Evidence-based Medicine as a Patient Safety Tool
Key Concepts, Emerging Applications

The Quality Colloquium at Harvard University
Boston, Massachusetts

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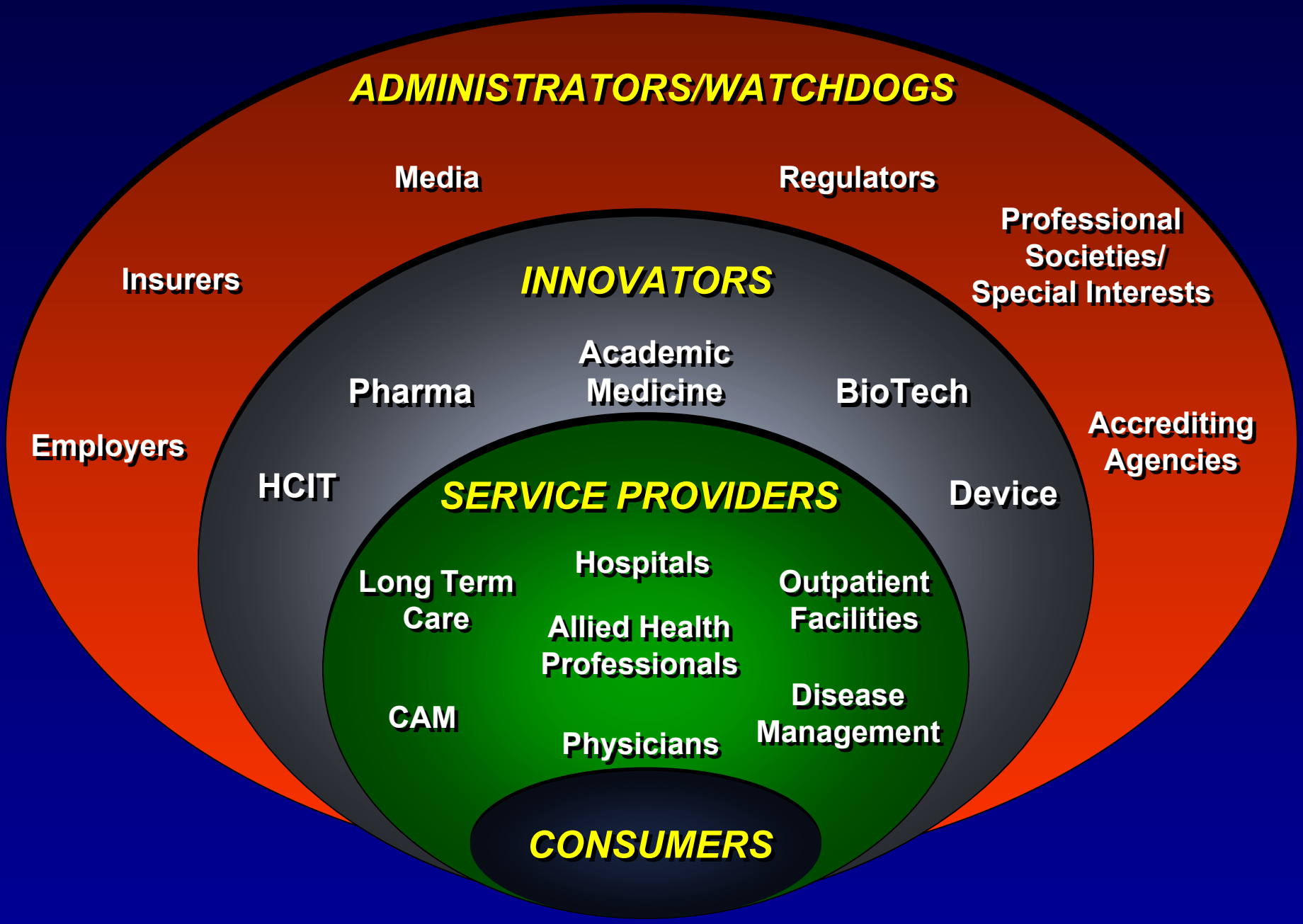
Vanderbilt Medical Center

