Informed Consent, Goals and Targets

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Objectives

- Understand the nature of true informed consent
- Describe how “goals” are different that “treatment targets”
- Describe how “goal directed care” is different that “guideline directed care”
- Describe how you can take an active role in informed consent

- Challenge assumptions
- Critical thinking
- Skepticism
- Diverse viewpoints
- Your input!!!

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- March 20 - Informed consent, goals and targets
- March 27 - Symptom versus prevention treatments
- April 3 - When something recommended becomes not recommended

- May 8 - Choosing Wisely
- May 15 - The Medical-Industrial Complex
- May 22 - Getting clarity about what is right for you

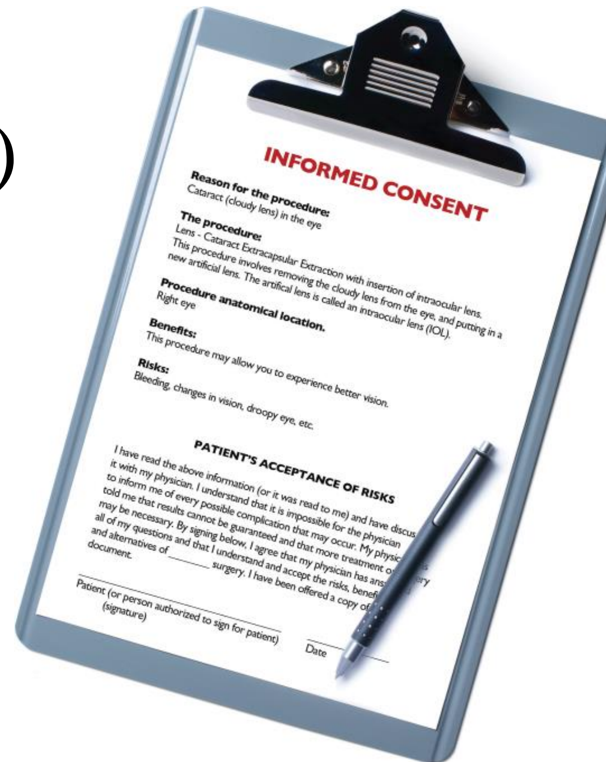
Common "Informed Consent"

- Dr: "Blah blah blah."
- Patient: (Nod, and look like you're paying close attention.)
- Dr: "Did you understand everything I said?"**
- Patient : "Yes."
- Dr: "Any questions?"
- Patient : "No."

** This question is asked 2% of the time

Another Common Informed Consent

- Nurse: “We need you to sign this form before we do the surgery.”
- Patient: (signs form)



Elements of Informed Consent

- The recommended treatment
  - Benefits and harms
- The alternative treatments
  - Benefits and harms of each
- The benefits and harms of no treatment

Drs. discuss harms and benefits only 9% of the time

They assess understanding only 2% of the time

Video - Doctor

Braddock, *J Gen Intern Med.* 1997;12: 339–345

IC and Different Populations

- Healthy people and people with acute, time-limited conditions
- People with stable or early chronic conditions
  - Maintain their usual social role and have long life expectancy
- People with serious, progressive, eventually fatal illness
  - Meet the “surprise question” criterion

Lunney JR JAMA 2005;289:2387-2392

Two Kinds of Treatments

- Treatment of symptoms
  - Pain, shortness of breath, skin itching, painful feet
  - What is the goal?
- Prevention of diseases or bad outcomes
  - Primary – prevent a disease from happening
  - Secondary – prevent a complication
  - Tertiary – prevent a progression or improve functioning

Kinds of Prevention Treatments

- High blood pressure
- Diabetes
- High cholesterol
- Most cancers
- Heart failure
- Kidney failure
- Emphysema and asthma (mixed)

Prevention "Goals"

- High blood pressure
  - BP less than 150/90?
  - Not having a stroke or a heart attack?
  - Not dying?
- Diabetes
  - A1C less than 7?
  - Not having a stroke, kidney failure, amputation, heart attack?
  - Not dying?

