

Shared Decision Making, Ethics and Shared Responsibility



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We Believe Patients Should Be



Supported & encouraged to participate in their health care decisions



Fully informed with accurate, unbiased & understandable information



Respected by having their goals & concerns honored

Themes for Today's Lecture

Rethinking Informed consent- Shared Decision Making

How Decisions are made

Why Patients need to be engaged

Impact of Shared Decision Making on Clinical Practice

Why Patients should see it as a fundamental right

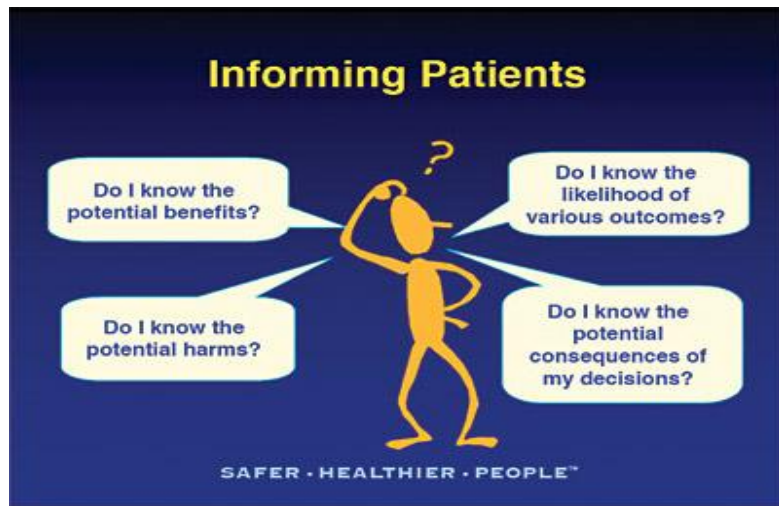
National Health Care Spending Stats

- According to CBO...
 - In 2005, National spending on health care totaled 1.9 Trillion or 14.9% of GDP
 - Spending on Health Care was 16% of GDP in 2007, projected to rise to 25% by 2025
 - 49% of GDP by 2050- Not sustainable
 - In 2009, Medicare spent \$55 Billion for physician and hospital bills during patient's last two month's of life

National Health Care Spending Stats

- That \$55 Billion is more than Dept. of Education or Homeland Security...
 - And it is estimated that 20-30% may have had no meaningful impact at all
- Vast majority of Americans want to die at home, yet 75% die in a hospital or nursing home with many medical interventions

Shared Decision-Making: a Definition



- **Integrative process between patient and clinician that:**
 - **Engages the patient in decision-making**
 - **Provides patient with information about alternative treatments**
 - **Facilitates the incorporation of patient preferences and values into the medical plan**

(Charles C, Soc Sci Med 1997; 44:681)