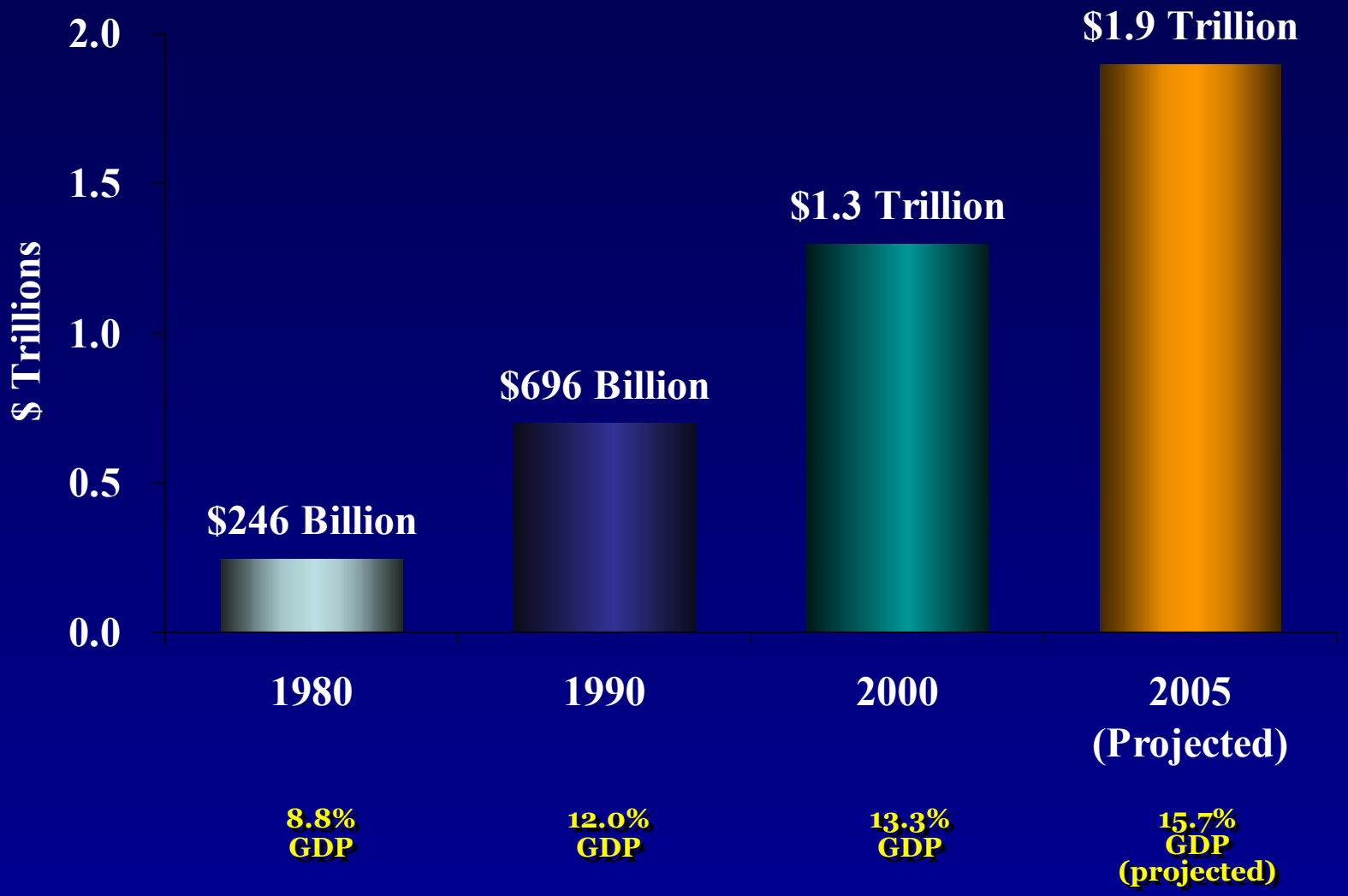
August 20, 2006

What we'll cover

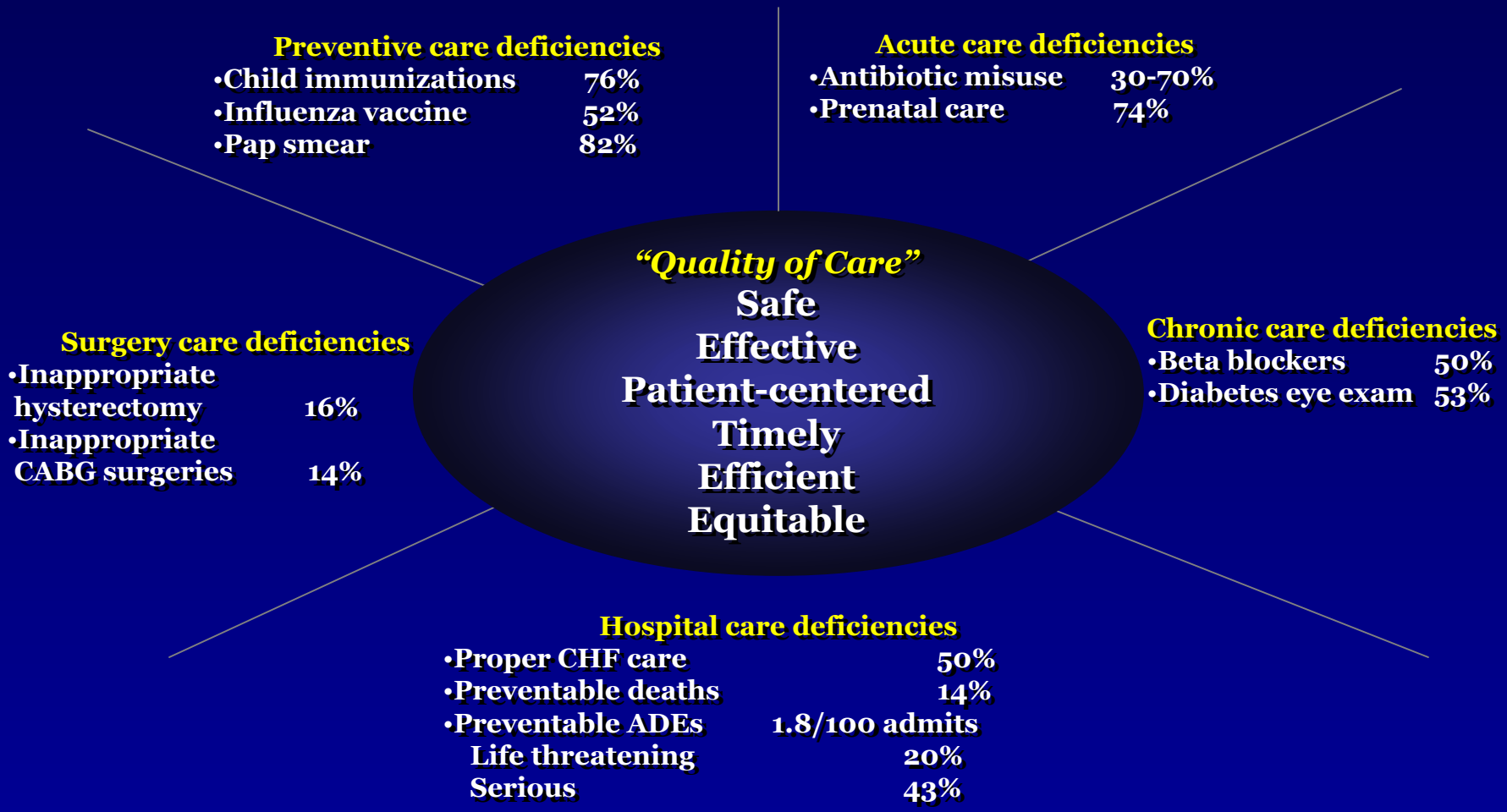
- The momentum for safety
- EBM as a means to an end
- Implications for provider organizations


ADMINISTRATORS/WATCHDOGS
Media
Regulators
Professional Societies/ Special Interests
Insurers
INNOVATORS
Academic Medicine
Pharma
BioTech
Accrediting Agencies
Employers
HCIT
SERVICE PROVIDERS
Device
Hospitals
Long Term Care
Outpatient Facilities
Allied Health Professionals
Disease Management
CAM
Physicians
CONSUMERS

$6320 per person in the U.S.!



"The quality of care we get is far from the care we should be getting" — *Don Berwick, IHI*



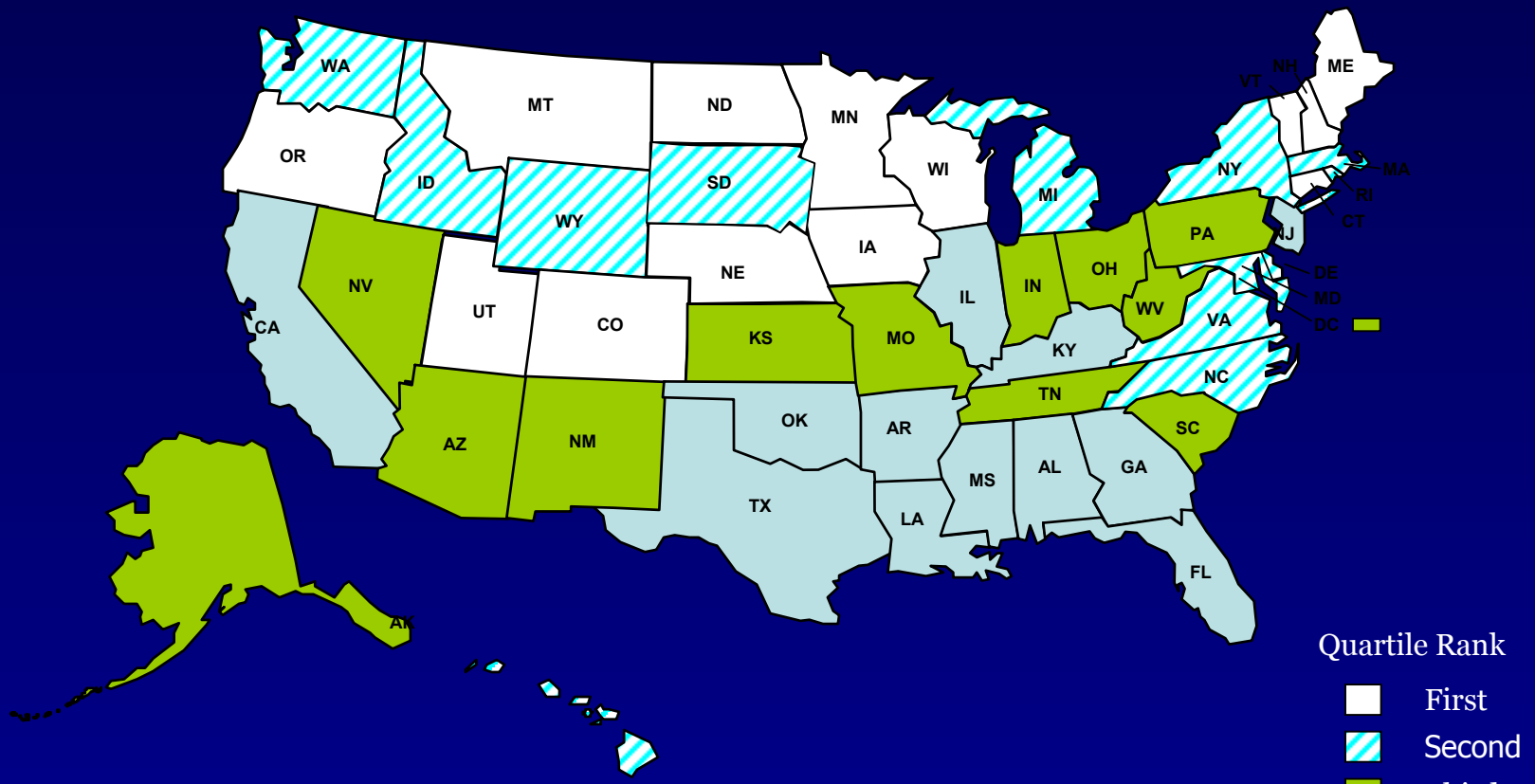
What the evidence says is what you get (half the time)

McGlynn et al "The Quality of Health Care Delivered to Adults in the United States" NEJM June 26, 2003

Condition	% Recommended Care Received
Senile Cataract	78.7
Breast cancer	75.7
Prenatal Care	73.0
Low back pain	68.5
Coronary artery disease	68.0
Hypertension	64.7
Congestive heart failure	63.9
Cerebrovascular disease	59.1
Chronic obstructive pulmonary disease	58.0
Depression	57.7
Orthopedic conditions	57.2
Osteoarthritis	57.3
Colorectal cancer	53.9

Condition	% Recommended Care Received
Asthma	53.5
Benign prostatic hyperplasia	53.0
Hyperlipidemia	48.6
Diabetes mellitus	45.4
Headache	45.2
Urinary tract infection	40.7
Community acquired pneumonia	39.0
Sexually transmitted diseases	36.7
Dyspepsia/peptic ulcer disease	32.7
Atrial fibrillation	24.7
Hip fracture	22.7
Alcohol dependence	10.5

Quality depends on where you live



Note: State ranking based on 22 Medicare performance measures.

Source: S.F. Jencks, E.D. Huff, and T. Cuerdon, "Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001," *Journal of the American Medical Association* 289, no. 3 (Jan. 15, 2003): 305–312.