Treatment Effects vs. Benefits

- Treatment effects are measurable outcomes
  - Weight maintained
  - Blood pressure controlled
  - These are called **"surrogates"**
- Benefits are positive outcomes <u>perceived by the person</u>
- It is possible to have a positive treatment effect that is not wanted by the person!

Video – Surrogate Measures

- Cure illness
- Prolong life
- Maintain function
- Maintain independence
- Quality of life
- Not burden family
- To die at home

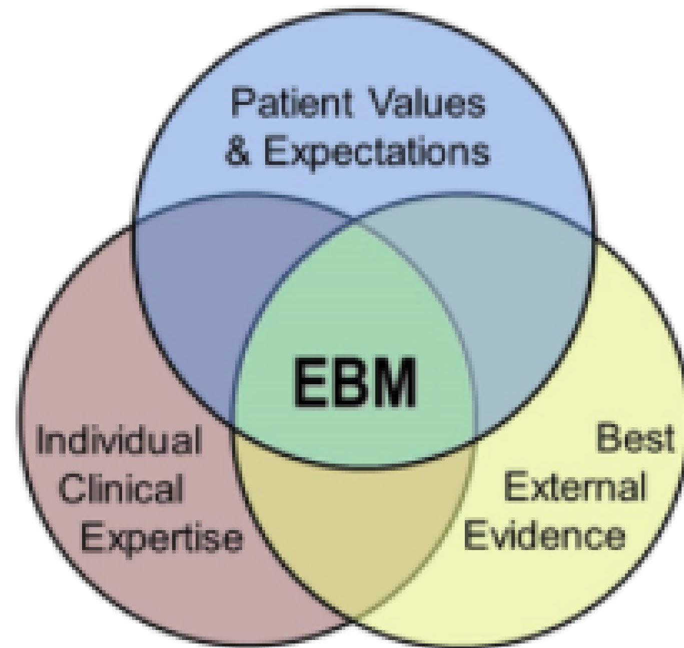
- What is most important in your life now?
- What experiences have you had with serious illness?
- Which fits your values?
  - Treat intensively even if it means suffering to try to extend life
  - Use medical treatments but stop if you are suffering, even if it means a shorter life
  - Use all measures to promote comfort, even if it means a shorter life
- Can you imagine a health situation that would be worse than death?
- Have you changed your mind about what is important over time?

Goals of Care video

Evidence Based Medicine

"Evidence-based medicine (EBM) requires the integration of the best research evidence with our clinical expertise and our patient's unique values and circumstances."

Straus SE. *Evidence-based medicine: How to practice and teach it.* 4th ed. Edinburgh: Elsevier Churchill Livingstone; 2011.



