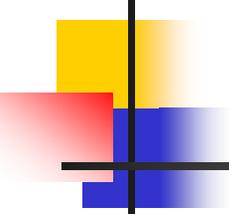


Systematic reviews of amputation healthcare

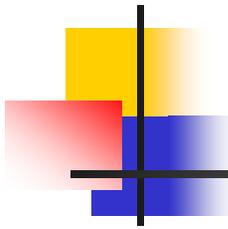
Mark Helfand
Oregon EPC
May 2004

(some material courtesy of CDR Ken S. Yew)



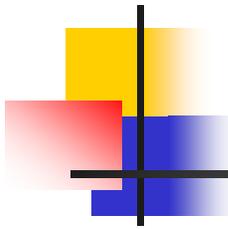
Evidence-based Practice Centers

- Created in 1997; 10 centers (now 13)
- Produce
 - “evidence reports”
 - systematic reviews
 - technology assessments
 - Methods manuals and articles
 - meta-analyses and cost analyses
 - analysis of large databases
- Work with public and private sector partners



Outline

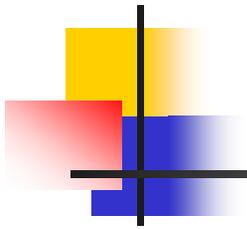
- Evidence-based guidelines
- Systematic reviews
- The role of evidence-based resources in developing a research agenda across disciplines



What is evidence-based medicine?

“Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values.”

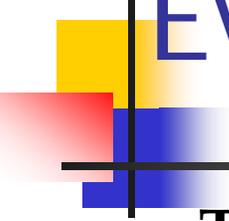
David Sackett



What is a clinical practice guideline?

Clinical guidelines are systematically developed statements to assist practitioners and patients in choosing appropriate healthcare for specific conditions

The Institute of Medicine



Evidence Based Guidelines

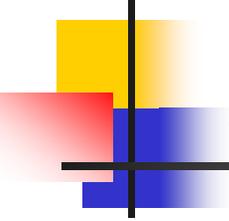
Traditional Paradigm

- Unsystematic Experience
 - Anecdote
 - Apprenticeship
 - Expert opinion
- Pathophysiologic Rationale
- Clinical Intuition
- Possible Benefit

System
➔
Resources

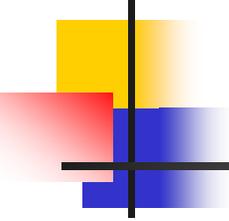
Evidence-based Practice Paradigm

- Knowledge of
 - Evidence &
 - Strength of evidence
- Quantitative statement of benefit and risk
- Patients' values & preferences
- Informed decision-making



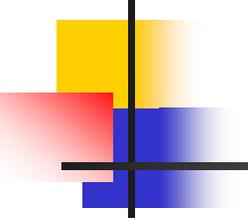
An evidence-based guideline

- Makes use of an independent, systematic review of the evidence



Systematic literature reviews

- Are *systematic* to remove bias in finding and reviewing the literature.

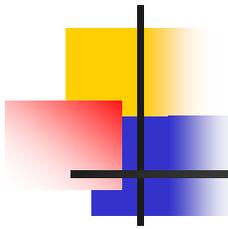


Systematic literature reviews

- Are *systematic* to remove bias in finding and reviewing the literature.
 - *Experts may underplay controversy or select only supportive evidence*

How sure are we?

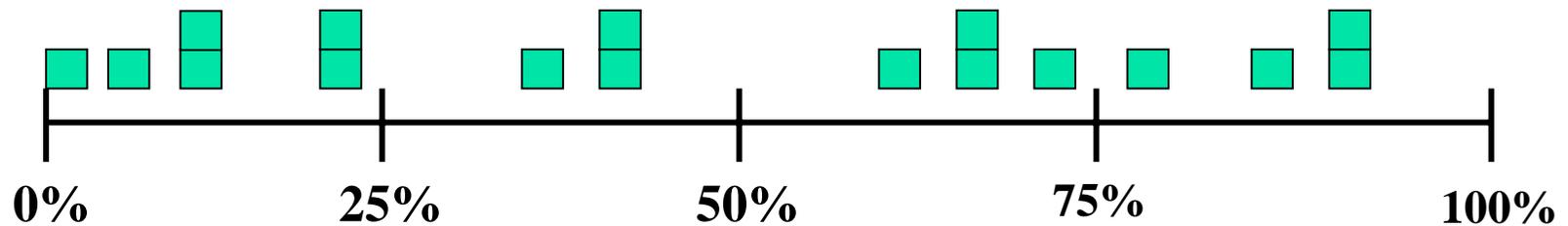
Expert estimates of breast implant rupture rates