Errors abound

1. Adverse drug events (ADEs, ADRs)
2. **Iatrogenic infections**
   - Post-operative deep wound infections
   - Urinary tract infections (UTI)
   - Lower respiratory infections (pneumonia or bronchitis)
   - Bacteremias and septicemias
3. Decubitus ulcers
4. Mechanical device failures
5. Complications of central and peripheral venous lines
6. Deep venous thrombosis (DVT) / pulmonary embolism (PE)
7. **Strength, agility and cognition**
8. Blood product transfusion
9. Patient transitions

80% of ADE's avoidable

Class	%	Description	Avoidable?
Pharm Expected	28.0	Know drug reactions	Yes
Physio Renal	23.0	Failure to adjust for decreased Renal function	Yes
Physio Age	14.2	Failure to adjust for patient age	Yes
Physio Weight	5.7	Failure to adjust for patient body mass	Yes
Order Dosage	5.0	Error in dosage on order	Yes
Physio Hernal	4.6	Failure to adjust for known hematologic	Yes
Total preventable	**80.3**		

Study: Health Care Costs, Error Rates Higher in U.S. Than in Other Countries

November 04, 2005

For the report, researchers surveyed 6,957 adults between March and June 2005 who recently had been hospitalized, had surgery or reported health problems in the U.S., Australia, Canada, Britain, New Zealand and Germany. The survey, which is the largest to examine health care in several nations during the same time period, found that U.S. residents were more likely than patients in other nations to forego medical care because of costs. In addition, U.S. respondents reported the easiest access to specialists but the most difficulty getting care during nights and weekends (*Washington Post,* 11/4). Patients from all six countries reported medical errors, uncoordinated care and poor management of chronic diseases (*CQ HealthBeat,* 11/3).

The study also found the following:

34% of U.S. patients surveyed reported getting the wrong medication or dose, incorrect test results, a mistake in their treatment or late notification of abnormal test results, compared with 30% of Canadians, 27% of Australians, 25% of New Zealanders, 23% of Germans and 22% of Britons;

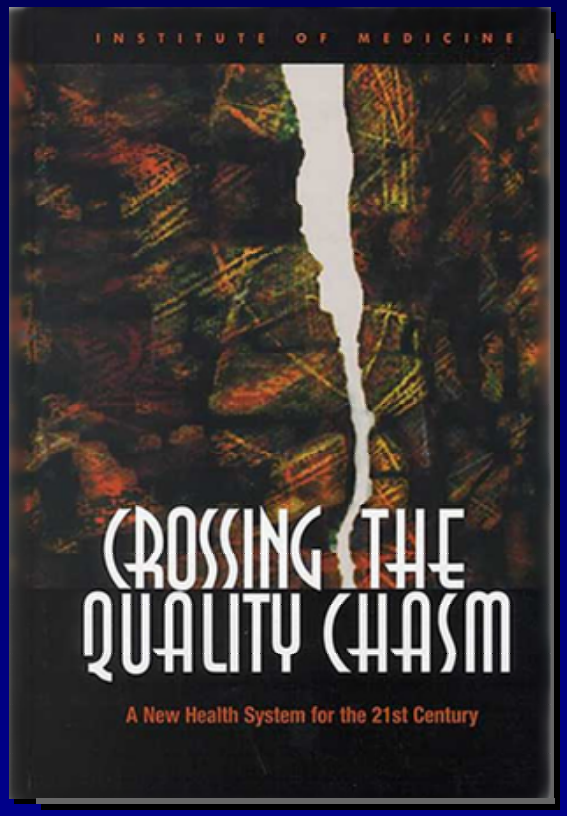
About half of U.S. residents reported that they had decided not to fill a prescription, see a physician when sick or have recommended follow-up tests because of costs, compared with 38% of patients in New Zealand, 34% in Australia, 28% in Germany, 26% in Canada and 13% in Britain;

Nearly one-third of U.S. patients reported paying more than $1,000 in out-of-pocket medical expenses in the past year, compared with 14% of Canadian and Australian patients and a much lower proportion of patients in the other countries (*Washington Post,* 11/4);

7% of U.S. residents who had been hospitalized in the past two years reported developing an infection while in the hospital, compared with 10% of Britons and 3% of Germans

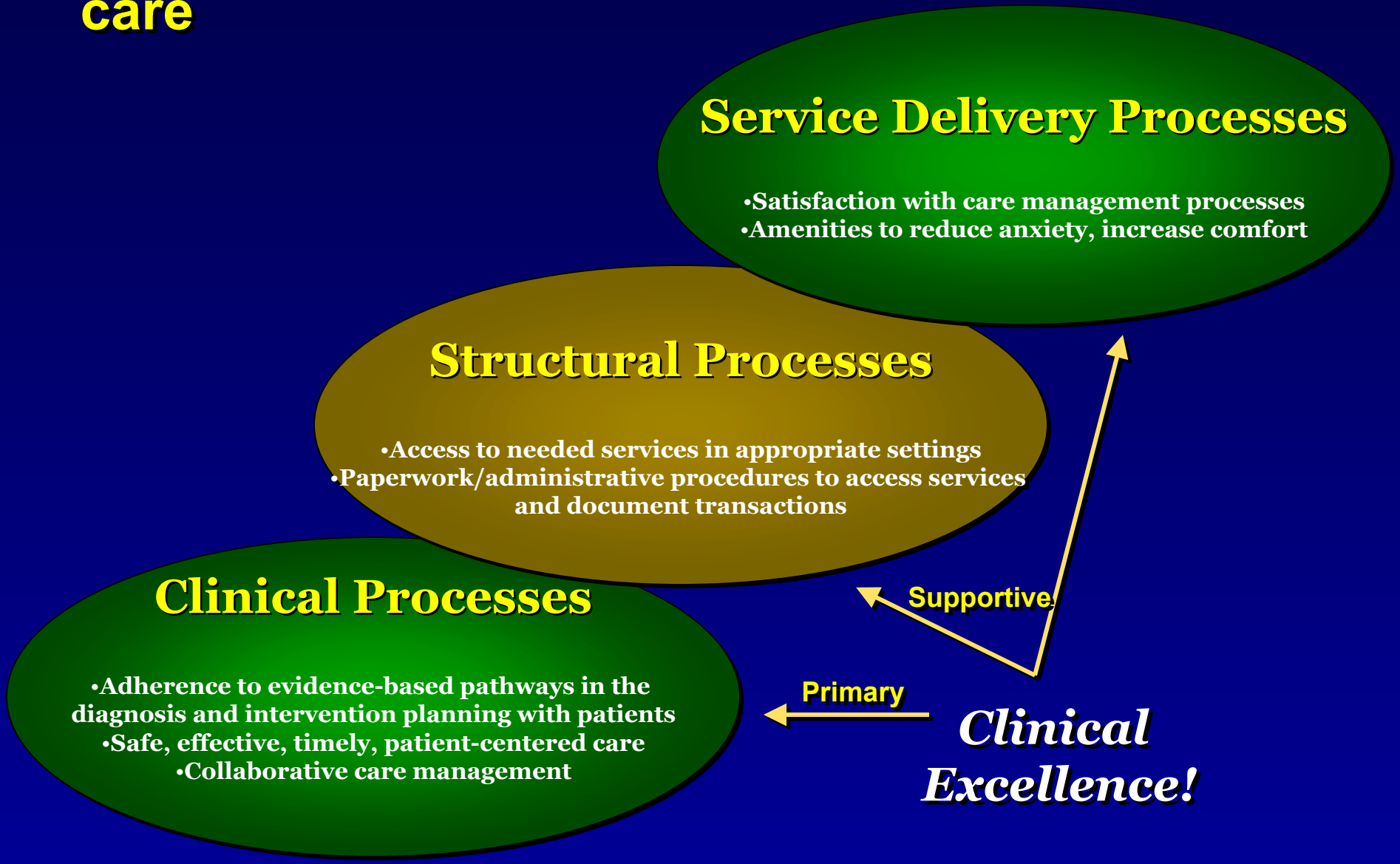
The system is in meltdown..

“Quality” is our number one concern!!