The enduring ethical imperative

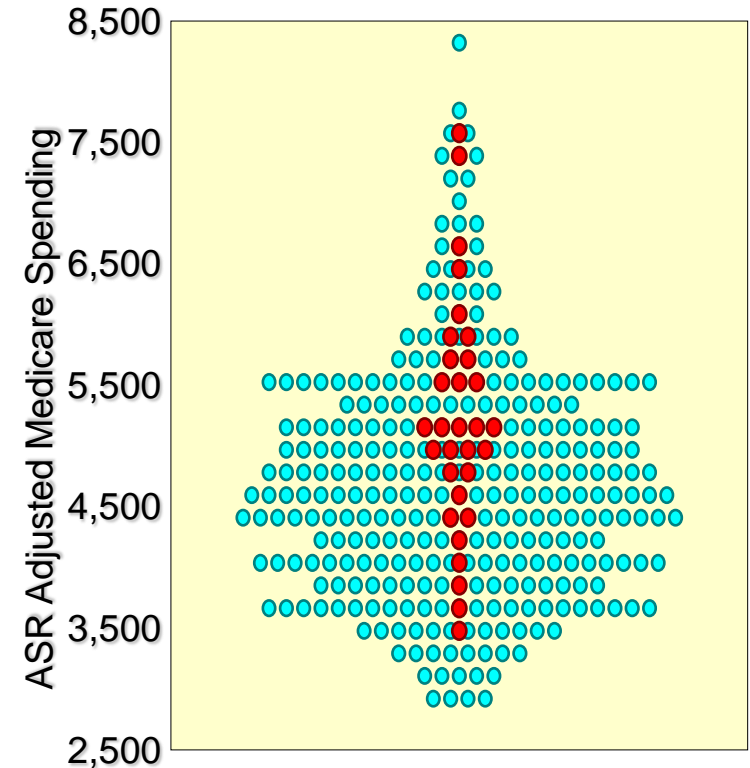
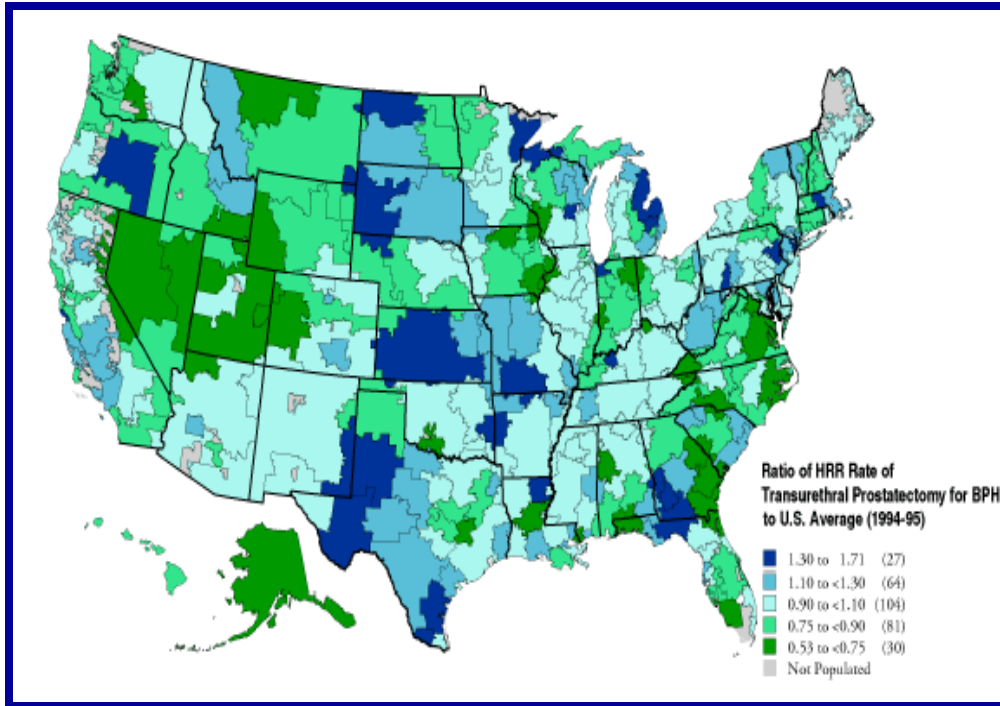


“ . . . these strange bare facts of incidence . . . ”
“ . . . tendency for the operation to be performed for no particular reason and no particular result.”
“ . . . sad to reflect that many of the anesthetic deaths . . . were due to unnecessary operations.”
1931-1935 Tonsillectomy listed as cause of death 513 times of those 369 were children