0%	0.2%	0.5%	1%	1%	1%	1.5%	2%	3%	3%	4%	
5%	5%	5%	5%	5%	5%	5%	5%	6%	6%	6%	8%
10%	10%	10%	10%	13%	13%	15%	15%	18%			
20%	20%	20%	25%	25%	25%	30%	30%	40%			
50%	50%	50%	62%	70%	73%	75%	75%	75%			
75%	80%	80%	80%	80%	80%	80%	80%	100%			

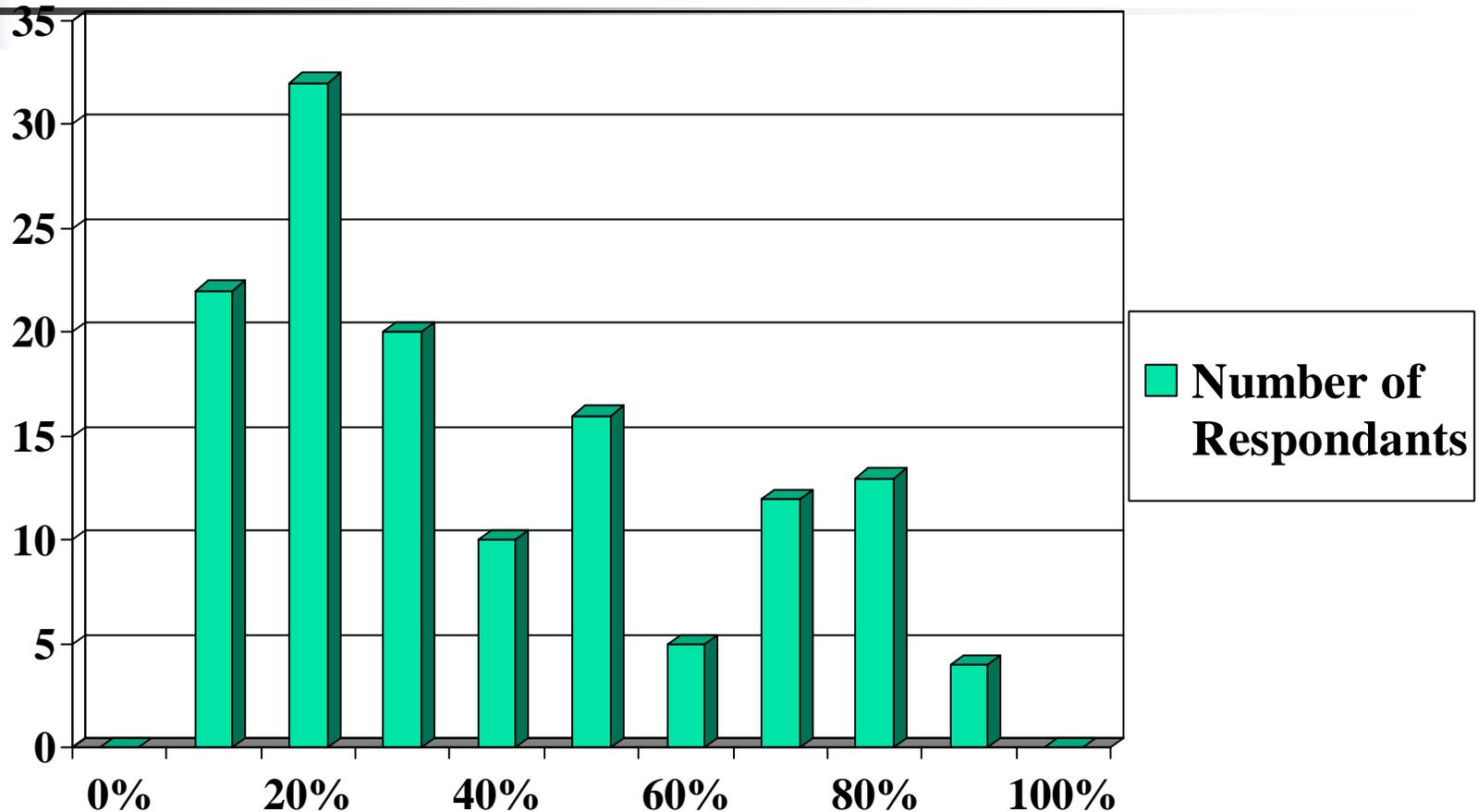
Source: Dr. David Eddy

Experts estimates of the effect of colon cancer screening on chance of dying

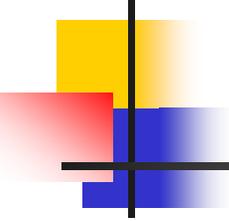


Source: Dr. David Eddy

Experts' estimates of probability of acute retention in men with BPH

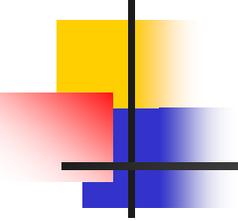


Source: Dr. David Eddy



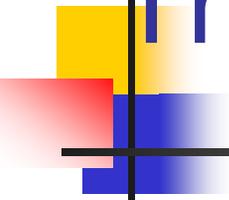
Cognitive Biases

- In fact we are not very good at converting facts into accurate beliefs and actions
 - Complexity of medical practice
 - Complexity of research
 - Limitations of the human mind
 - Personal & professional biases



Systematic literature reviews

- Are *systematic* to remove bias in finding and reviewing the literature.
 - *Experts may underplay controversy or select only supportive evidence*
- Emphasizes the best evidence



The best evidence

- addresses health outcomes rather than intermediate outcomes.

Direct vs Indirect evidence

Brain-injured patients

Cognitive
Rehabilitation



PASAT, neuropsych battery

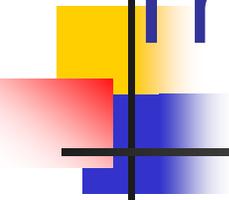


**Function return to work,
work maintenance, social
