



Evidence-based care management: the landscape for predictive models

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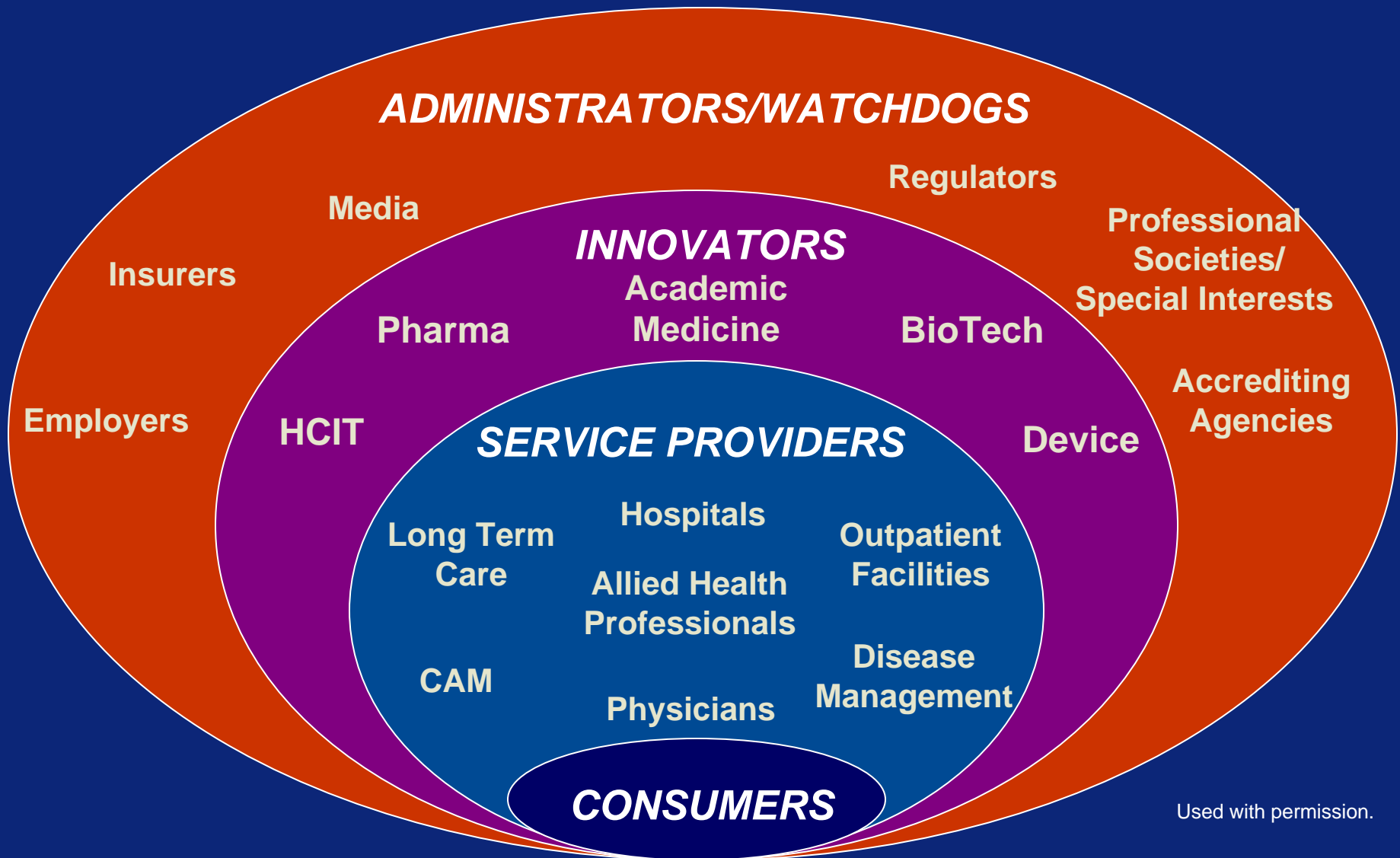
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The National Predictive Modeling Summit

December 13, 2007

System: big, complex, change resistant . . .



Used with permission.

The system has achieved much . . .

The most important medical developments of the last millennium

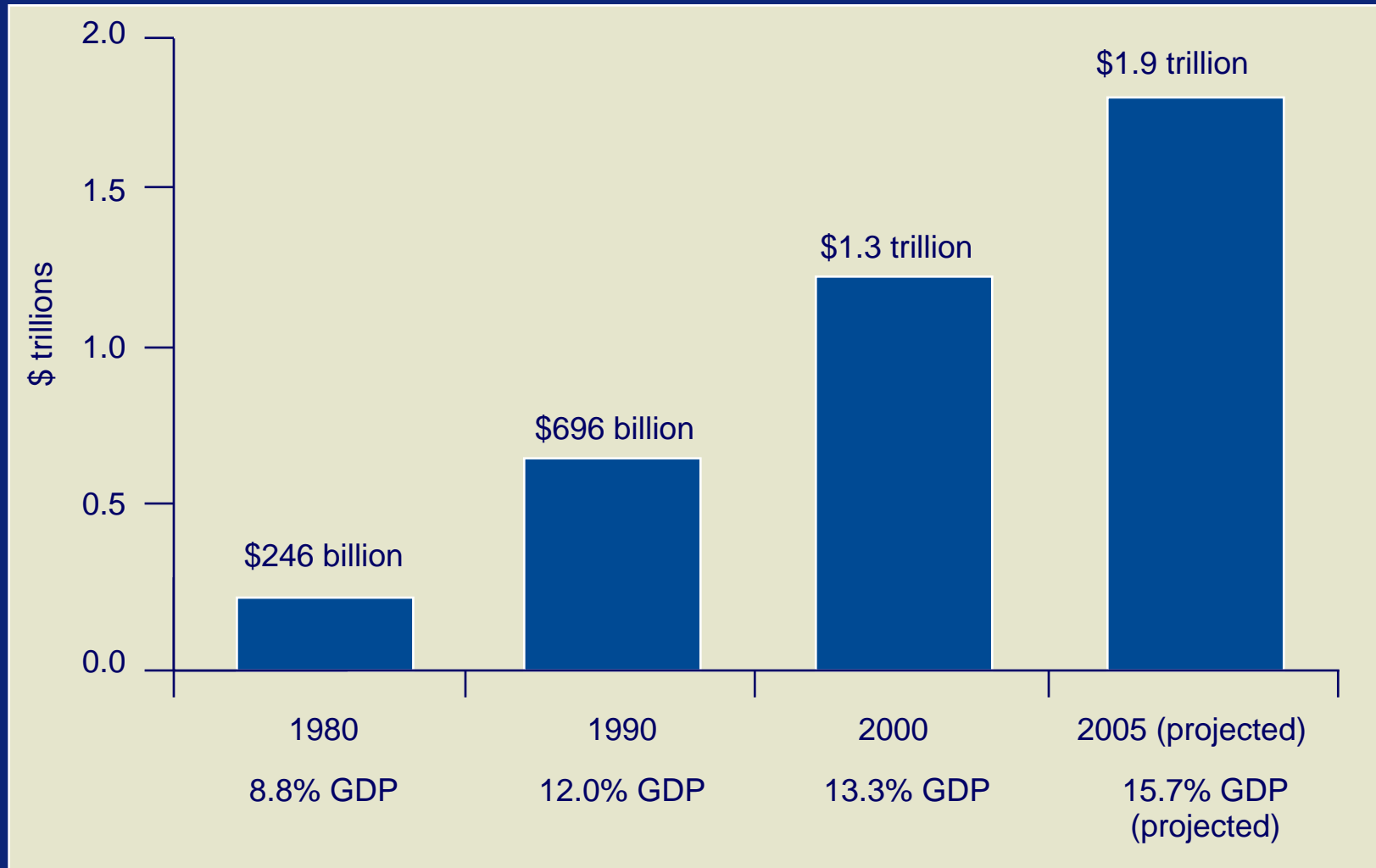
- Elucidation of Human Anatomy and Physiology
- Discovery of Cells and Their Substructures
- Elucidation of the Chemistry of Life
- Application of Statistics to Medicine
- Development of Anesthesia
- Discovery of the Relation of Microbes to Disease
- Discovery of the Immune System
- Development of Body Imaging
- Discovery of Antimicrobial Agents
- Development of Molecular Pharmacotherapy
- Sequencing of the Human Gene*
- Nanoscience tools for diagnostics and treatments*
- Biology of human behavior sequenced*
- Rational drug designs via proteomics, chemical biology, structural biology*