Glover, 1938



Practice Variation: Evidence for Poor Decisions

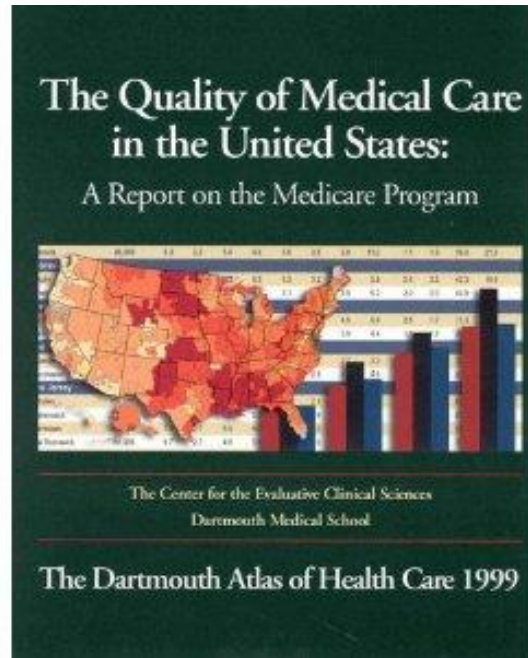


Red Dots Indicate HRRs Served by U.S. News 50 Best Hospitals for Geriatric Care

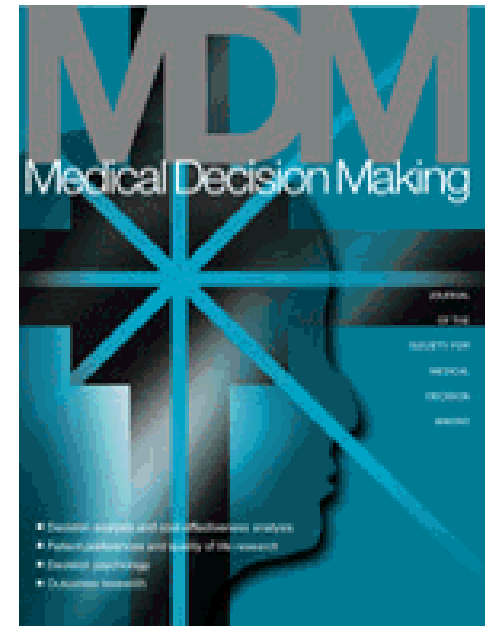
Why Shared Decision Making in Health Care?



Evidence of the Problem



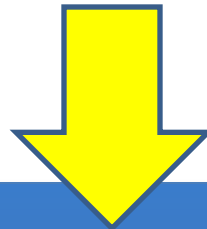
Medical Practice Variation
*40 Years of Research Documenting
Inconsistent Care*



The DECISIONS Study
*A Portrait of How Americans Make
Common Medical Decisions*

Patients:
Making Decisions in the
Face of Avoidable
Ignorance

Clinicians:
Poorly “Diagnosing”
Patients’ Preferences



Poor Decision Quality

DECISIONS Survey



- **Conducted by University of Michigan**
- **Nationwide random-digit dial telephone survey**
- **Probability sample of 2575 English speaking Americans age 40⁺**
- **Reported a discussion of 1 of 9 medical decisions with a health care provider within the past 2 years**
- **Response rate 51%**

Decisions Survey: Decisions Addressed

- **Surgery**
 - Back surgery,
 - knee/hip replacement
 - cataract extraction
- **Cancer screening**
 - Prostate,
 - Colorectal
 - Breast
- **Medications**
 - Hypertension,
 - Hyperlipidemia,
 - Depression



Epidemiology of Medical Decisions in US

- **In the past 2 years:**
 - **56% discussed starting or stopping meds for hypertension, hyperlipidemia or depression**
 - **72% discussed a screening test for cancer**
 - **16% discussed one of the 4 operations**

What did Clinicians Recommend?

- **Surgery:**
 - about **65%** of recommendations: “do it”
- **Screening:**
 - about **95%** of recommendations: “do it”
- **Medications:**
 - over **90%** of recommendations: “do it”

JUST DO IT.



Were Patients Asked for their Opinions?