Type of Studies

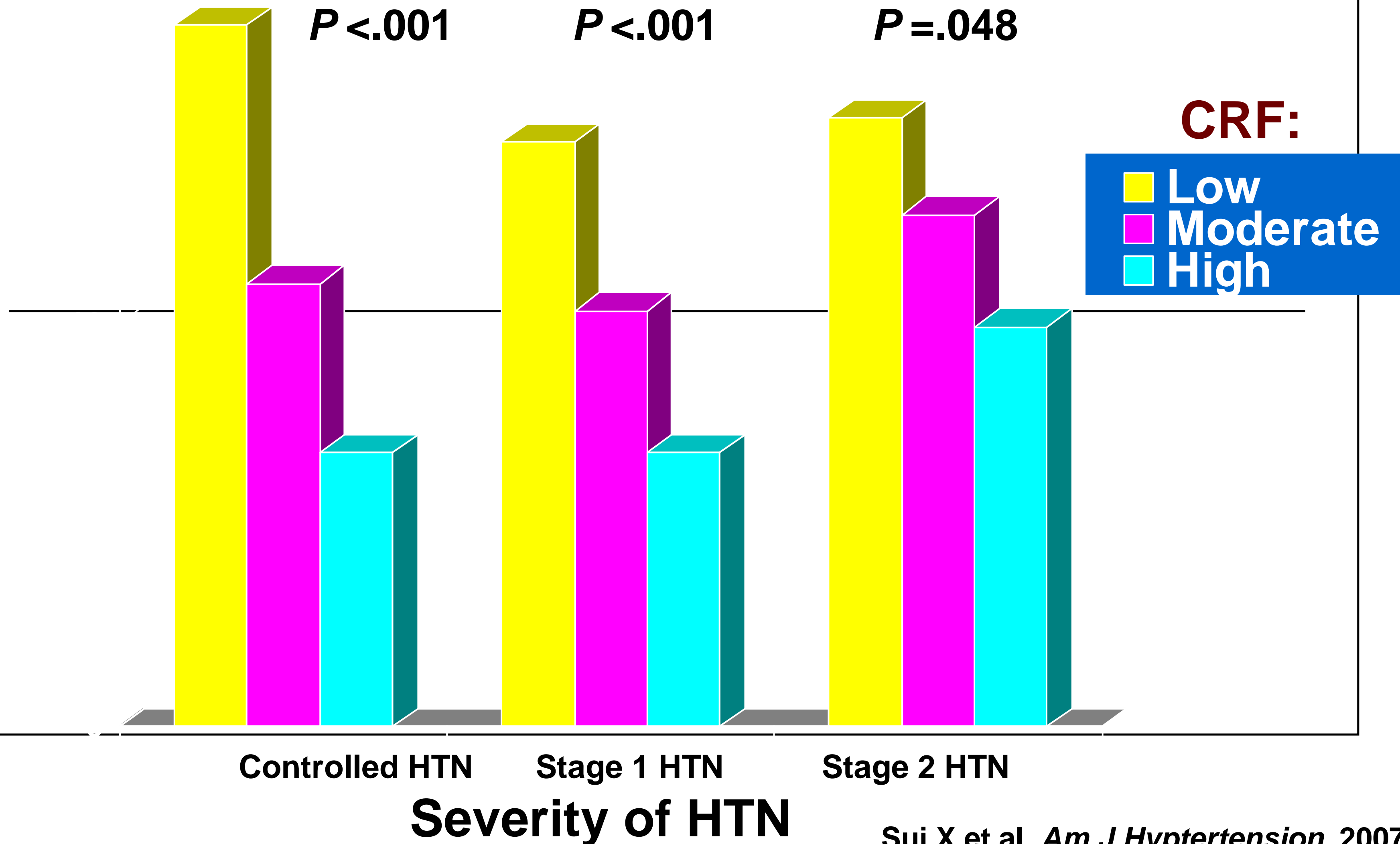
Components of Clinical Questions

Patient/ Population	Intervention/ Exposure	Comparison	Outcome
In patients with acute MI	does early treat-ment with a statin	compared to placebo	decrease cardio-vascular mortality?
In women with suspected coronary disease	what is the accuracy of exercise ECHO	compared to exercise ECG	for diagnosing significant CAD?
In post-menopausal women	does hormone replacement therapy	compared to no HRT	increase the risk of breast cancer?