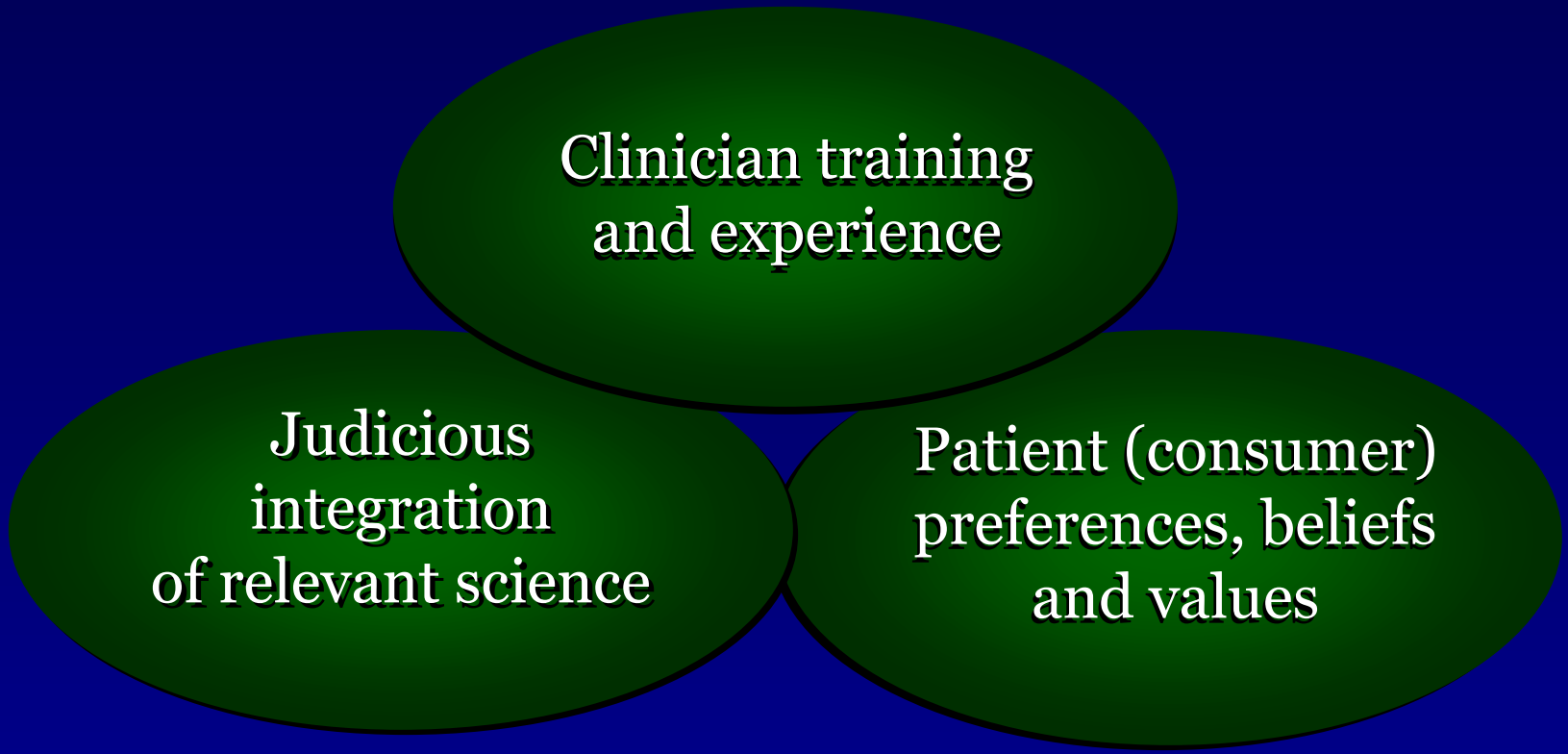


- Evidence Based Care
- Patient Centered Approach
- System Orientation

To most, quality means safe, accessible care



Evidence-based medicine is not understood



"Evidence-based medicine is the judicious application of relevant scientific studies to patient preferences and values."

Guidelines:
The Framework for Evidence-based Medicine

"Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"

– IOM '92

- Derived from…
- 20,000 RCTs annually
- 4,000 guidelines since 1989
- 2,500 periodicals in NLS

Every guideline is not evidence-based, and some guidelines are about who, what should be done

PICO: the framework for guidelines…

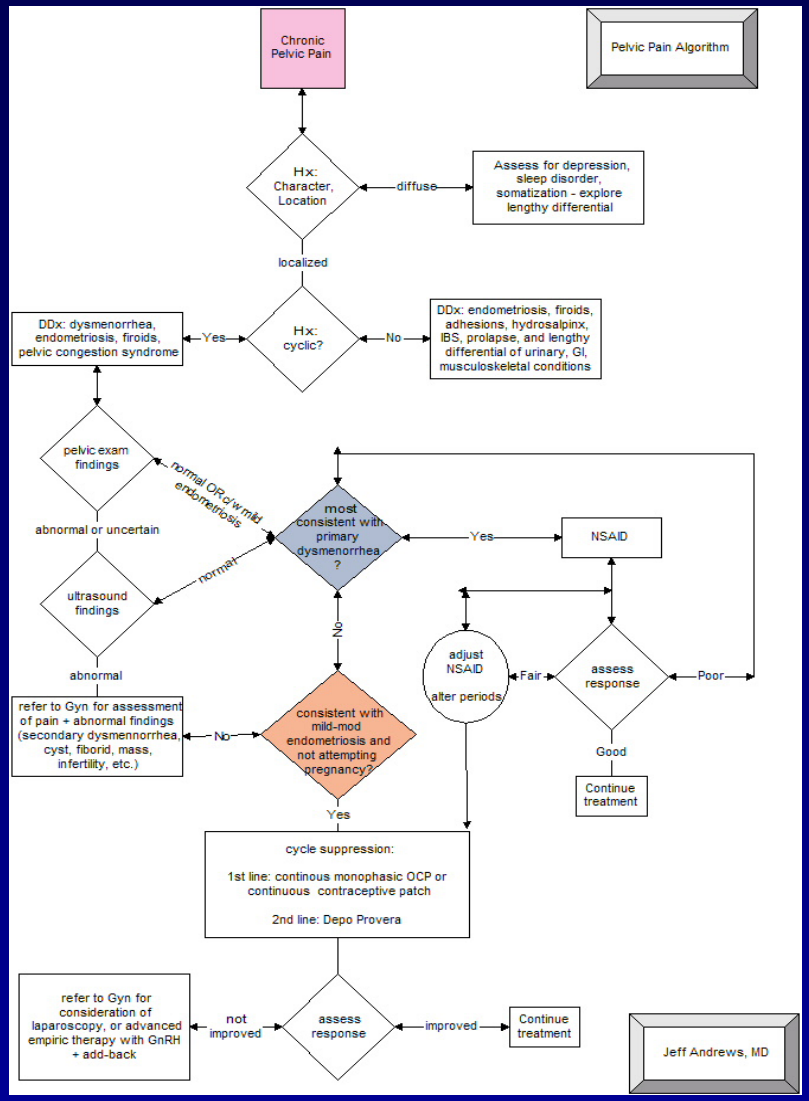
P… what's the population?

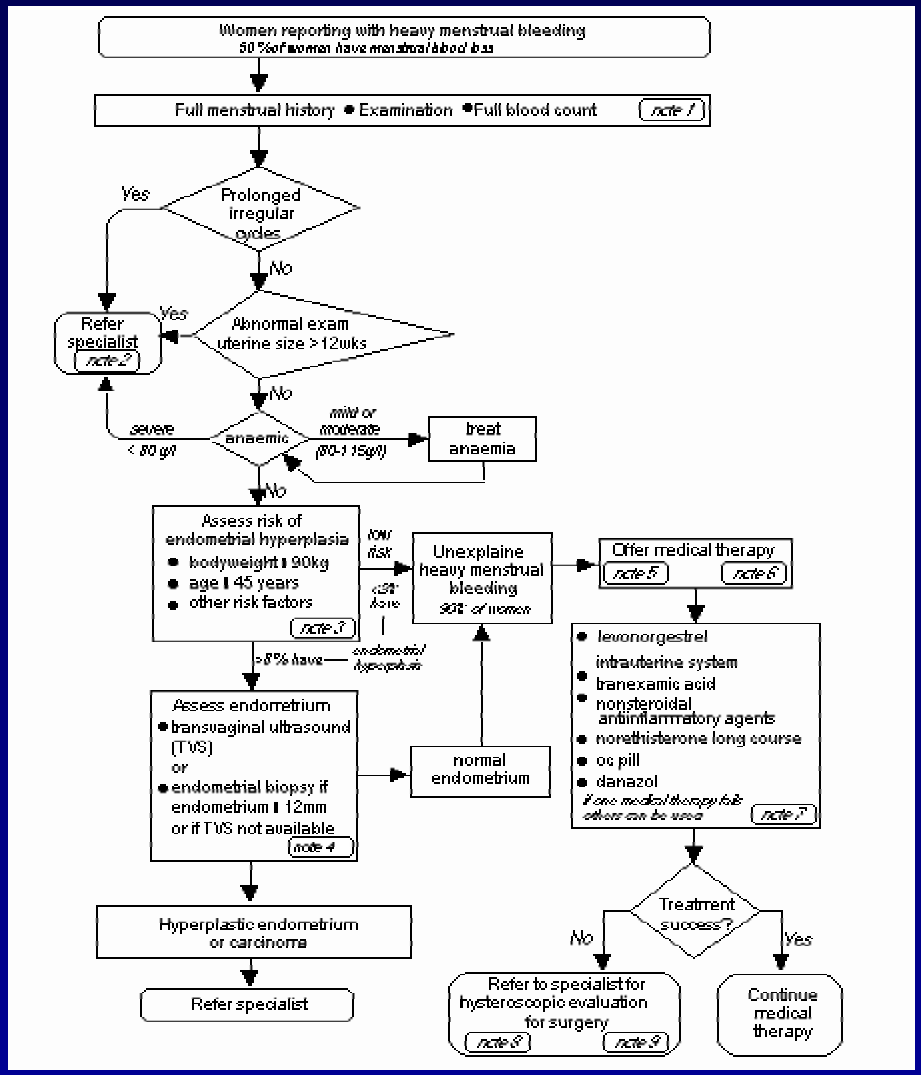
I…what intervention am I testing?

C… compared to what other intervention?

O… what outcome is being tested?