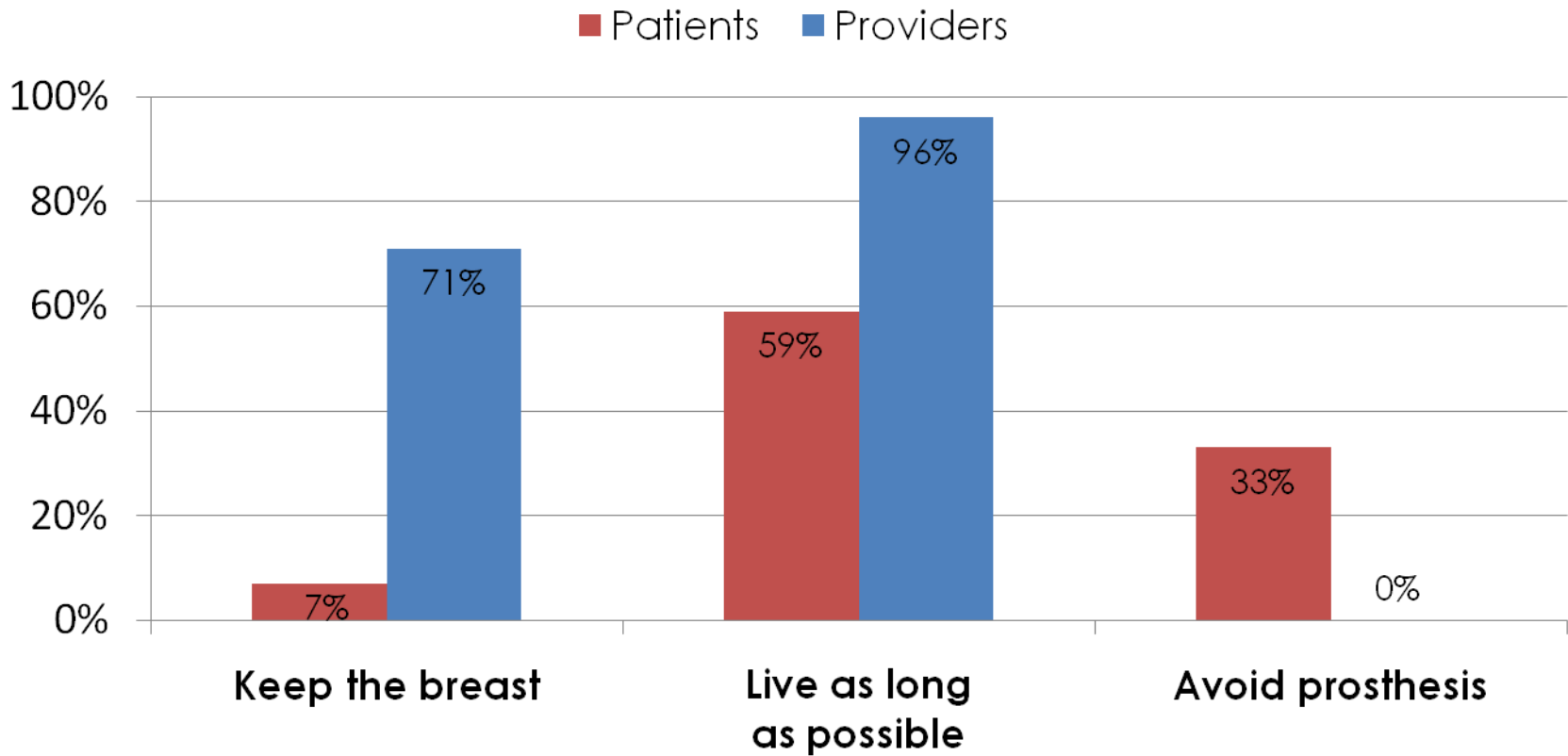
- **For surgery:**
 - **About 1/2 the time for the orthopedic surgeries;
1/3 of the time for cataracts**
- **For screening:**
 - **Less than 1/5 of the time for decisions about
cancer screening**
- **For medications:**
 - **About 1/3 of the time**

How Much did Patients Know ?



- **Clinical experts identified 4-5 facts a person should know, for example, common side effects of medications or surgery**
- **Respondents were asked the knowledge questions related to their decision**
- **For 8 out of the 10 decisions, fewer than half of respondents could get more than one of the knowledge questions right.**

How Well Do Providers Predict Patient Preferences?



Rhode Island Hospital Performed Surgery on Wrong Body Part for Fifth Time

The Rhode Island Department of Health is investigating Rhode Island Hospital in Providence after the hospital admitted to operating on the wrong body part for another patient, marking at least the fifth wrong-site surgery at the hospital since 2007.



Published: October 30th, 2009
AboutLawsuits.com

Two Stories: A Bed versus B Bed Errors



Is Informed Consent “Real”?

