, double-blind trial in

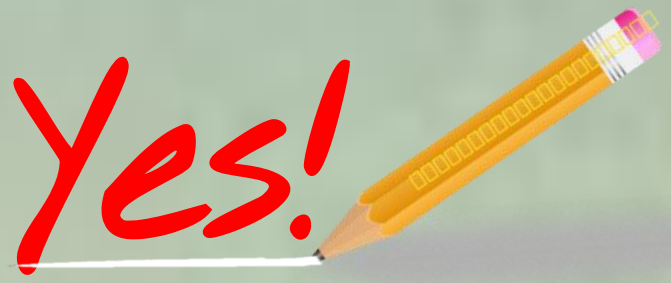
provided written informed consent to participate in the study.

Patients with a history of heart failure were excluded. Eligible patients had a documented diagnosis of angina pectoris for at least 3 months and experienced at least 3 episodes of angina per week, were on optimal medical therapy as determined by current ACC/AHA clinical guidelines for the management of angina pectoris, were naïve to myoceptimab and had multivessel coronary artery disease untreatable by PCI.

Patients were allowed to take their usual antihypertensive medications and cardiac medications which included aspirin, individualized therapy of nitrates, beta-blockers, ACE or ARB, calcium channel blockers and statins. Efforts to prevent loss to follow-up included an explanation to patients about the importance of keeping in contact with study staff and supportive messages at each follow-up visit. All patients were advised of the importance of providing

- 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?



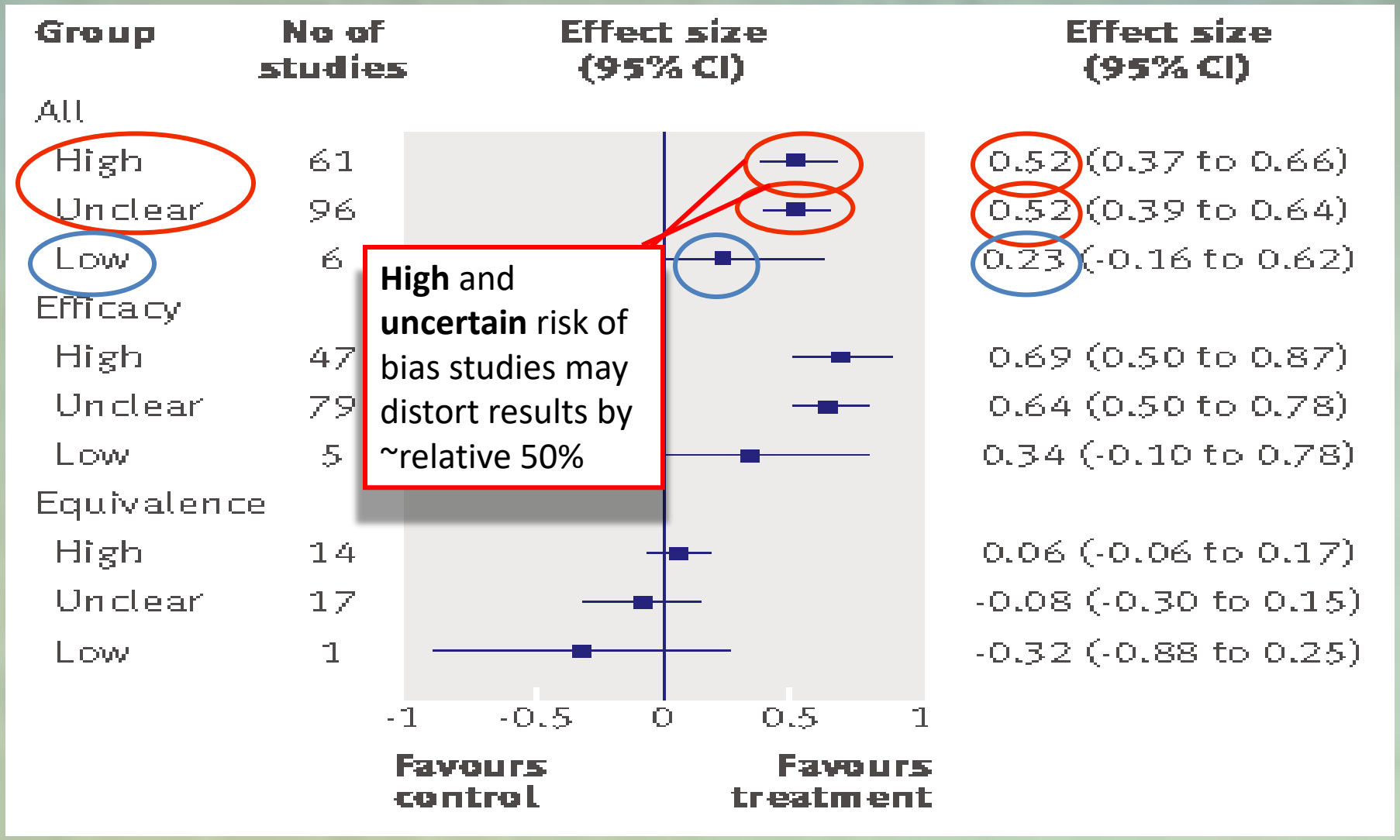
- Low quality clinical trials compared to high quality are **likely to overestimate benefit** by up to a relative 30-50% or more
- This would result in interventions tending to appear more effective than they are—or effective when they are not