** Last 10 years!!*

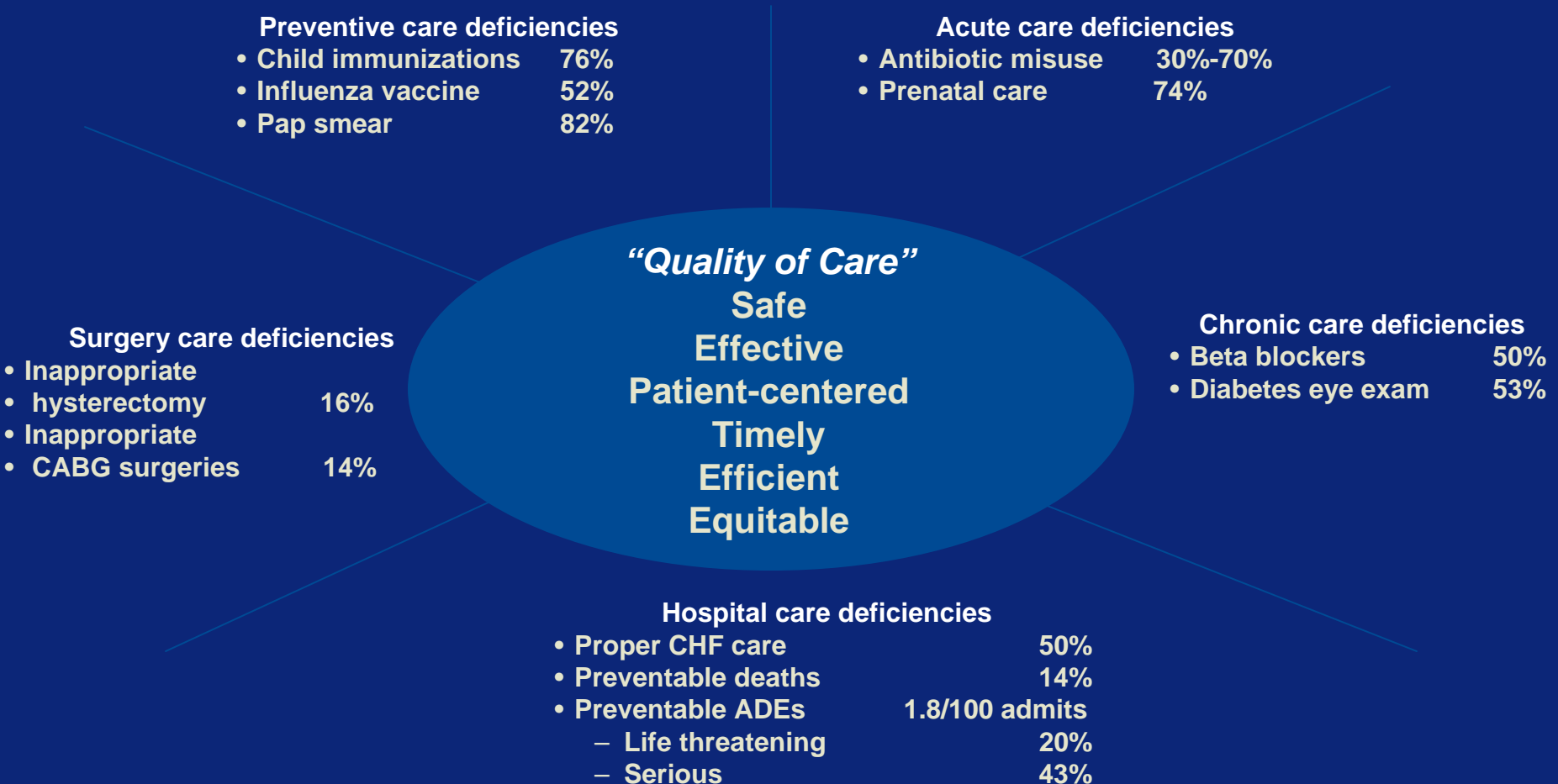
Results are impressive

- Virtual elimination of diphtheria, whooping cough, measles and polio
- Death rate from pneumonia reduced by 85%
- Over 90% reduction in deaths from tuberculosis
- Deaths from ulcers reduced by 60%
- In Hospital mortality from acute myocardial infarction reduced by 55% from 1975-1995 largely through the use of 3 drugs
- In industrialized nations there is a strong positive relationship between per capita pharmaceutical expenditure and life expectancy.
- In the 19 most prevalent diseases causing death, 73% of the reduction in life years lost before age 75 is due to new drug development.
- AIDS deaths in the U.S. reduced by over 50%