Then evidence-linked algorithms form the framework for guidelines





Studies are graded using various schemes..

http://38.144.38.99/webebm/protocol/inc/showgrade.asp?Grade=A2&Back=yes - Microsoft Internet Explorer

A: Methods strong, results consistent-RCTs, no heterogeneity*
1: Effect clear-Clear that benefits do (or do not) outweigh risks

A: Methods strong, results consistent-RCTs, no heterogeneity
2: Effect equivocal-Uncertainty whether benefits outweigh risks

B: Methods strong, results inconsistent-RCTs, heterogeneity present
1: Effect clear-Clear that benefits do (or do not) outweigh risks

B: Methods strong, results inconsistent-RCTs, heterogeneity present
2: Effect equivocal-Uncertainty whether benefits outweigh risks

C: Methods weak-Observational studies
1: Effect clear-Clear that benefits do (or do not) outweigh risks

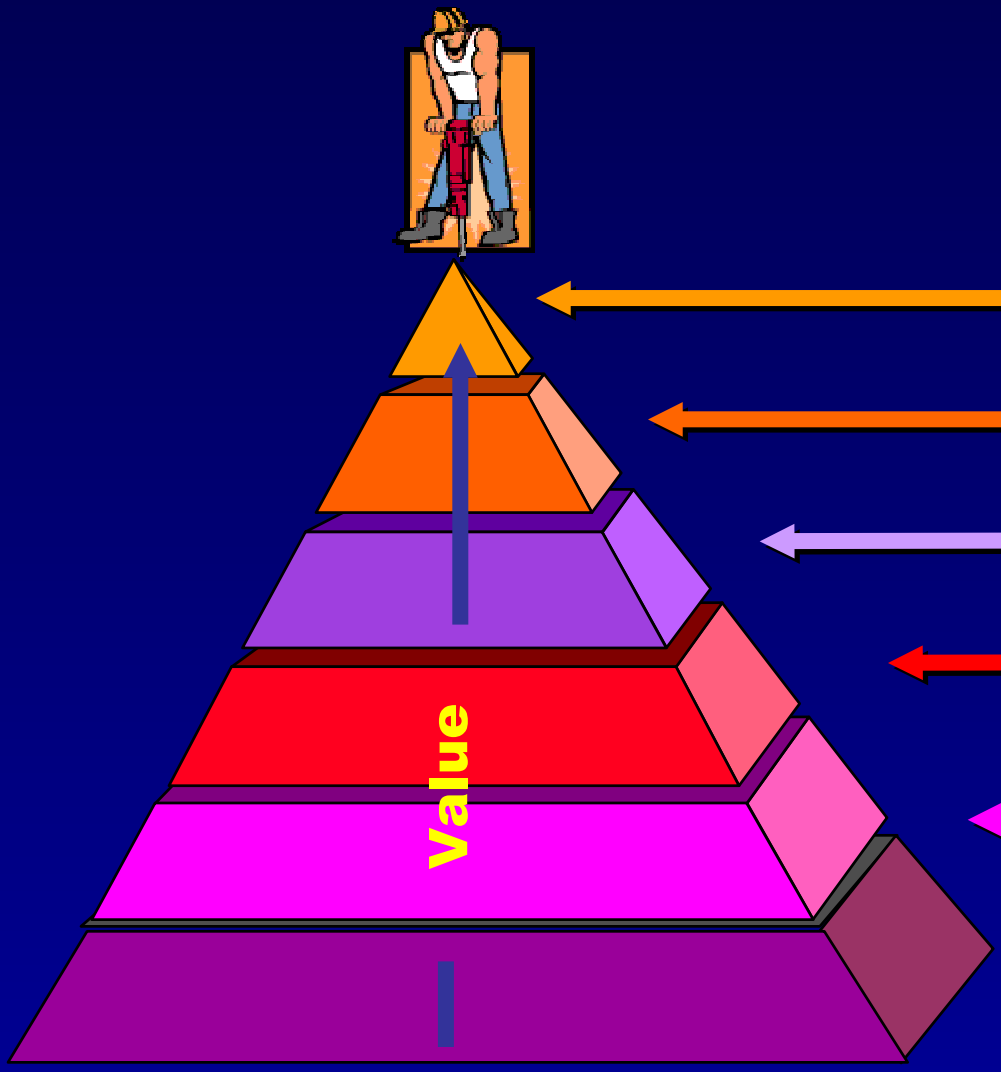
C: Methods weak-Observational studies
2: Effect equivocal-Uncertainty whether benefits outweigh risks

*Heterogeneity describes the situation when several RCTs yield widely differing estimates of treatment effect for which there is no explanation.
Grading system source: American College of Chest Physicians (ACCP)

Evidence Grade: A1

Back Close

In practice, tools are used to stay abreast..



EBM Practice Guideline

Clinical Evidence
POEMs

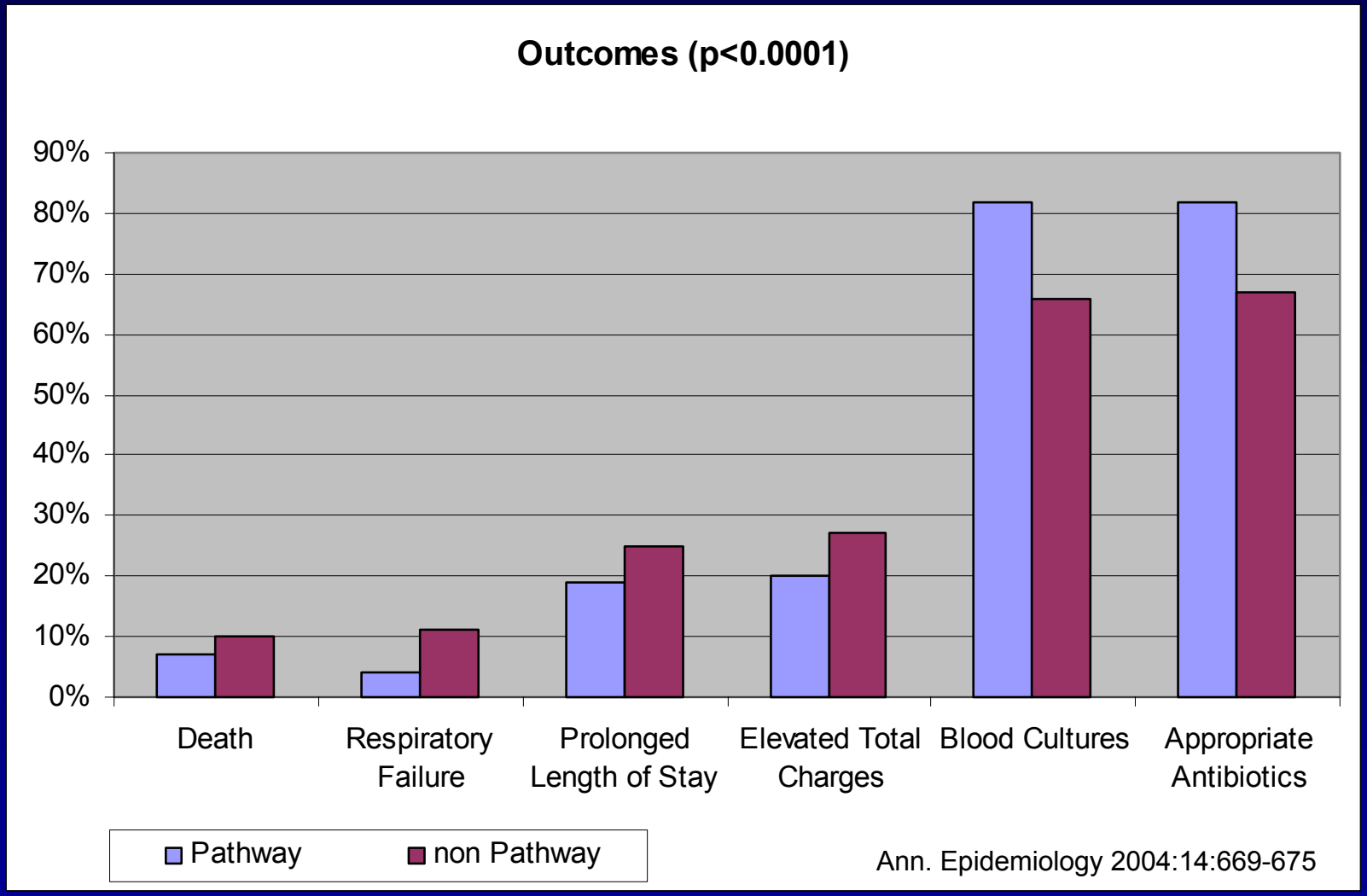
Systematic Reviews
Cochrane Library

CATs, Best Evidence,
ACP Journal Club

Reviews: Up-to-Date,
5-Min Clinical Consult

Medline, PubMed

Better care is the result; it is also a more efficient way to operate a clinical enterprise



And then we draw conclusions: what do we learn by examining the evidence?

Observational Study (n=1): why women live longer than men!"