function**

Intermediate
or
Surrogate
Outcome

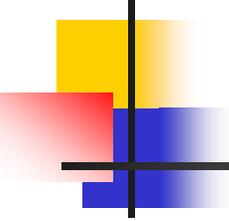
Health
Outcomes

1



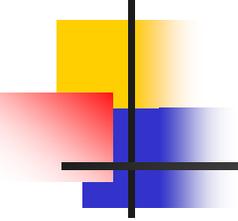
The best evidence

- addresses health outcomes rather than intermediate outcomes.
 - uses outcome measures important to the patients
 - “Issues of importance”
 - Recreational activities



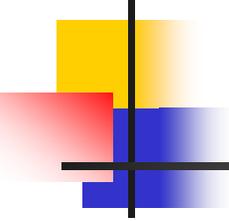
The best evidence

- addresses health outcomes and not just intermediate outcomes
- Fits the circumstances
 - not just highly selected patients in research studies.
 - Uses a study design that matches the question



The best evidence

- addresses health outcomes and not just intermediate outcomes
- fits the circumstances
- considers the potential disadvantages as well as the advantages of the intervention being considered.
 - *The most useful sources of information have both.*

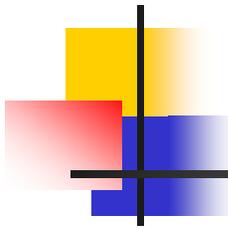


The best evidence

- addresses health outcomes and not just intermediate outcomes
- is from “real” patients like ours, not just highly selected patients in studies.
- considers the potential harms as well as the benefits of the intervention being considered.
- Fits the circumstances.
- Comes from well-designed studies.

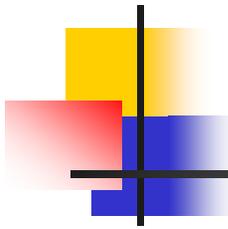
We follow the *consequences*, not merely the fact, of study design “flaws.”