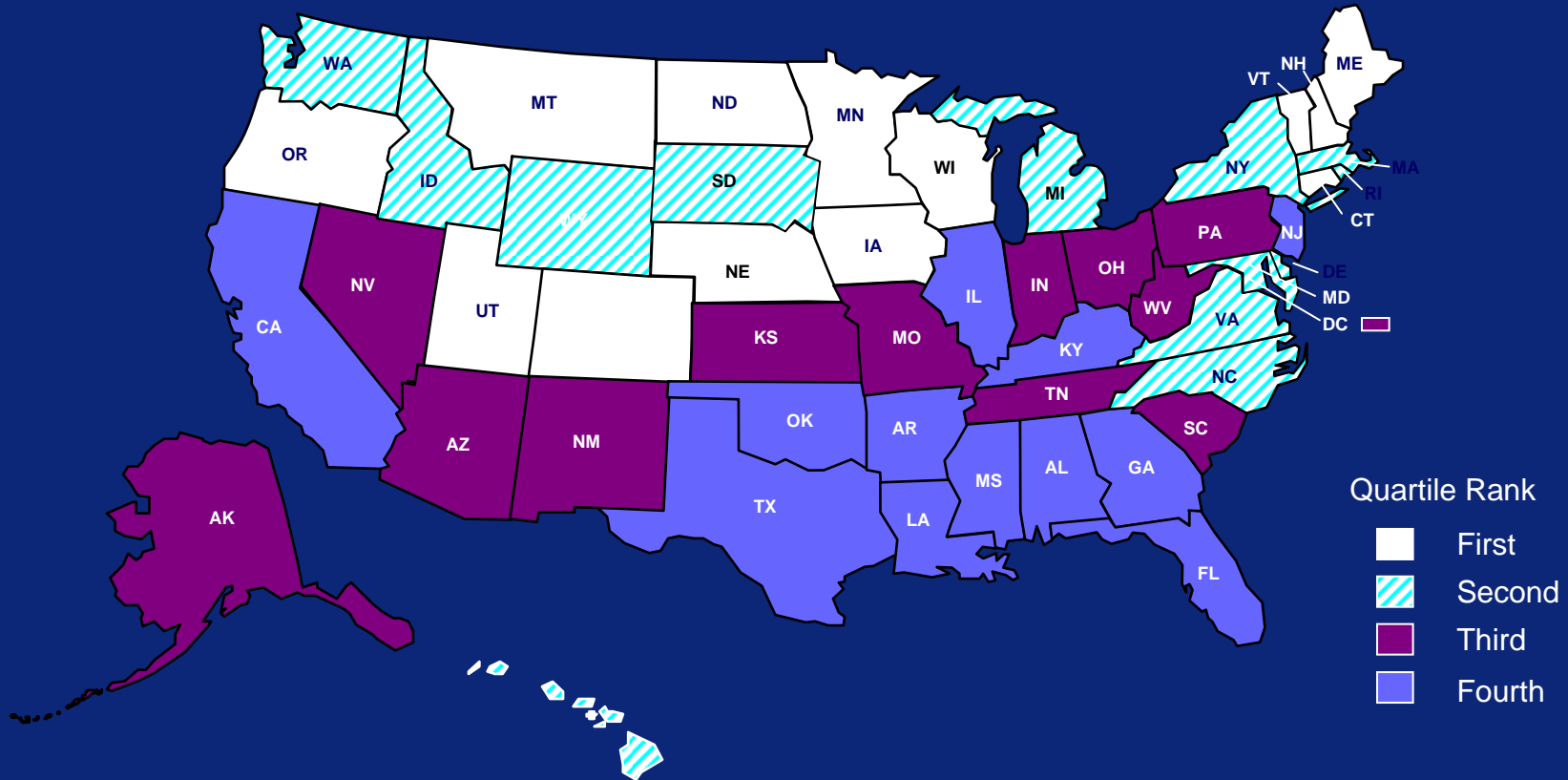
But it's costly: \$7,523 per person in the U.S.!



Quality is suboptimal: “The quality of care we get is far from the care we should be getting” —Don Berwick, IHI



Quality varies depending 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.

Why does “care” vary by where people live?

Two possible answers . . .

- People have different medical needs and expectations (preference-sensitive care)
 - Epidemiology and population health
 - Patient preferences (preference sensitive care)
- Physicians practice differently (supply sensitive care)
 - Practice patterns vary
 - Composition of medical community vary (supply sensitive care)

“Variation”: A basic framework

- Two major categories
 - Appropriate variation: *when the evidence isn't strong*
 - Inappropriate variation: *when the evidence is strong*
- Three types of inappropriate variation
 - Overuse
 - Underuse
 - Misuse

Example: Variation in chronic care during last six months of life

	<i>U.S. Average</i>	<i>Lowest</i>	<i>Highest</i>
<i>Days Spent in Hospital</i>	11.7	7.3 (UT)	16.4 (NY)
<i>Days in ICU</i>	3.2	1.5 (ND)	4.7 (FL)
<i>Physician Visits</i>	29.0	17.0 (UT)	35.5 (NY)
<i>% Seeing 10 or More Physicians</i>	27.5%	13.3% (ID)	35.6% (NY)
<i>% Deaths Associated with Admission to ICU</i>	18.5%	11.7% (SD)	25.1% (NJ)
<i>% Deaths enrolled in Hospice</i>	27.2%	6.7% (AK)	39.3% (CO)
<i>Medicare Expenditures (A,B) in Last Two Years</i>	\$29,199	\$23,855 (ND)	\$39,637 (DC)

Example: Geographic variation in the appropriate use of cesarean delivery

- There is enormous geographic variation in the use of cesarean delivery:
 - For births over 2,500 grams, adjusted cesarean rates vary fourfold between low and high-use areas.
 - Even for births under 2,500 grams, high-use counties have rates that are double those of low-use ones. Higher cesarean rates are only partially explained by patient characteristics but are greatly influenced by non-medical factors such as provider density, the capacity of the local health care system, and malpractice pressure. Areas with higher usage rates perform the intervention in medically less appropriate populations—that is, relatively healthier births—and do not see improvements in maternal or neonatal mortality.

Health Affairs 25 (2006): w355-w367; 10.1377/hlthaff.25.w355

Examples of inappropriate variation

Misuse

- 22% of patients take less medication than prescribed
- Antibiotic use for acute otitis media in children
- Bed rest instead of routine activity for back pain
- Cox2 inhibitors over older NSAIDS/ibuprofen (vioxx, celebrex 8-16 x more harmful)
- 16% of hysterectomies not necessary
- 14% of CABG procedures not necessary
- 7% of hospital patients experience serious medication error
- Antibiotic use for upper respiratory infections (physicians say it increases patient satisfaction)

Underuse

- Only 45% of diabetic patients receive appropriate care
- Only 53% of diabetics have retinal exam
- Only 50% of heart attack patients receive beta blockers
- Only 82% of women of pap smear
- Only 76% of children have immunizations
- Only 50% of elderly receive pneumococcal vaccine

Overuse

- No correlation between # of prenatal visits and outcome (birth)
- Urinalysis and culture for UTI in symptomatic women
- Tests for asymptomatic patients routinely done for which there is not evidence of efficacy:
 - Chest X Ray for elderly, smokers
 - Hemoglobin for anemia
 - ESR for inflammatory infective disease
 - Liver function tests in blood
 - Renal function tests
 - Calcium in blood
 - Uric acid in blood
 - PSA in men 50+
 - Glucose in blood
 - HDL/LDL ratio
 - Mammographs for women 40+
 - Ultrasound exam: ovaries
 - Bone densitometry in women
 - Resting ECG
 - Exercise ECG on treadmill
 - Ultrasound exam of aorta: males 55+
- 30% of children get excessive antibiotics for ear infections
- 20-50% of surgeries not necessary (IHI)
- 50% x-ray for low back pain not needed

Why so much variation? Adherence to evidence varies widely

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

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

And, we make mistakes

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

Study: health care costs, error rates higher in U.S. than in other countries

November 4, 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 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;

Study: health care costs, error rates higher in U.S. than in other countries (cont.)

- 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

A compounding problem: the uninsured

- **47,000,000 without insurance including 11,000,000 poor or un-insurable**
 - Most work . . .
 - Most are young . . .
 - Most would pay “something” . . .
 - Most receive services (but maybe too late or in the wrong place)

Our challenges are many . . .