The data correlates adherence to evidence-based practice with…

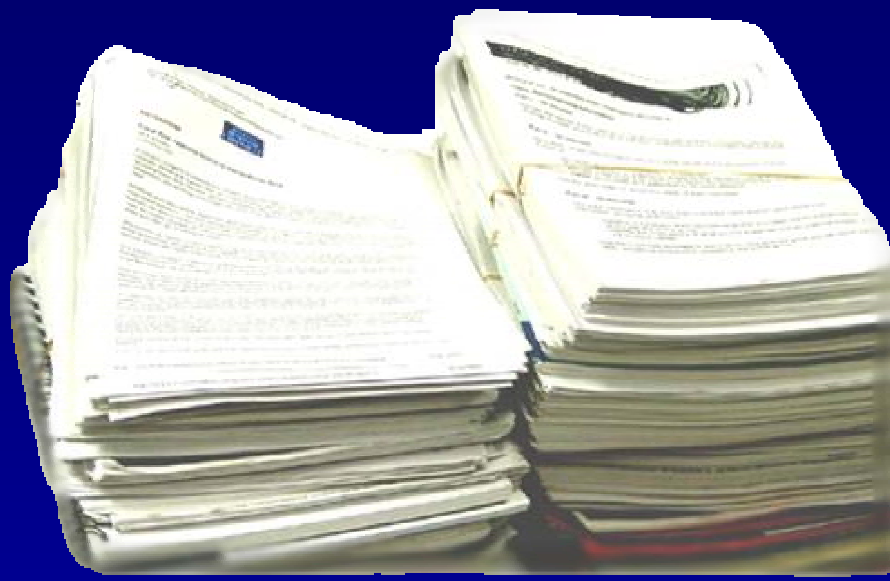
- Improved outcomes
- Reduced variation
- Improved patient adherence
- Improved efficiency
- Reduced errors

So why isn't evidence-based practice more consistently provided?

Challenge: Knowledge Explosion

- 20,000 biomedical journals
- >150,000 medical articles published each month
- >300,000 randomized controlled trials

"We are drowning in information but starved for knowledge."—Naisbitt, '82



Challenge: Lack of Evidence

How many questions have any evidence? (BMJ 2000)

Challenge: Source Credibility

- *Shaneyfelt et al: (JAMA, 1999)*

  Of 279 guidelines developed by medical societies, most do not adhere to IOM standards for methodological review (evidence-grading)

- *Grilli et al: (Lancet, 2000)*

  431 guidelines reviewed; 82% lack evidence-grading review assessment

Challenge: Reliability

Gathering Evidence

Where to find the latest data on evidence-based guidelines

SOURCE	WEB SITE	COMMENT
National Guidelines Clearinghouse	guidelines.gov[3]	Government-sponsored site allows users to gain access to more than 1,400 guidelines and register for e-mail updates on new evidence.
Institute for Clinical System Improvement	icsi.org[4]	Guidelines cover 59 diseases and conditions; sponsored by Minnesota health plans; links to new and recently revised guidelines.
The Cochrane Library	informedhealthonline.org[5]	Australian site provides information from Cochrane Collaboration, developer of evidence-based guidelines from research world-wide.
Vanderbilt Center for Evidence-Based Medicine	ebm.vanderbilt.edu[6]	Site has links to information about evidence-based medicine and guidelines issued by specialty medical groups and international organizations.

• **Send e-mail** to Informedpatient@wsj.com[7].

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(6) http://www.ebm.vanderbilt.edu
(7) mailto:Informedpatient@wsj.com

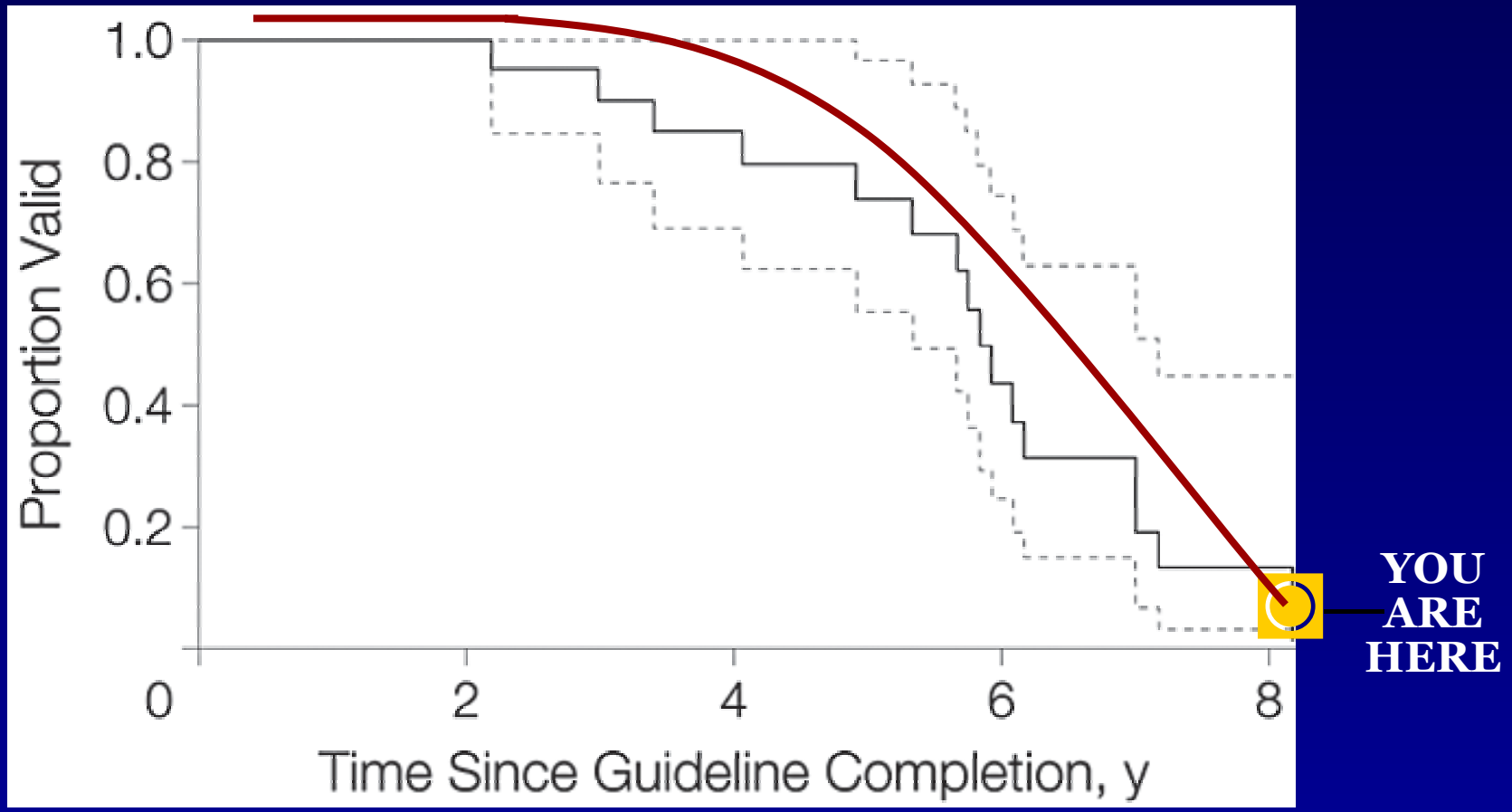
THE WALL STREET JOURNAL.

January 26, 2005

Challenge : Timeliness

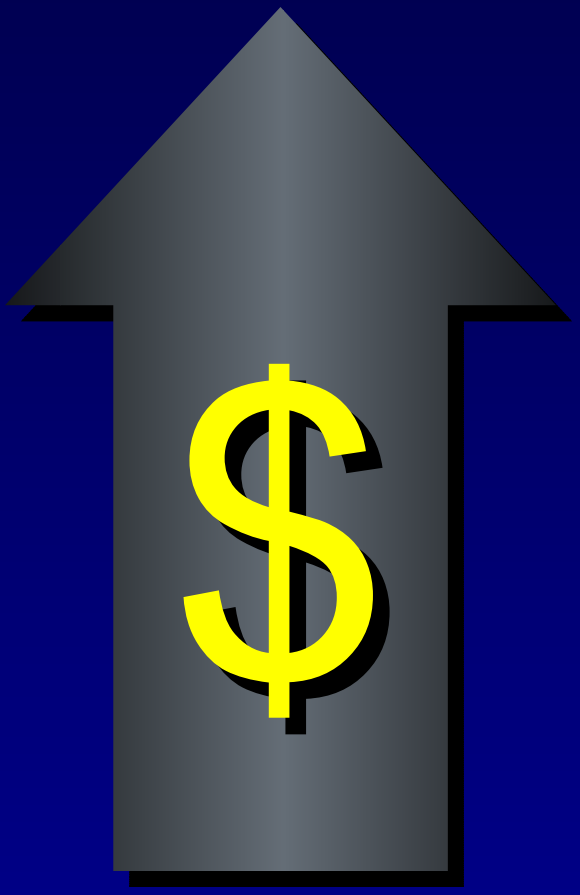
The solid line represents the Kaplan-Meier curve for the Agency for Healthcare Research and Quality (AHRQ) guidelines.