Because they lack the same protections, observational studies must meet HIGHER, not lower standards of quality



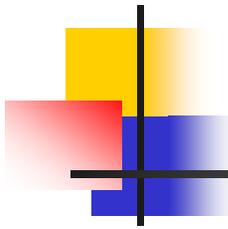
Systematic Reviews in amputation medicine

- VATAP *Computerized lower limb prosthesis* (2000)
- Halbert et al *Optimal management of acute and chronic phantom pain* (2002)
- Cochrane Review (Hofstad) *Prosthetic prescriptions* (2003)
 - SACH vs. Flex Foot



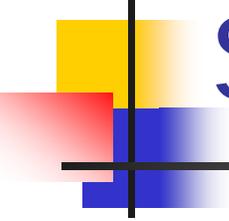
Systematic Reviews in amputation medicine

- Smith, DG... Czerniecki, *Postoperative dressing and management strategies for transtibial amputations: a critical review*, (2003)
“Analysis of 10 controlled studies supported only 4 of the 14 claims cited in uncontrolled, descriptive studies.”



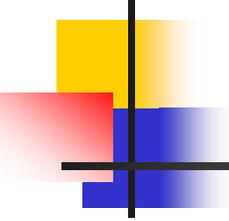
Most common problems with observational studies

- Unclear goals
- No inception cohort
 - Identifying cases by presence of an outcome measure
- Biased sample
 - Patients who take a drug long-term are at lowest risk of problems
- Inadequate ascertainment
- Suggestibility
- Don't report on harms (to examine trade-offs)



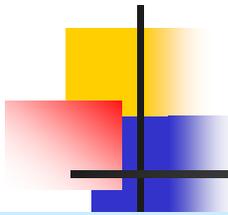
Systematic reviews

- Define the strengths and limits of the evidence.
- Clarify what is based on evidence and what is based on other grounds.
- Do not necessarily tell you what to do when the evidence is limited. Other factors, such as equity, judgment, values, and preferences play a role in using the evidence.



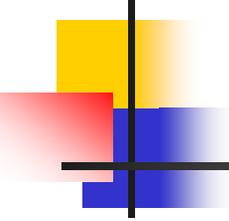
An evidence-based decision process

- Makes use of an independent, systematic review of the evidence
- Employs rules for linking evidence to recommendations



Strength of recommendations

Quality of Overall Evidence	Estimate of Net Benefit (Benefit Minus Harms)			
	Substantial	Moderate	Small	Zero/Negative
Good	A	B	C	D
Fair	B	B	C	D
Poor	I – Insufficient Evidence			



An evidence-based decision process

- *Makes use of an independent, systematic review of the evidence*
- *Employs rules for linking evidence to recommendations*
- Produces explicit, defensible recommendations based on evidence and values
 - The evidence determines the conclusion, not vice versa
 - Not, the citation of papers supporting a preformed conclusion (and trashing of those that don't)
 - Not, the use of evidence when it is 'positive' but judgement when it isn't