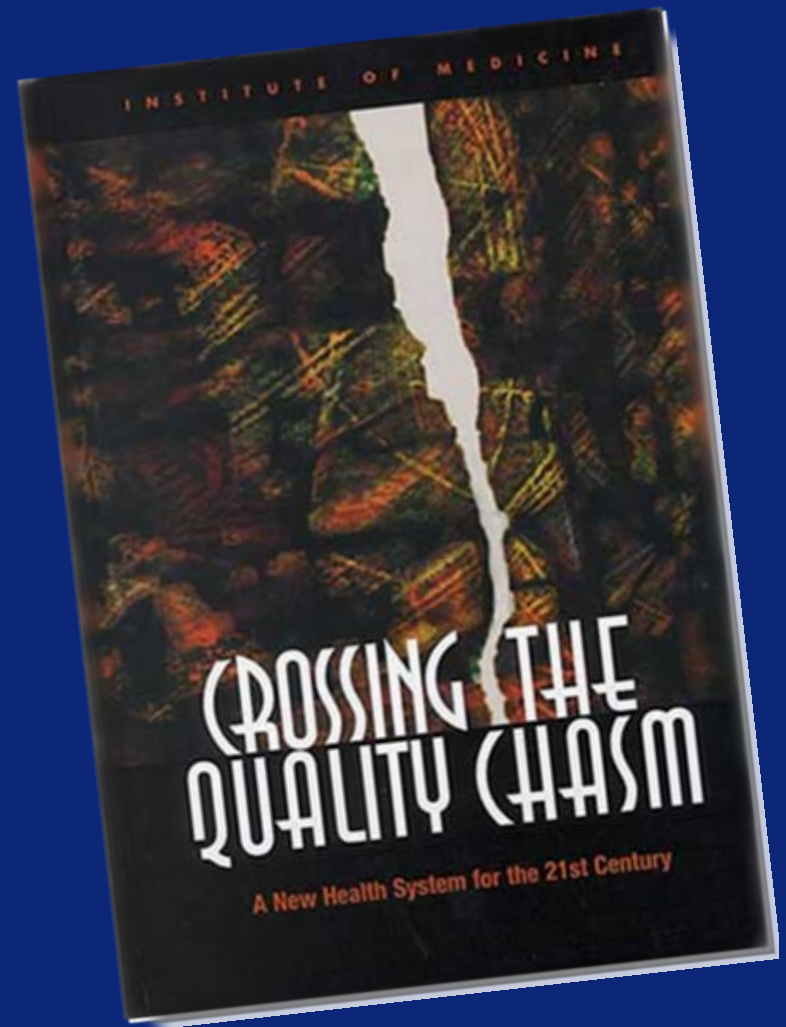
Context: health system transformation



Quality is our number one concern!!

- Evidence based care
- Patient centered approach
- System orientation

*It's the basis for our purpose,
worthwhile work, and
making a difference*



Evidence-based care management is the fundamental process for the delivery of safe and effective care

Service delivery processes

- Satisfaction with care management processes
- Amenities to reduce anxiety, increase comfort

Structural processes

- Access to needed services in appropriate settings
- Paperwork/administrative procedures to access services and document transactions

Evidence-based care management

- Adherence to evidence-based pathways in the diagnosis and intervention planning with patients
- Safe, effective, timely, patient-centered care
- Collaborative care management

Supportive

Primary

**Clinical
Excellence!**

Evidence-based care management is the confluence of three ongoing processes –

Clinician training and
experience
Life-long learning

Judicious integration
of relevant science
Knowledge management

Patient (consumer)
preferences, beliefs
and values
*Patient relationship
management and
information sharing*

“In an information dependent profession, there is far too often an alarming lack of access to needed information. It’s not that doctors don’t want to deliver the best care. The problem is that every physician can’t always remember for a given patient what the best care ought to be. They too often can’t remember or don’t know if a particular test was run by another doctor, or whether a patient filled or refilled a prescription”

Quote by George Halverson, Chairman and CEO
Kaiser Foundation Health Plans Inc. and Kaiser Foundation Hospitals
“Industrial Revolution”
Managed Care Executive December, 2004 (pp. 22-26).

Common misconceptions about EBM

<i>Misconception</i>	<i>Correct Concept</i>
EBM is cookbook medicine	EBM is based on population-based guidelines ; by definition, it's not applicable to every patient
EBM is a cost-containment strategy	EBM is a quality improvement strategy; consistently applied, it can reduce costs by reducing inappropriate variation
EBM is about changing physician behavior	EBM is about increasing adherence by clinicians and patients
EBM benefits payers most	EBM benefits patients most

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 . . .



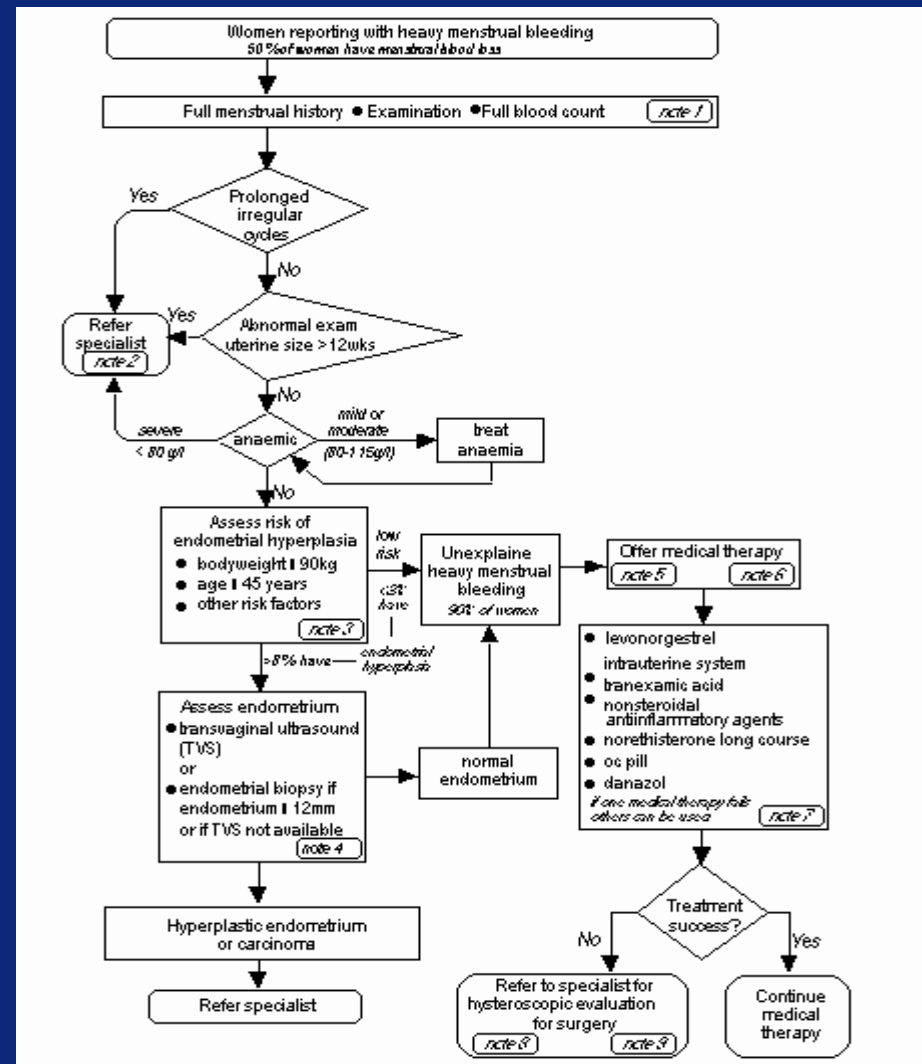
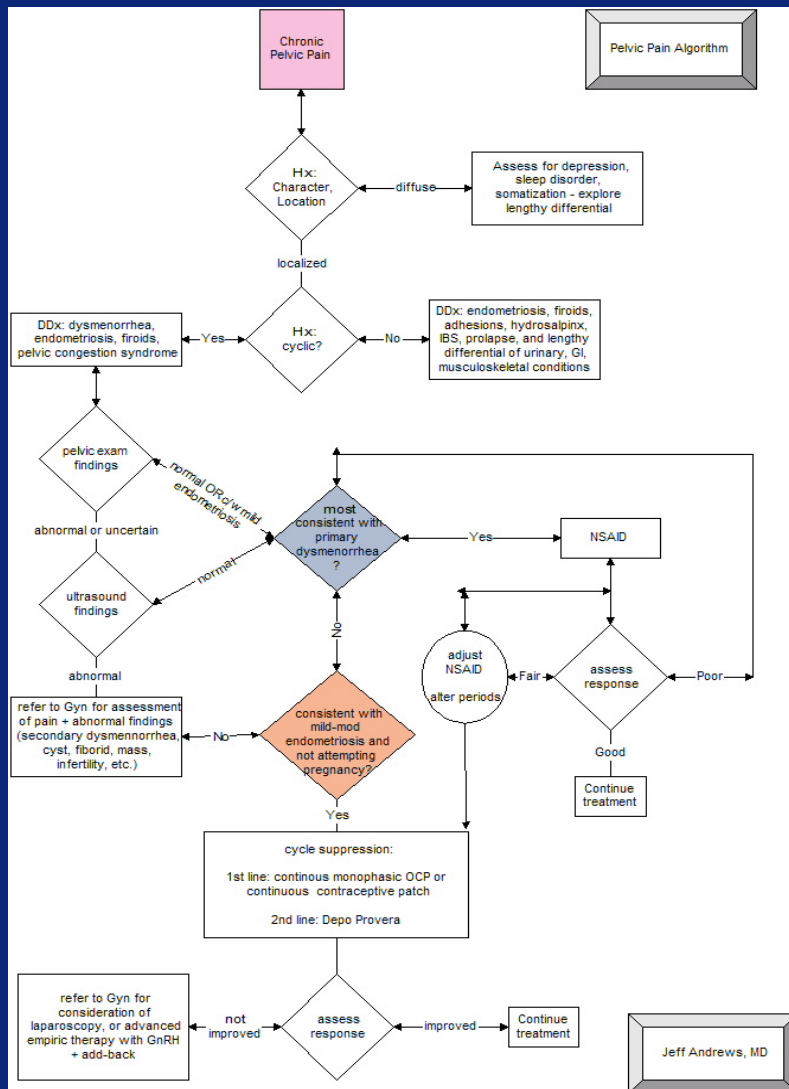
P... what's the population?