Dashed lines represent the 95% confidence interval (JAMA. 2001;286:1461-1467)

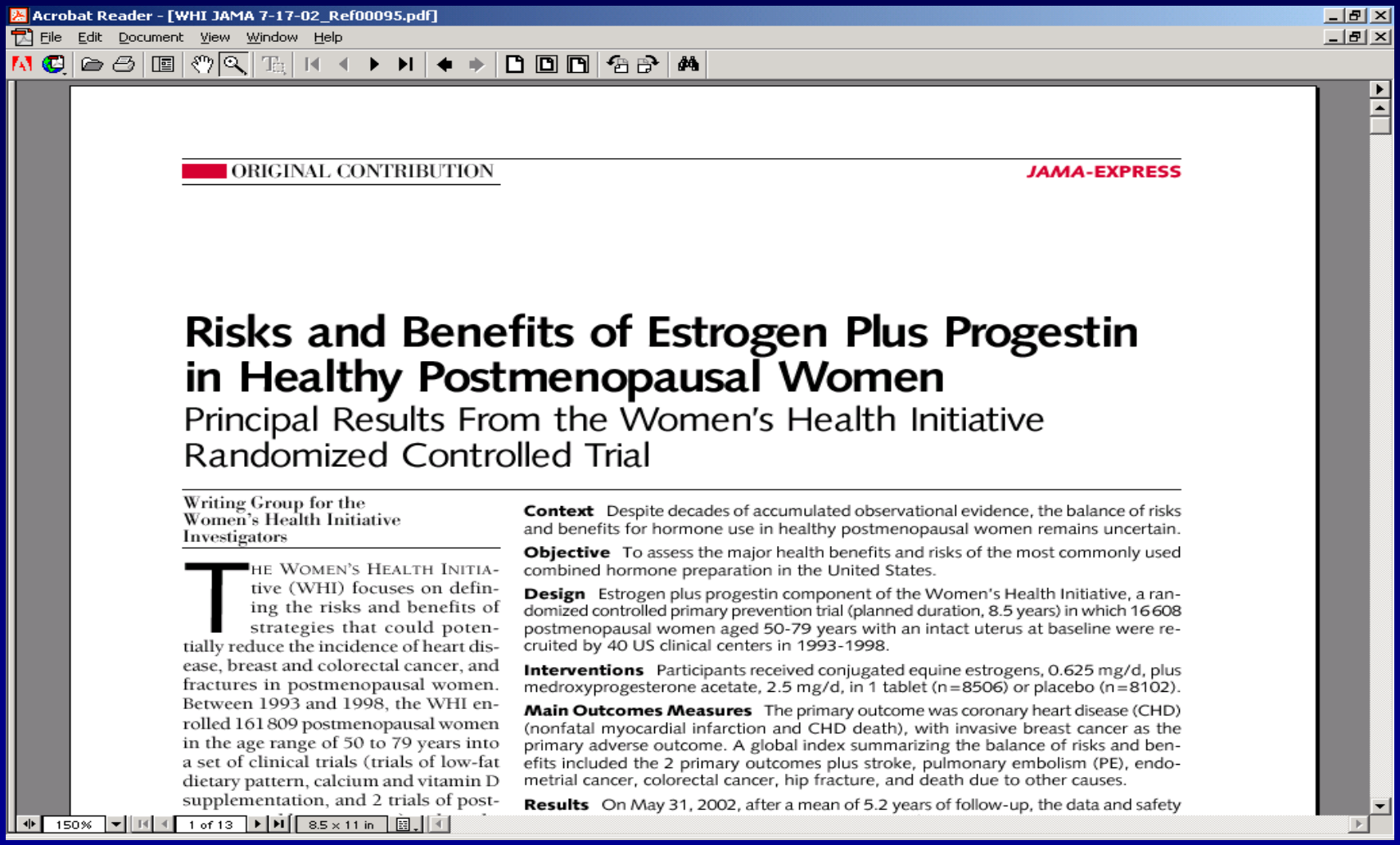


Challenge: Commercial Interests

1. Digital imaging
2. Drug-coated stents
3. Oral cancer treatments
4. Minimally invasive surgery
5. Sepsis treatment
6. Implantable devices
7. Microscopic cameras
8. Diabetes devices
9. At-home health test kits
10. Embryonic stem cell research



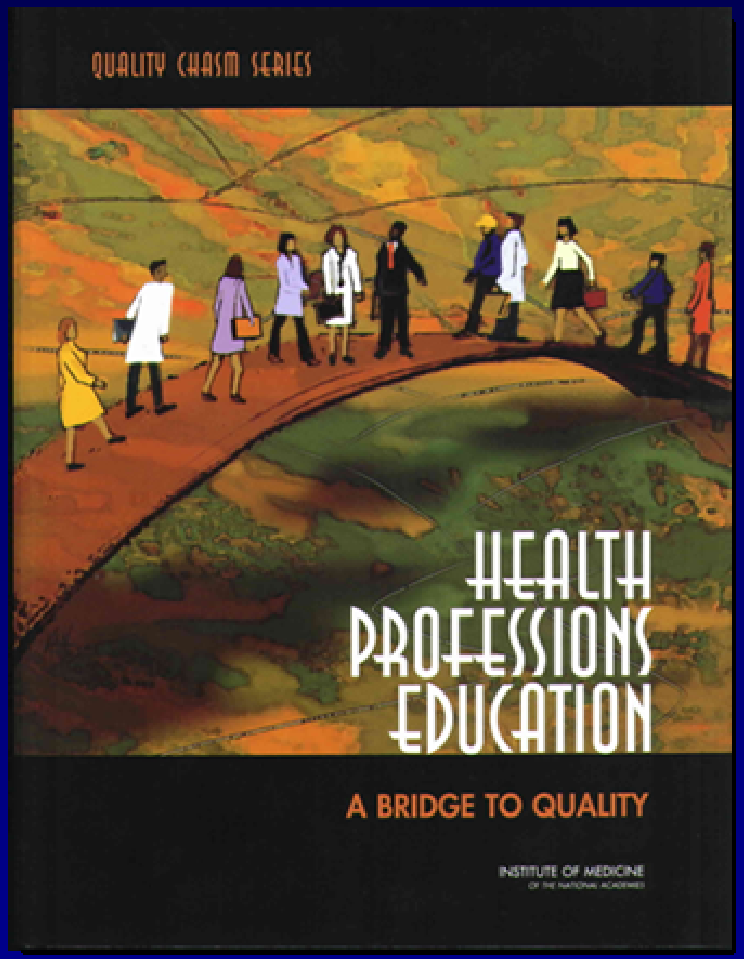
Challenge: Media Attention



Challenge: Physician Training

- Provide patient centered care
- Work in interdisciplinary teams
- Employ evidence-based practice
- Apply quality improvement
- Utilize informatics

Health Professions Education: A Bridge to Quality
Institute of Medicine 2003



Challenge: Consumer Expectations

73% of patients depend on physicians to make decisions for them!

17.1% Strongly Agree	45% Agree	11%	22.5% Disagree	4.8% Strongly disagree

*Adapted from Guyatt et al. Incorporating Patient Values in: Guyatt et al. Users' Guide to the Medical Literature: Essentials of Evidence –based Clinical Practice. JAMA 2001

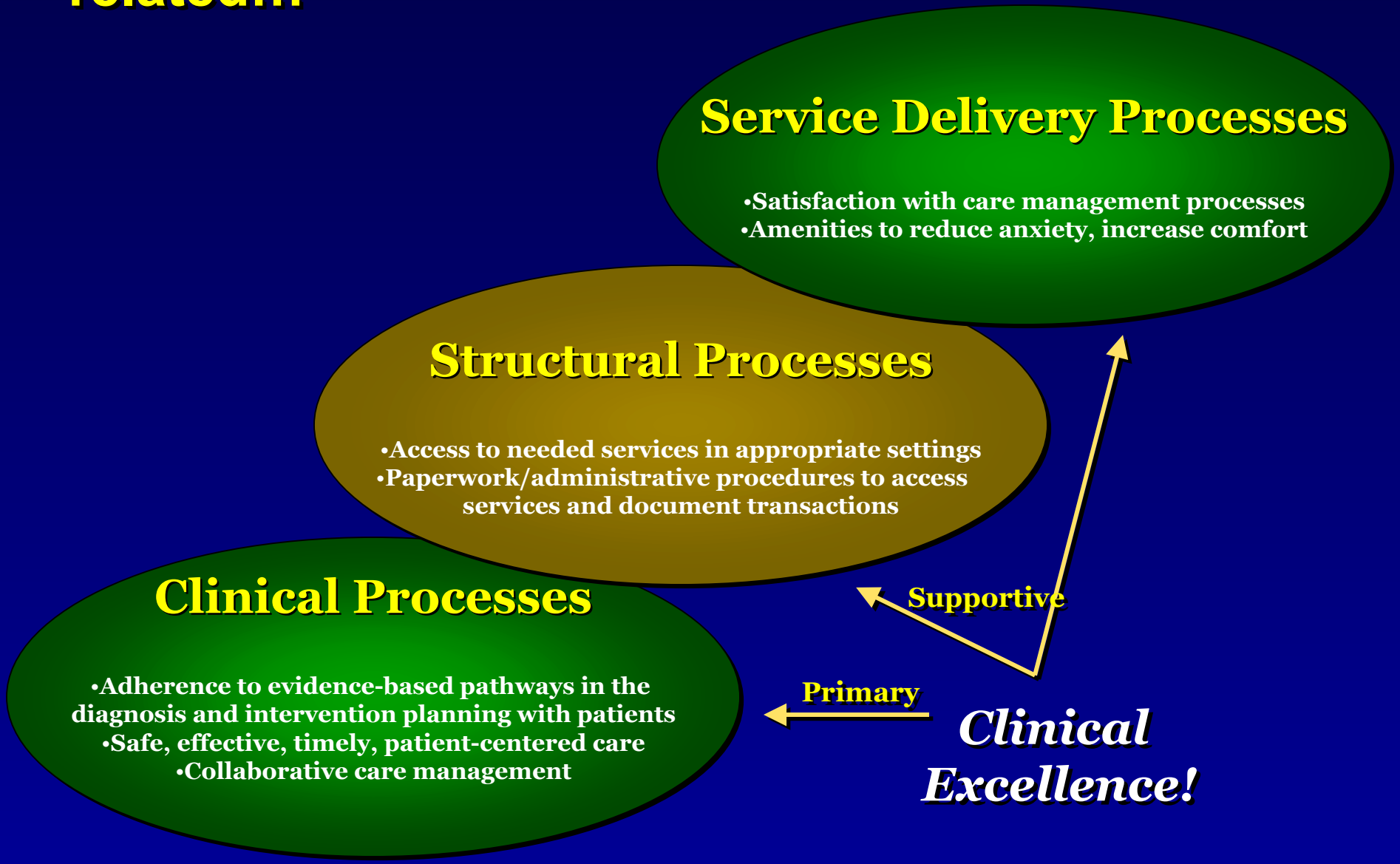
**Arora NK and McHorney CA. Med Care. 2000; 38:335