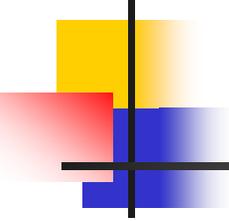


+ Rules for linking
evidence to
recommendations

+
local judgments
and values

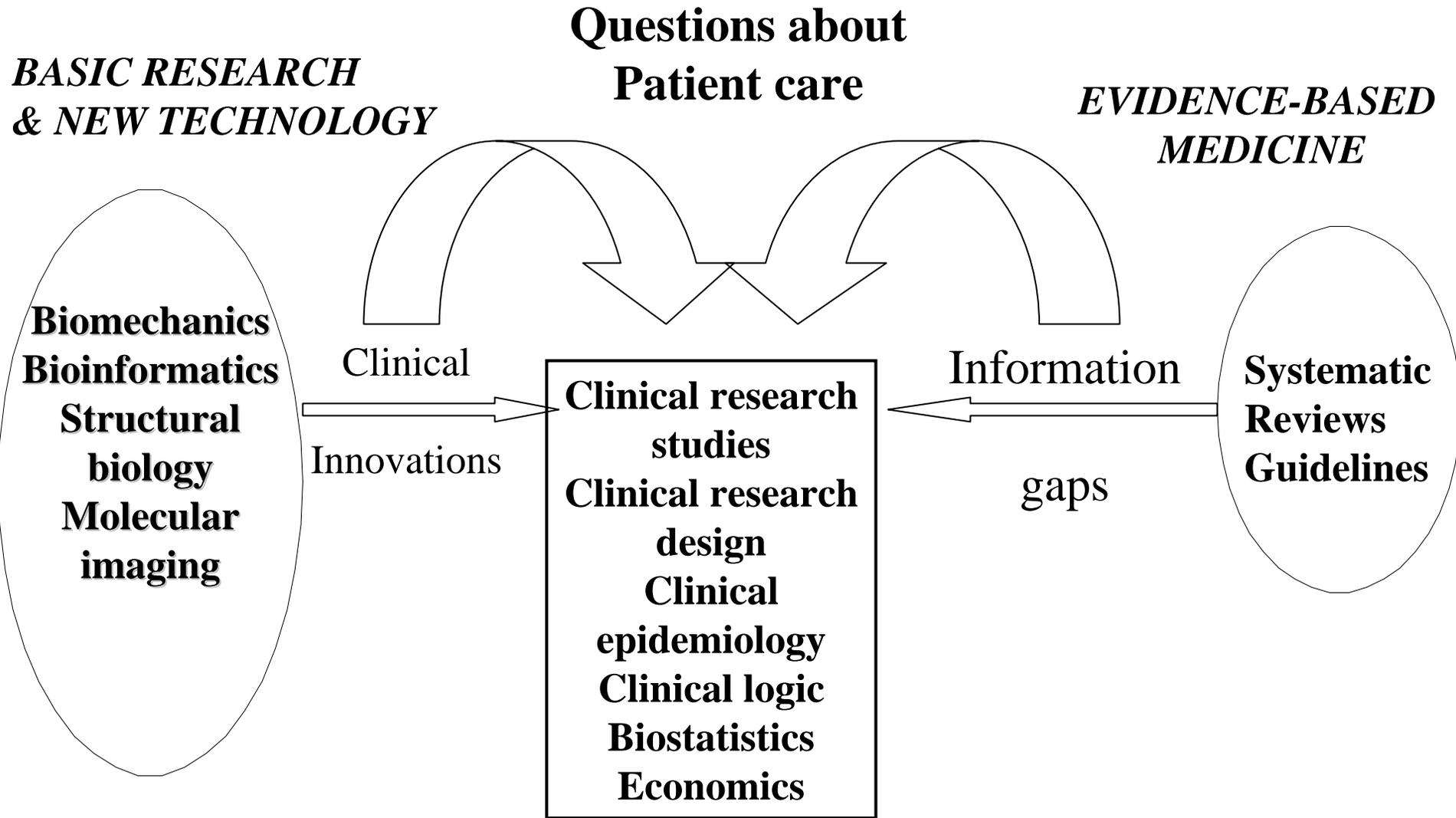
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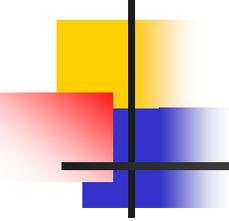
Evidence-based decision-making



Research Issues

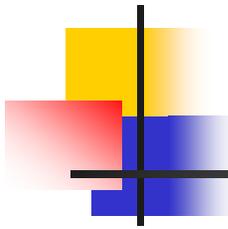
- Focuses on clinical logic
 - *Sometimes challenging conventional wisdom*
- Focuses of outcomes patients care about
- Identify information gaps and gaps in logic
 - *To develop a research agenda that directly takes on questions underlying controversy or uncertainty*





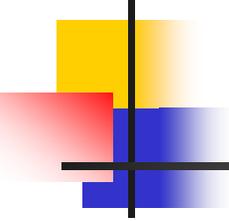
EPC Roles

- Conduct *independent*, systematic reviews to identify information gaps and research needs
 - Put focus on outcomes important to patients
 - Validity of measures
 - Effectiveness of alternative treatments/devices
- Assist with priority-setting
- Identify *practical trial designs* and stronger *observational study designs*
- Find relevant systematic reviews
- Provide consultation to investigators doing evidence syntheses
 - Short bulletins on methodologic topics and new resources



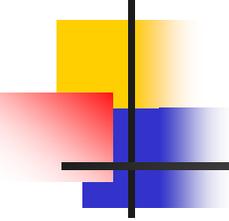
Steps in conducting a SR

- **problem formulation (selecting questions)**
- finding evidence
- selecting evidence
- synthesizing & presenting evidence
- Identify information gaps and future research agenda
- peer review and revision
- maintaining and updating reviews