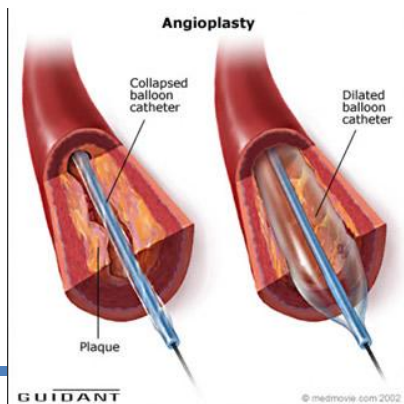
- **In a survey of consecutive patients scheduled for an elective coronary revascularization procedure at Yale New Haven Hospital in 1997-1998**
 - **75% believed PCI would help prevent an MI**
 - **71% believed PCI would help them live longer**
 - **Less than half could name even one possible complication of PCI**
 - **85% were “consented” just before the procedure (by a fellow or an NP)**

(Holmboe ES. JGIM 2000; 15:632)



Is Informed Consent “Real”?

- **While even through the latest meta-analysis in 2009 (61 trials, 25,388 patients):**
 - **“Sequential innovations in catheter-based treatment for non-acute coronary artery disease showed no evidence of an effect on death or myocardial infarction when compared to medical therapy.”**



(Trikalinos TA. Lancet 2009; 373:911)

Is Informed Consent “Real”...10 years later?

- **In a survey of consecutive patients consented for an elective coronary angiogram and possible percutaneous coronary intervention at Baystate Medical Center in 2007-2008**
 - **88% believed PCI would help prevent an MI**
 - **76% believed PCI would help them live longer**

(Rothberg MB. Annals Intern Med 2010; 153:307)



Physician Based Standard Defined

Physician Based Standard requires physician to inform patient of risks, benefits and alternatives to treatment in the same manner that a *reasonably prudent practitioner* in the field would

-Tashman V Gibbs (VA 2002)



Physician Based Standard: Why it fails

- Assumes that physicians provide universal standard of acceptable treatment.
- Divides patients & physicians
- Preserves paternalism
- Hinders improvements in treatment and communication



Patient Based Standard Defined

Patient based standard requires physician to provide patients with all the Information on risks, benefits and alternatives to treatment that a *reasonable patient* would attach significance to in making a treatment decision

-Canterbury vs Spence (D.C. 1972)



Patient Based Standard: Why it fails

- Based on belief that all reasonable people value the same health outcomes and lifestyle choices in the same manner
- Physician continues to control dissemination of information



Video Facilitates SDM Discussion

VOLUME 28 • NUMBER 2 • JANUARY 10 2010

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Use of Video to Facilitate End-of-Life Discussions With Patients With Cancer: A Randomized Controlled Trial

Areej El-Jawahri, Lisa M. Podgurski, April F. Eichler, Scott R. Plotkin, Jennifer S. Temel, Susan L. Mitchell, Yuchiao Chang, Michael J. Barry, and Angelo E. Volandes

From the Departments of Medicine, Neurology and Cancer Center, and Oncology, Massachusetts General Hospital; Harvard Medical School; Hebrew Senior Life; Department of Medicine, Beth Israel Deaconess Medical Center, Boston, MA;

A B S T R A C T

Purpose

To determine whether the use of a goals-of-care video to supplement a verbal description can improve end-of-life decision making for patients with cancer.