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



Process: evidence from scientific studies is critically appraised . . .



Considerations . . .

- Type of study
- Number of patients
- Quality of research
- Strength of effect
- Balance of benefits and risks
- Bias and influence
- Patient values and preferences
- Role of experience, expertise, consensus

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.

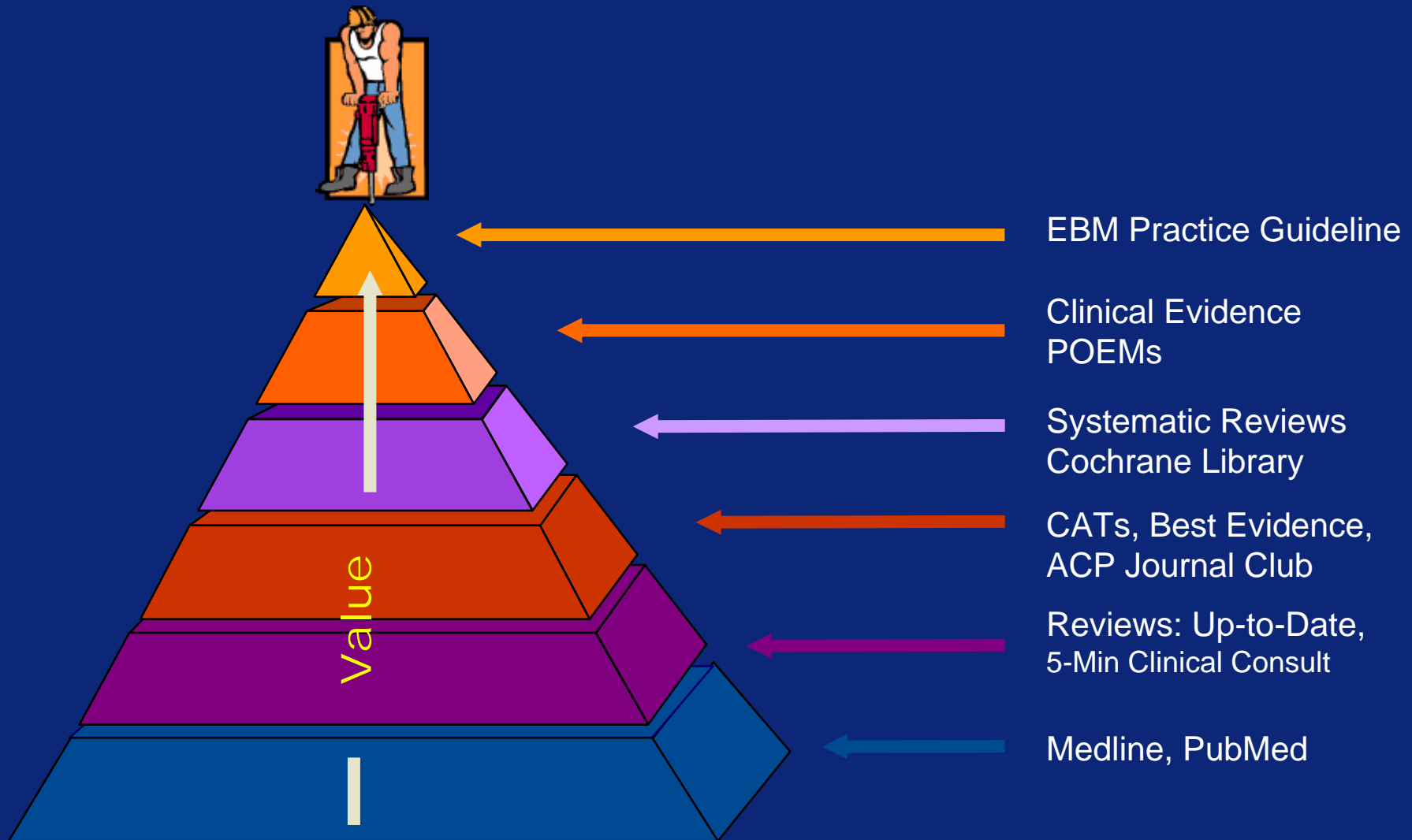
Grading system source: American College of Chest Physicians (ACCP)