Positive Predictive Values of Various Study Types

Well-done RCT	0.85
Meta-analysis of well-done RCTs	0.85
Meta-analysis of small, inconclusive RCTs	0.41
Well-done epidemiological (observational) study	0.20
Epidemiologic study with threats to validity	0.12
Discovery-oriented exploratory research	0.0010

Ioannidis JPA. Why Most Published Research Findings are False. PLoS Med 2005; 2(8):696-701 PMID: 16060722

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



Hartling et al.
PMID: 19841007

Why Critical Appraisal Matters

WITHOUT BEING INFORMED OF
VALID SCIENCE,
PATIENTS

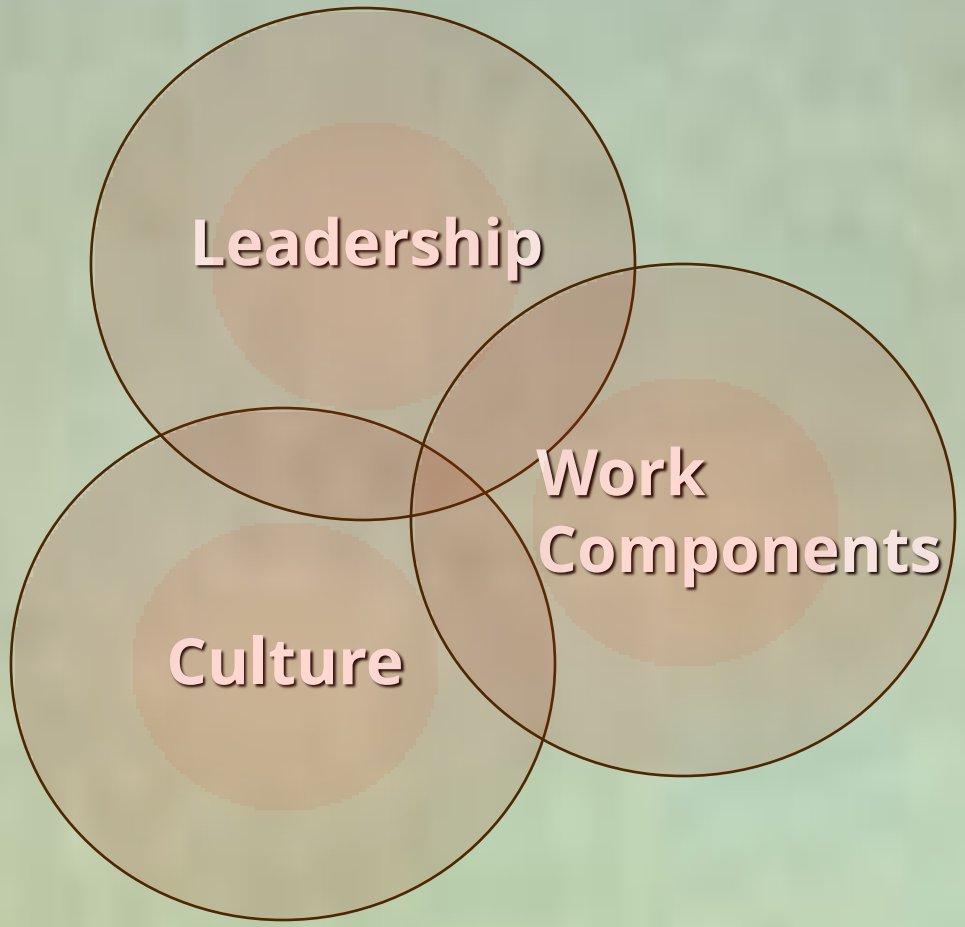
CANNOT GIVE INFORMED CONSENT

RISK GREATER HARMS

MISS OPPORTUNITIES FOR RIGHT CARE

SUFFER WASTE

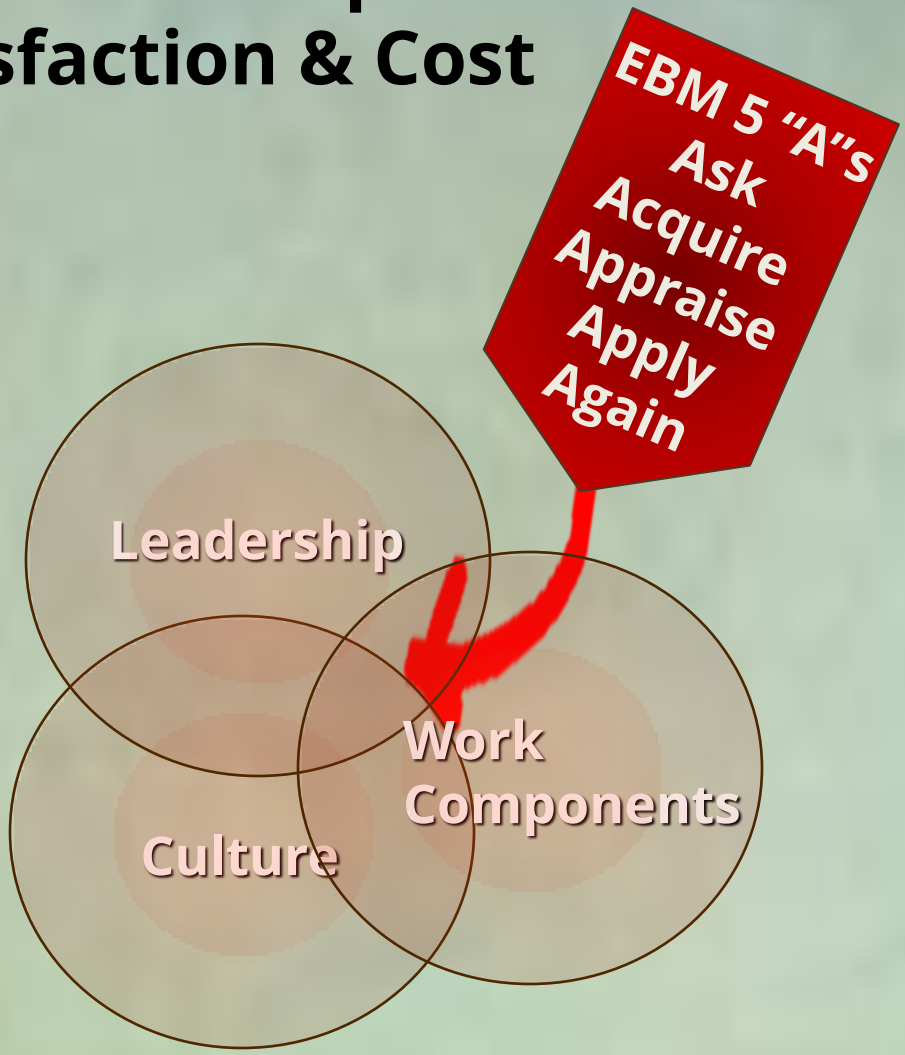
What Health Care Systems Need To Do



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



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

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