Video Prompts Goals-of-Care Change

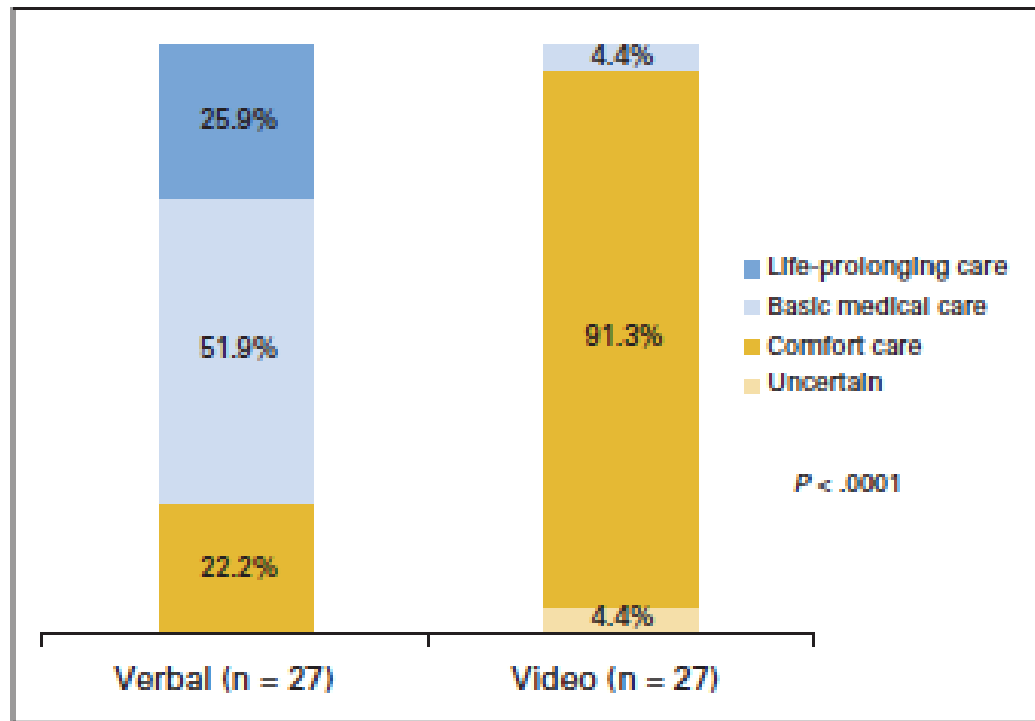


Fig 3. Participants' goals-of-care preferences for advanced cancer in the verbal and video groups.

Foundation National Survey of Physicians

- **Conducted in 2008 by Lake Research Partners**
- **Internet survey**
- **Sample of 402 primary care physicians from Harris Interactive's Physician Panel**



Foundation National Survey of Physicians

- **78%** - changes in reimbursement had decreased the time they could spend with each patient
- **82%** - “very” important for patients to be informed about taking new prescription meds...but only **16%** said the majority of their patients *are* well informed.
- **93%** - **SDM** was a “positive” or “very positive” process

Foundation National Survey of Physicians

- **The majority of physicians endorsed SDM for:**
 - **Chronic condition management (81% “very important”)**
 - **Surgery (73% “very important”)**
 - **Cancer screening (64% “very important”)**
 - **New medications (62% “very important”)**
- **Nearly all physicians said they would use decision aids that met their standards “frequently” (48%) or “sometimes” (48%)**
- **Main barrier to SDM: “Not enough time with patients for detailed discussions”**



Cochrane Review of Decision Aids

- **In 55 trials of decision aids addressing 23 different screening or treatment decisions, use has led to:**
 - **Greater knowledge**
 - **More accurate risk perceptions**
 - **Greater comfort with decisions**
 - **Greater participation in decision-making**
 - **Fewer people remaining undecided**
 - **Fewer patients choosing major surgery, PSA tests**



(O'Connor et al. *Cochrane Database of Systematic Reviews* 2009, Issue 3. Art. No.: CD001431)



The “Doctor Merenstein” Problem



- However, physicians may fear a malpractice suit for an “error of omission” if they follow the guidelines, a patient declines PSA testing, subsequently develops advanced cancer, and regrets his decision.

The “Doctor Merenstein” Problem

- **This concern was reinforced by a 2004 JAMA article, “Winners and Losers”, by Dr. Daniel Merenstein, whose residency program was successfully sued for \$1 million for his not performing a PSA test, despite documenting a discussion of the risks and benefits:**
“A major part of the plaintiff’s case was that I did not practice the standard of care...Four physicians testified that when they see male patients over 50 years, they have no discussion with the patient about prostate cancer screening: they simply do the test.”

(Merenstein D. JAMA 2004;291:15)



Doctor Merenstein Revisited



- In 2007, we conducted 6 focus groups with a total of 47 potential jurors recruited through an ad in a Boston newspaper
- Focus groups were presented with up to three scenarios in a hypothetical malpractice case involving an allegation of failure to order a PSA test.