Evidence Grade: A1

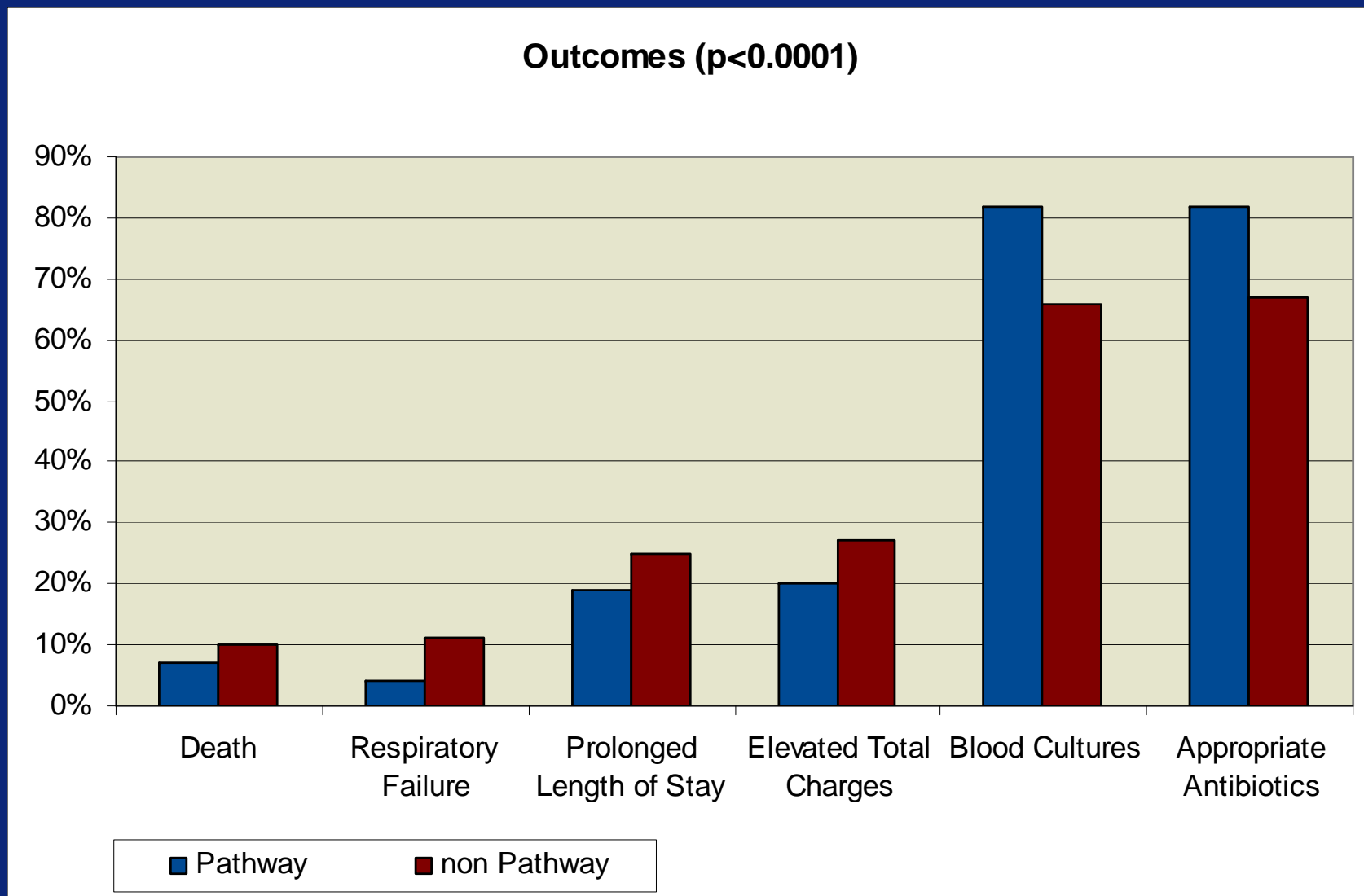
Back

Close

In practice, tools are used to stay abreast . . .



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



Ann. Epidemiology 2004;14:669-675

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

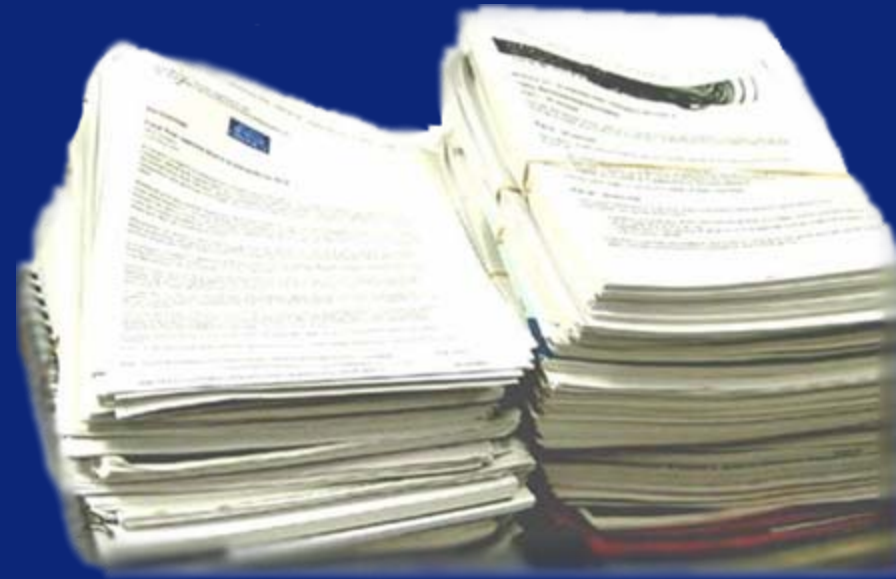
So why is variation so prevalent?

Why is inappropriate variation a problem?

Challenge: knowledge explosion

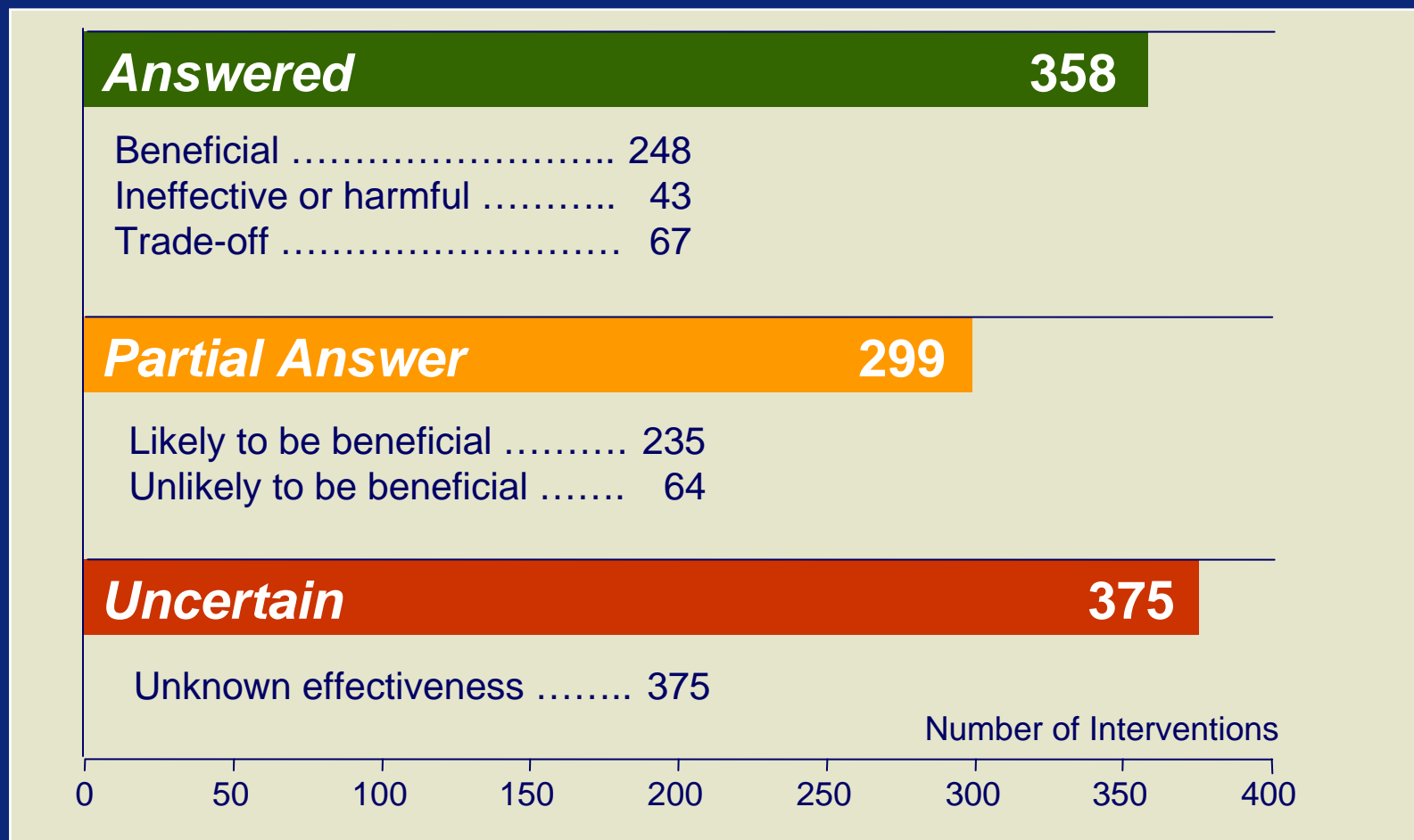
- 20,000 biomedical journals
- >150,000 medical articles published each month
- >300,000 randomized controlled trials