Lots of explanations and excuses…

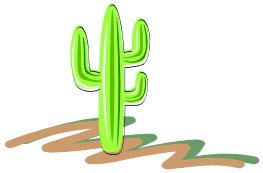
- “they don’t pay for it..”
- “the tools aren’t available”
- “my patients don’t care”
- “it’s a fad”
- “the only evidence I need is what I know”

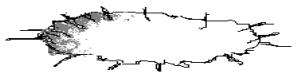
So what does this have to do with safety?

EBM, quality and safety are closely related…



Clinical Excellence
"Do right things well"

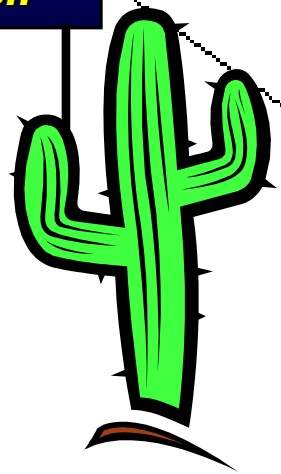




"It's cookbook Medicine"

Quality Improvement
"Do things well"

"we don't have the tools"

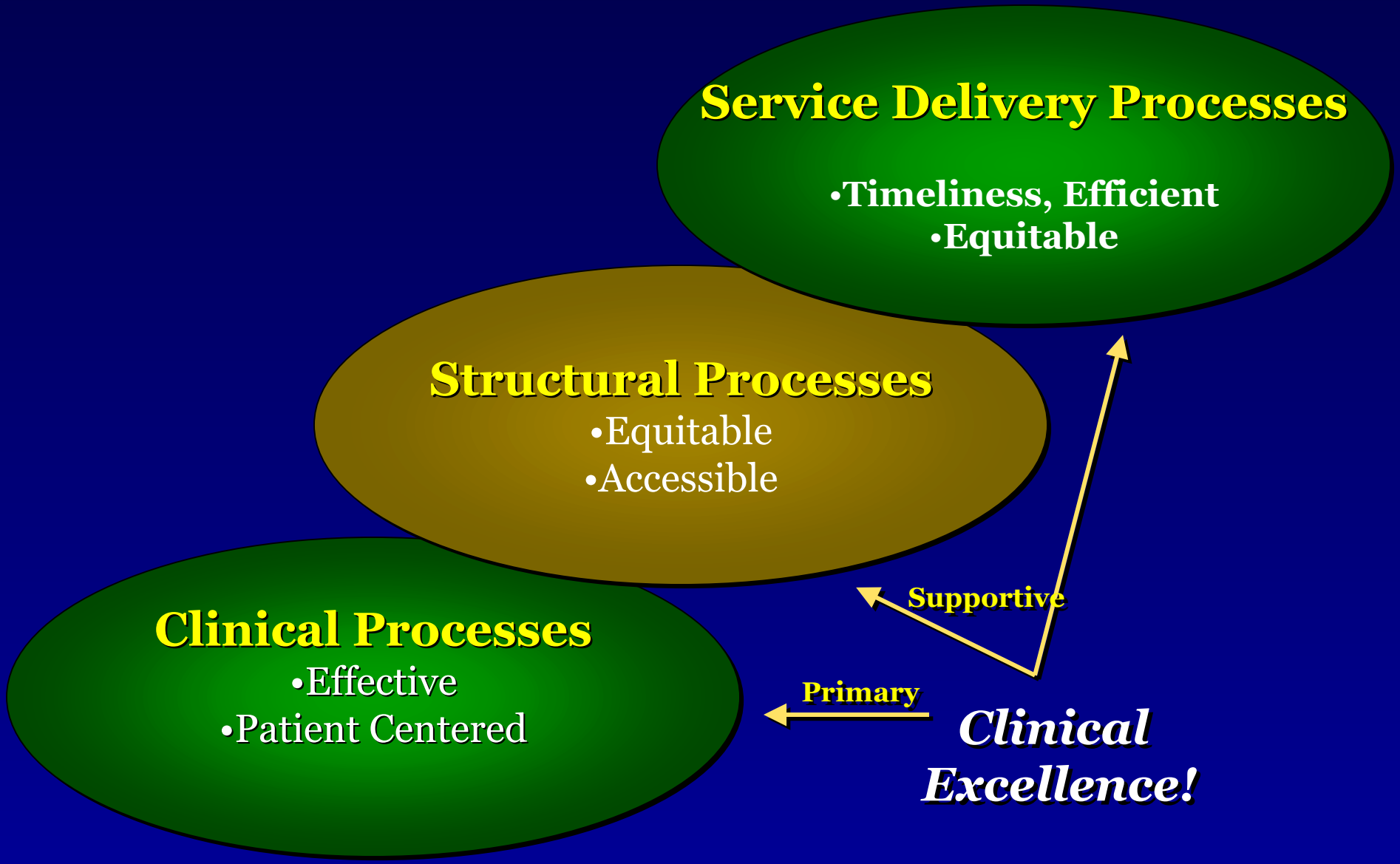


Safety
"Do no harm"

"we never did it that way before"

The application of EBM to safety is foundational

Safe, evidence-based care



For a provider organization, there are six key operational applications where EBM is central…

Pathway Management
Building and updating pathways, order sets and guidelines for care teams

Risk Management
Avoiding error, conducting root cause analysis

Care Team Management
Recruiting, equipping and holding accountable care teams

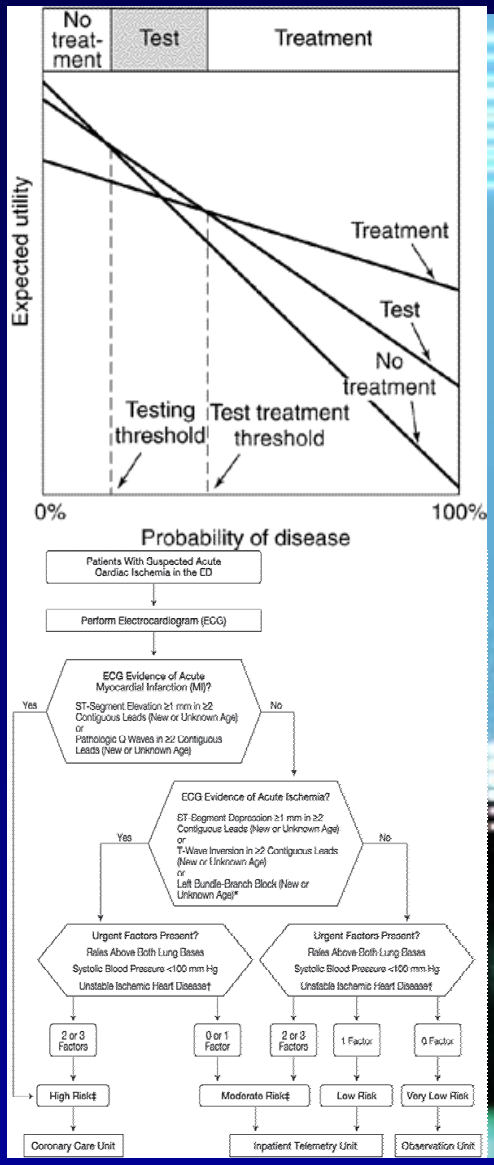
Outcome Management
Measuring what works best and why

Admissions Management
Evaluating appropriately, directing resources effectively

Discharge Management
Teaching, equipping patients for guided self-care, follow-up

Physician leadership is essential!

Point of care decision-support tools are essential



HCIT: Where do we start selecting companies?

Numbers of companies currently supporting these applications

Source: 2005 Healthcare Informatics, Resource Guide

The cat is out of the bag!!

Summary

- EBM is a journey to clinical excellence: it's about safety, quality improvement and evidence-based care
- Applying EBM to error avoidance is fundamental: it leverages research about efficacy and effectiveness
- To deliver safe evidence-based care, an organization must invest in processes and information technologies to support leaders in the journey
- Our results will be public.

Contact

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