Limits of EBM

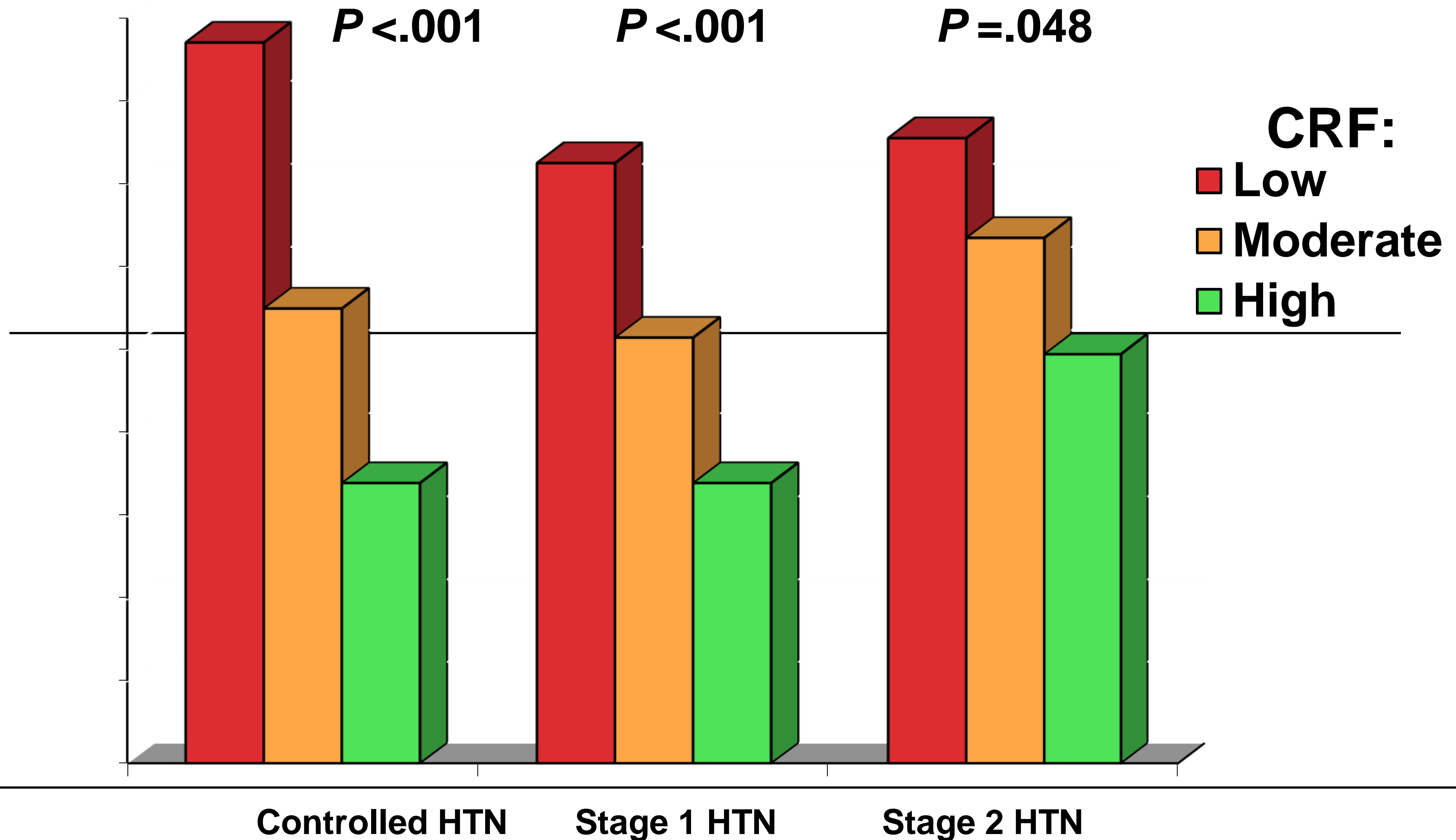
- Studies don’t include people like you
- Studies don’t look at key factors
- Studies have outcomes unimportant to you
- Bias in publications of studies
  - Positive versus negative results
  - Influence of drug companies on authors
  - Presentation of data (alternative facts)