“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.com⁷.

URL for this article:

<http://online.wsj.com/article/0,,SB110669525595535929,00.html>

Hyperlinks in this Article:

- (1) <http://www.guideline.gov>
- (2) <http://www.icsi.org>
- (3) <http://www.guidelines.gov>
- (4) <http://www.icsi.org>
- (5) <http://www.informedhealthonline.org>
- (6) <http://www.ebm.vanderbilt.edu>
- (7) <mailto:Informedpatient@wsj.com>

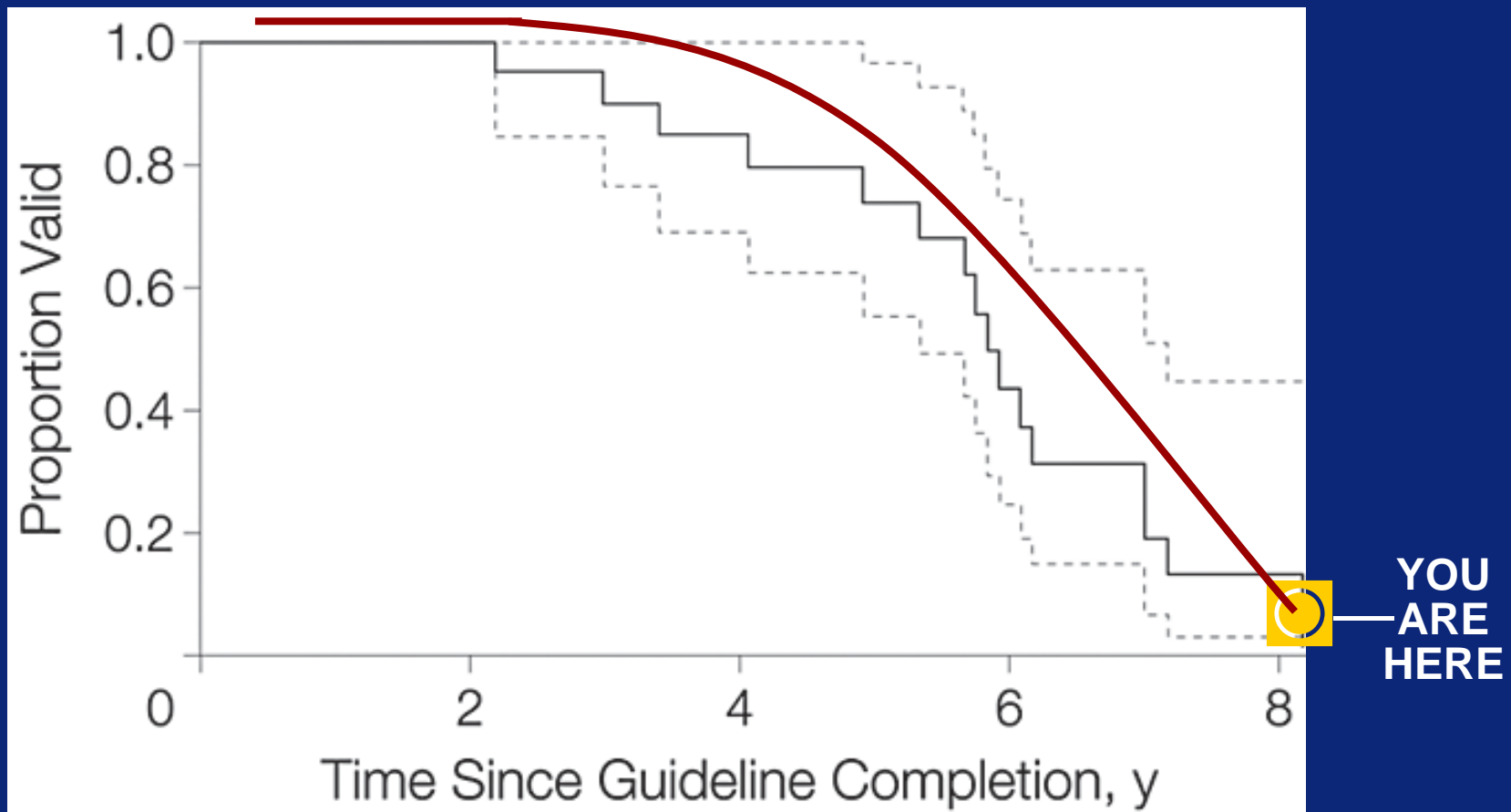
THE WALL STREET JOURNAL.

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

Acrobat Reader - [WHI JAMA 7-17-02_Ref00095.pdf]

File Edit Document View Window Help

ORIGINAL CONTRIBUTION JAMA-EXPRESS

Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women

Principal Results From the Women's Health Initiative Randomized Controlled Trial

Writing Group for the Women's Health Initiative Investigators

THE WOMEN'S HEALTH INITIATIVE (WHI) focuses on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in postmenopausal women. Between 1993 and 1998, the WHI enrolled 161 809 postmenopausal women in the age range of 50 to 79 years into a set of clinical trials (trials of low-fat dietary pattern, calcium and vitamin D supplementation, and 2 trials of post-

Context Despite decades of accumulated observational evidence, the balance of risks and benefits for hormone use in healthy postmenopausal women remains uncertain.

Objective To assess the major health benefits and risks of the most commonly used combined hormone preparation in the United States.

Design Estrogen plus progestin component of the Women's Health Initiative, a randomized controlled primary prevention trial (planned duration, 8.5 years) in which 16 608 postmenopausal women aged 50-79 years with an intact uterus at baseline were recruited by 40 US clinical centers in 1993-1998.

Interventions Participants received conjugated equine estrogens, 0.625 mg/d, plus medroxyprogesterone acetate, 2.5 mg/d, in 1 tablet (n=8506) or placebo (n=8102).