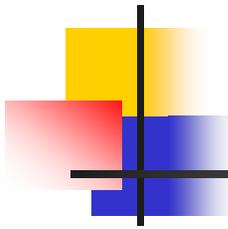
Selecting questions

- *Important questions arise from experience.*
- *“Experts in practice”—clinicians and patients--select the populations, interventions, and outcome measures of interest.*



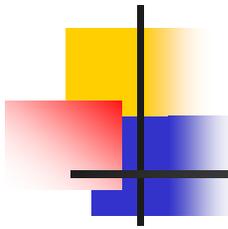
Medical Systems Do Not Support Answering Questions

- Practice environment not supportive
 - Reimbursement geared towards procedures and volume
 - Inadequate time
- Data sources inadequate
 - Not up to date
 - Too time-consuming to access
 - Not geared to questions docs have
- Education often inadequate
 - Many journal articles have significant biases
 - CME often interest-sponsored and didactic



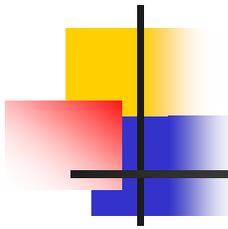
Selecting questions

- We can learn from discrepancies between what decision-makers want to know and what researchers measure
- *Often, clinical reasoning is based on hidden assumptions*



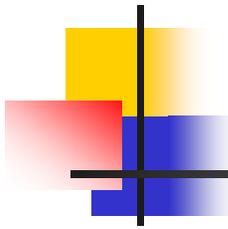
Oregon EPC "partners"

- Institute of Medicine
 - skin cancer prevention
 - screening for thyroid cancer
- National Institutes of Health
 - rehabilitation for brain injury
 - tests for osteoporosis
 - interventions to prevent youth violence
- Medicare
 - treatment for actinic keratosis
 - telemedicine



Oregon EPC "partners"

- Private Foundations
 - RWJ Foundation (self-care manuals, counseling to change health behaviors)
 - Susan Komen Foundation (which methods of promoting mammography are most effective?)
- Professional societies
 - American Academy of Neurology (stroke)
 - Brain Injury Association (rehabilitation)



Oregon EPC "partners"

- AHRQ
 - Patient safety and the healthcare workplace
 - Hyperbaric oxygen therapy for brain injury
- U.S. Preventive Services Task Force
- Multistate Drug Evaluation Project

Evidence Based Practice

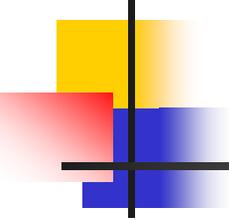
Traditional Paradigm

- Unsystematic Experience
 - Anecdote
 - Apprenticeship
 - Expert opinion
- Pathophysiologic Rationale
- Clinical Intuition
- Possible Benefit

System
➔
Resources

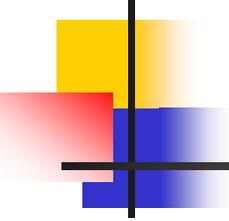
EBP Paradigm

- Knowledge of
 - Evidence &
 - Strength of evidence
- Quantitative statement of benefit and risk
- Patients' values & preferences
- Informed decision-making



Hierarchy of Guidelines

- Explicit evidence-based guidelines
 - Based on outcomes and patient preference
 - Projects / weighs benefits and harms
- Evidence-based without extrapolation of impacts
 - Do not look at impacts of guideline implementation on the healthcare outcomes of the population
- Consensus based or global subjective judgment
 - May also be “evidence-sprinkled”
- No development process evident



Attributes of Good Guidelines

- Provide genuine guidance
- Population defined clearly
- **Evidence-based**
- Clear
- Flexible
- Exceptions described
- Measurable
- Implementable
- Current

Level 1: *“Would you have this done for yourself or for someone else in your immediate family?”*

Influenced by one's personal experience with the disease and capacity to deal with risk.

Affects few people.

Level II: *“What would I recommend to my patient/client?”*

Physician making a recommendation for his/her patients. Influenced by prior experience, but the scientific evidence may play a greater role.

Affects possibly hundreds of people.