(Barry et al. J Law Med Ethics 2008;36:396)

Doctor Merenstein Revisited

- **Basic Facts of the Case, all Scenarios:**
 - **Visit to a PCP at age 50 in 1998 in MA**
 - **No lower urinary tract symptoms**
 - **No risk factors for prostate cancer**
 - **Patient moves to VA, PSA done without discussion by another PCP at age 52**
 - **PSA is elevated, biopsies show aggressive PCA**
 - **Patient ultimately has evidence of progressive, hormone-refractory prostate cancer despite undergoing surgery, radiation, and androgen deprivation**

(Barry et al. J Law Med Ethics 2008;36:396)



Doctor Merenstein Revisited

- **Testimony at Trial, all Scenarios:**
 - **Plaintiff testifies that if he had been better informed in 1998, he would have wanted a PSA test**
 - **Plaintiff's expert testifies the standard of care was to order a PSA without discussion, and that if a PSA had been done, the cancer would have been cured**
 - **Defendant testifies he always discussed the pros and cons of the PSA test starting at age 50**
 - **Defendant's expert testifies defendant met the standard of care based on national guidelines, and earlier detection might not have led to a cure**

(Barry et al. J Law Med Ethics 2008;36:396)



Doctor Merenstein Revisited

- **“No Note” Scenario (First three focus groups only)**
 - No note in the records documenting discussion
 - Defendant testifies he always had such a discussion
 - Plaintiff testifies he recalled no such discussion
- **“Note” Scenario (All six focus groups)**
 - “Pros and cons of PSA discussed, patient declines.”
 - Defendant recalls PSA mentioned, test discouraged
- **“Decision Aid” Scenario (All six focus groups)**
 - “Patient watched PSA decision aid, declines test.”
 - Defendant recalls watching, test discouraged

(Barry et al. J Law Med Ethics 2008;36:396)



Doctor Merenstein Revisited

- **“No Note” Scenario (First three focus groups only)**
 - 4/23 (17%) voted the standard of care had been met
 - 14/19 (74%) who voted standard of care not met also voted harm resulted
- **“Note” Scenario (All six focus groups)**
 - 34/47 (72%) voted standard of care had been met
 - 11/13 (85%) who voted standard of care not met also voted harm resulted
- **“Decision Aid” Scenario (All six focus groups)**
 - 44/47 (94%) voted standard of care had been met
 - 2/3 (67%) who voted standard of care had not been met also voted harm resulted



Doctor Merenstein Revisited

- **Better documentation that a patient made an informed decision to decline a PSA test appeared to provide much greater medical-legal protection for a physician following national guidelines, with the greatest protection coming from the use of a PSA decision aid**



Health Policy Reasons for Adoption of SDM on Large Scale

- Ethical imperative to do the right thing
- Perfected Informed Consent-Aligning preferences, values and lifestyle with individual's clinical decision
- Bridging Health Disparities
- Conservative Utilization of surgical interventions

Patient Protection and Affordable Care Act

HR3590 Section 936



1. Produce patient decision aids
2. Set quality standards and certify decision aids
3. Create Shared Decision Making Resource Centers
4. Grant funds to providers for development, use and assessment of SDM techniques using certified decision aids

Authorized not Appropriated

Section 302I CMS Innovation Center

Test innovative payment models to reduce costs
Enhance quality. To design, implement and evaluate
18 different models



9) ***“Assisting applicable individuals in making informed health care choices by paying providers for using patient decision support tools that improve individual understanding of medical options”***

AUTHORIZED AND APPROPRIATED

10 Billion FY 2011-2019



Patient Decision Aids Can Help!



- Tools designed to help people participate in decision making about health care options
- Provide information on the options and help patients clarify and communicate the personal values
- Prepare patients to make informed, values-based decisions with their practitioner.



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(The International Patient Decision Aid Standards Collaboration)



SDM: Implementation Needs

- **Patients interested in being informed and activated to participate in their health decisions**
- **Practical systems and protocols for routine use of decision support tools (decision aids)**
- **A health care environment with the appropriate incentives to reward good “decision quality” rather than simply “more is better”**
- **Clinicians and hospitals truly receptive to patient participation**

Did the patient know a decision was being made?
Did the patient know the pros and cons of the treatment options?
Did the provider elicit the patient's preferences?

Involvement

**Decision
Quality**

Values Concordance

Did the decision reflect the patient's
goals and concerns?

Knowledge

Did the patient know what he or she
needed to know?