Main Outcomes Measures The primary outcome was coronary heart disease (CHD) (nonfatal myocardial infarction and CHD death), with invasive breast cancer as the primary adverse outcome. A global index summarizing the balance of risks and benefits included the 2 primary outcomes plus stroke, pulmonary embolism (PE), endometrial cancer, colorectal cancer, hip fracture, and death due to other causes.

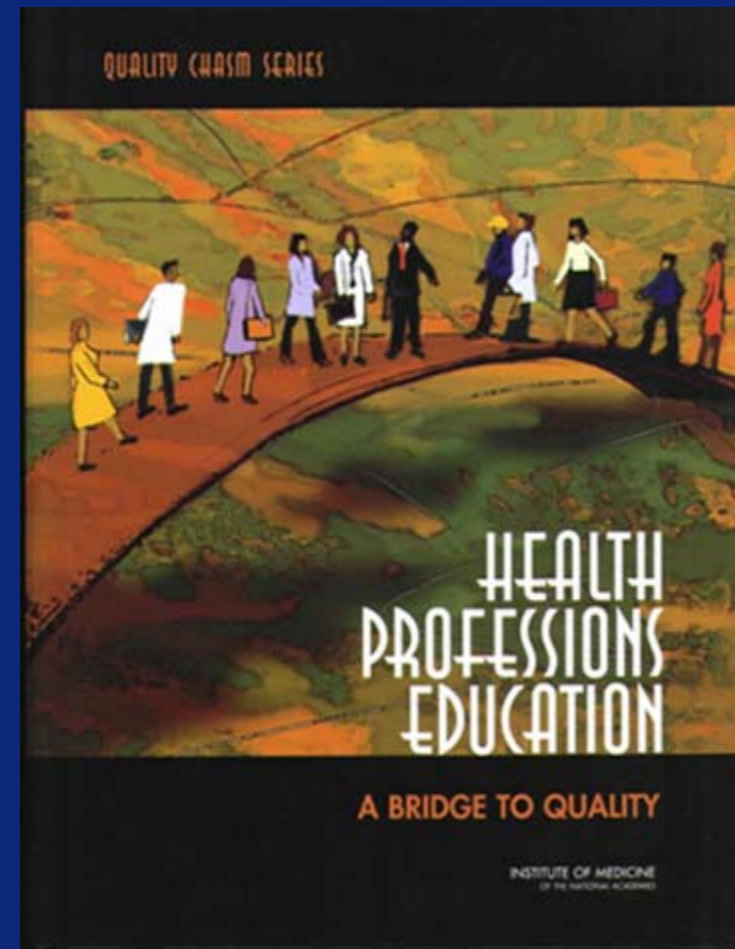
Results On May 31, 2002, after a mean of 5.2 years of follow-up, the data and safety

150% 1 of 13 8.5 x 11 in

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!



* 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 . . .

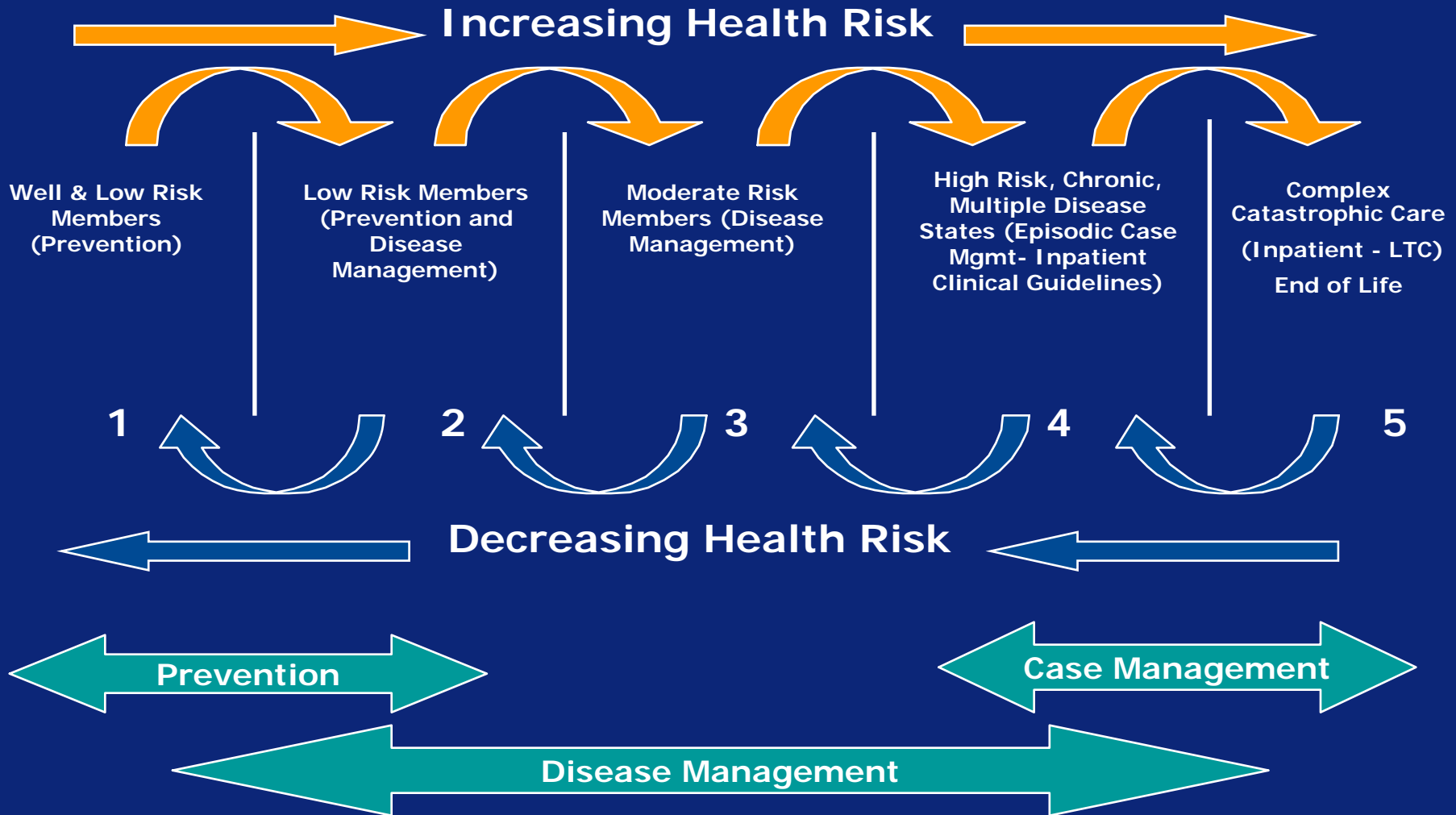
- “They don’t pay for it”
- “The tools aren’t available”
- “My patients don’t care”
- “It’s a fad”
- “The only evidence I need is what I know”

Is it going away?

Predictive models: a strategic framework

- Focus: to intervene early where there can be a positive impact on quality that yields cost savings
- Value Proposition:
 - Early identification allows clinicians to be proactive to mitigate any further deterioration in health
 - Positively influence patient habits and match to useful tools and resources

Population-based care management framework



Implications for predictive modeling

- Increased need for access to clinical data from provider and patient sources
- Increased integration with personalized therapeutics
- Increased visibility of processes (transparency)

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