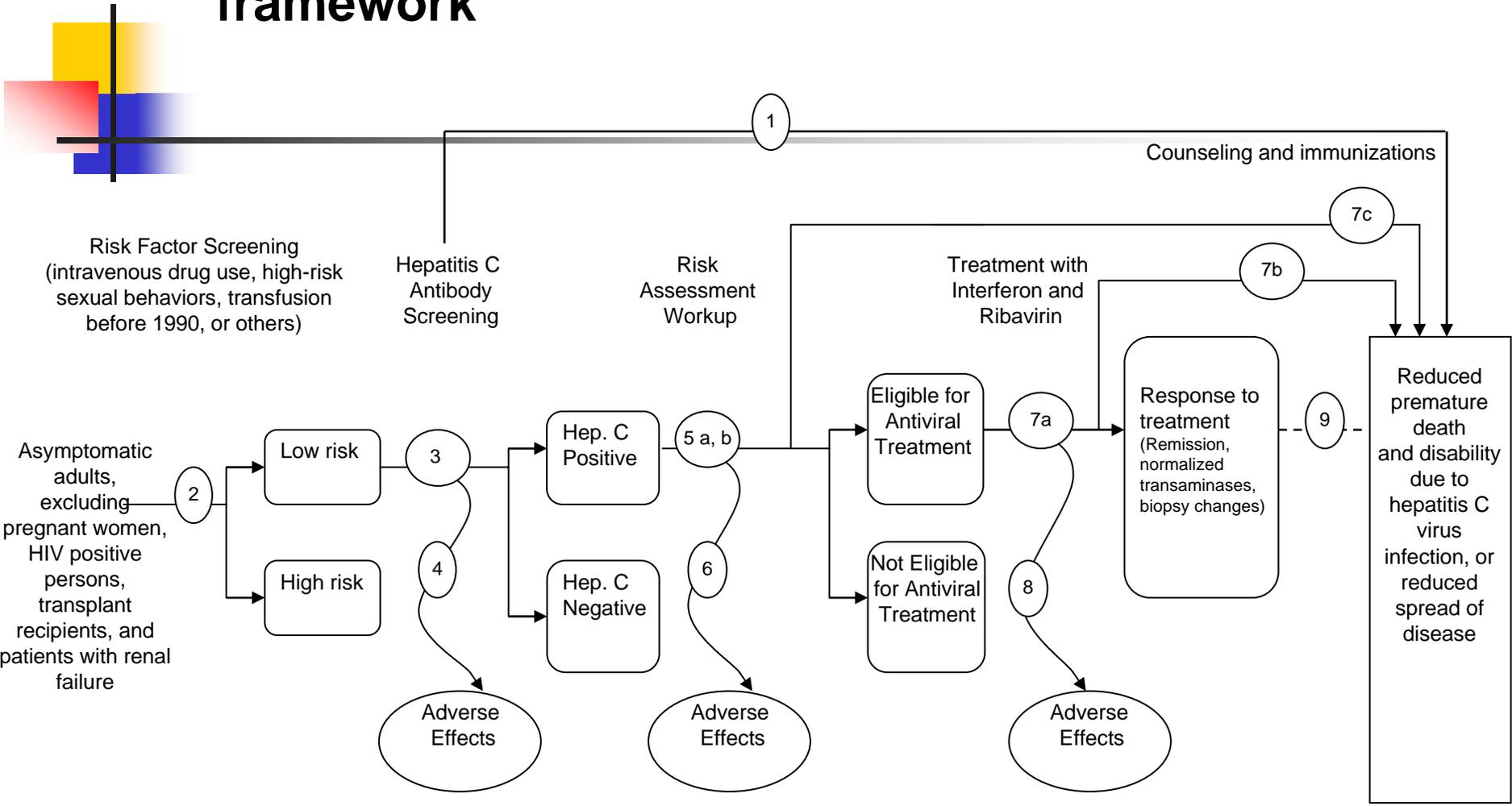
Level III: *“What would I recommend to the nation, the world?”*

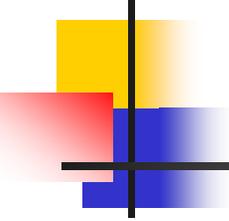
Across-the-board recommendations for a population.

Must be based on rigorous assessment of the scientific evidence.

Affects hundreds of thousands, even millions of people.

Screening for Hepatitis C: Analytic framework





Pitfalls

- Overstating the evidence about evidence
- Unreachable evidence
- Applicability (generalizability) and adverse events tend to get insufficient attention
- Operator-dependent