BP and Fitness in Men



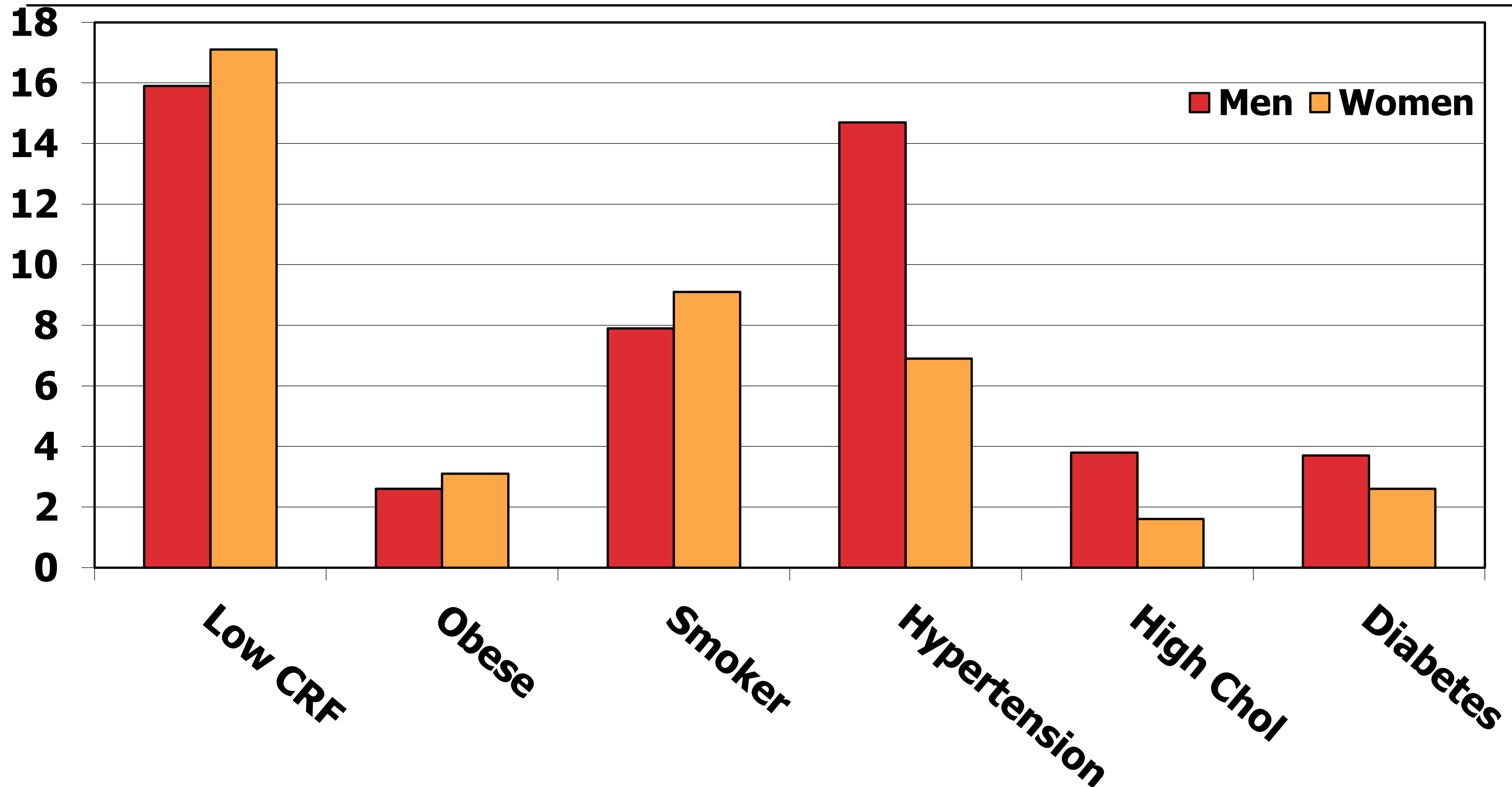
Sui X et al. *Am J Hyptertension.* 2007

Heart Events, BP and Fitness



Sui X et al. *Am J Hyptertension.* 2007

Attributable Fractions for All-Cause Mortality



Aerobics Center Longitudinal Study, 1970-2004. In progress

Prevention Meds – Risks/Benefits

Medication	Benefit	# of people out of 100 who will have an event prevented	# out of 100 who will be harmed
Statins (5 yrs)	Reduced heart attack (MI), stroke	1-2 if no risks 5-7 if risks	5-10 muscle aches 2 – liver prob 5/10,000 muscle damage
BP meds	Reduced MI, stroke	1-2 2-3 if BP>160	10 – low BP, falls
Metformin (5yrs)	Reduced MI, stroke	5 (1 meta-analysis says no benefit)	10 – stomach intolerance
Other glucose pills	Reduced MI, stroke	0	10 – hypoglycemia 10 – wt gain
Warfarin for a.fib for 1 yr	Reduced stroke	4	2-3 severe bleed

Prevention Meds – Risks/Benefits

Medication	Benefit	# of people out of 100 who will have an event prevented	# out of 100 who will be harmed
ACE/ B Blocker for heart failure for 3 yrs	HF, death	7	10 – low BP
Bisphosphonates for 2-3 yrs	Fractures	5 spine 1 hip	1-2 stomach symptoms 1-2/1000 osteonecrosis
PPI (Nexium) for 8 wks	Healing/decrease symptoms	50	2-5 due to side effects Increased risks?
SSRI for depression for 8 wks	Not depressed	0 – if mild to mod 7 – if severe	2-5 due to side effect Increase mortality?
Cholinesterase inhibitors 1 yr	Better day to day function	0	10 stomach side effects

Guidelines Versus Goals

- Clinical guidelines – recommendations to the medical community on treatment of specific conditions
  - Hypertension
  - Heart Failure
  - Osteoporosis
  - Falls
- Experts review the evidence and summarize the recommendation

Heart Failure Guidelines

177 related guidelines found on NGC

- 21 recommendations regarding assessment
  - One referred to ADL
- 22 recommendations regarding risk reduction
- 17 recommendations regarding treatment
  - One referred to exercise training

ACC/AHA Guideline on Heart Failure, 2001

AMDA HF Guidelines

- Decide whether to work up
- Decide whether to control risk factors
- Incorporate patient’s or surrogate’s wishes
- Evaluate effect of co-morbid conditions
- Management of end-of-life care

American Medical Director Assoc. Heart Failure Guidelines, 2002

Diabetes Guidelines

247 guidelines found on NGC

- Specific recommendations on carbohydrate, fat, and protein intake (28)
- Specific recommendations on mgt of high blood pressure, lipids, glycemic levels, and kidney problems (13)
- Only two recommendations on older adults
- Only one recommendation of exercise

ADA, 2001, republished 2003, Diabetes

Video - guidelines

- Starts with a guideline
- Asks if the guideline fits THIS patient
- Ask the patient what the goals are
- Adjust recommended treatments to the patient's goals

Getting True Informed Consent (1)

- **Ask Dr. to use common words and terms.**
  - If your doctor says that you'll end up with a "simple iliac ileal conduit" or a "urostomy," feel free to say "I don't understand those words. Can you explain what that means?"
- **Summarize back what you heard.**
  - "So I should split my birth control pills in half and take half myself and give the other half to my boyfriend?" That way, if you've misunderstood what we did a poor job of explaining, there will be a chance to straighten it out: "No, that's not right. You should take the whole pill yourself."

Getting True Informed Consent (2)

- **Request written materials, or even pictures or videos**.
  - We all learn in different ways and at different paces, and "hard copies" of information that you can take time to absorb at home may be more helpful than the few minutes in our offices.
- **Ask for best-case, worst-case, and most likely scenarios, along with the chance of each one occurring.**

Getting True Informed Consent (3)

- **Ask if you can talk to someone who has undergone the surgery or received the chemotherapy.**
  - That person will have a different kind of understanding of what the experience was like than we do.
- **Explore alternative treatment options, along with the advantages and disadvantages of each.**
  - "If I saw 10 different experts in my condition, how many would recommend the same treatment you are recommending?"

Informed Patient? Don't Bet On It. MA Sekeres, TD Gilligan, NY Times March 1, 2017

Patient's Control

- Keep a list of your drugs – show it every visit
- Use only one pharmacy
- Don't ask for any drug that is advertised on TV or in magazines
- Ask how long the drug has been on the market
  - Don't take any drug until it's been out for at least 2 years
- Ask if there are other things besides taking a drug you can do
- Ask if you should stop any current drugs

- Overdiagnosed – by Gilbert Welch
- Overdosed America – by John Abramson
- Overtreated – by Shannon Brownlee
- The Truth About the Drug Companies - by Marcia Angel
- Worried Sick – by Norton Hadler
- The Last Well Person - by Norton Hadler

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