

**What To Do When The Government Is Telling You To Do Less Mammograms/Paps**

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**Learning Objectives**

- Understanding who the stakeholders are in patient care
- Understanding the patient-physician relationship
- Understanding guideline development
- Pap & mammograms as examples

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**I have no financial disclosure**

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- A patient of yours brings her 19 year old daughter for a gyn exam & wants her to have a PAP smear

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- A 42 year old woman comes for a first visit and wants an order for a pelvic ultrasound and mammogram

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**Who is in the room with you making these decisions:**

- Doctor
- Patient
- Family
- ACOG – Practice guidelines
- City, state, federal agency
- Insurance company
- Hospital
- Med/mal carrier

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### Doctor Variables

- Mode of practice
  - time per patient
  - interactive style
  - beliefs
- Aware of a medical issue --- guidelines
  - agrees
  - disagrees
  - insufficient knowledge
- Not aware
- Reimbursement

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### Doctor Variables cont'd

- Physician ratings
  - Press-Ganey
  - CG-CAPS
  - Yelp
- Insurance company
  - Incentives
  - Mandates
  - Population Health/ Capitated plans
- Federal Programs/reporting
  - Value based purchasing
  - Patient safety indicator (PSI)

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### Patient Variables

- Knowledge
  - Education
  - Intelligence
- Social/religious/cultural beliefs
- Finances
- Personality Type (Briggs-Myers)
  - Extroverted – introverted
  - Sensing – intuition
  - Thinking – feeling
  - Judging – perceiving

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### Family

- Triangulation

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graph TD; Patient --> Doctor; Patient --> Family; Doctor --> Family;
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- City, State, Federal Agency
- Med/Mal Carrier
- Compensation
  - Reimbursement/time
  - Capitated models
  - Incentives
  - Dis-incentives

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### Why Don't Physicians Follow Practice Guidelines

Cabana, M et al  
Jama, October 1999

- Lack of awareness
- Lack of familiarity
- Lack of agreement
- Lack of self efficacy
- Lack of outcome expectancy
- Inertia
- External barriers

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### Autonomy

Respect for autonomy is one of the fundamental guidelines of clinical ethics. Autonomy in medicine is not simply allowing patients to make their own decisions. Physicians have an obligation to create the conditions necessary for autonomous choice in others. **For a physician, respect for autonomy includes respecting an individual's right to self determination as well as creating the conditions necessary for autonomous choice.**

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### Autonomy cont'd.

Individuals come to doctors for guidance in making choices because they do not have the necessary background or information for making informed choices. Physicians educate patients so that they understand the situation adequately. They calm emotions and address fears that interfere with a patient's ability to make decisions. They counsel patients when their choices seem to be disruptive to healing and well-being.

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### Beneficence

Physicians are expected to refrain from causing harm, but they also have an obligation to help their patients. The goal of medicine is to promote the welfare of patients and physicians possess skills and knowledge that enable them to assist others. **Due to the nature of the relationship between physicians and patients, doctors do have an obligation to 1) prevent and remove harms, and 2) weigh and balance possible benefits against possible risks of an action.**

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## Balancing Autonomy and Beneficence

Some of the most common and difficult ethical issues to navigate arise when the patient's autonomous decision conflicts with the physician's beneficent duty to look out for the patient's best interest. In these situations, the autonomous choice of the patient conflicts with the physician's duty of beneficence. **As long as the patient meets the criteria for making an autonomous choice (the patient understands the decision at hand and is not basing the decision on delusional ideas), then the physician should respect the patient's decisions even while trying to convince the patient otherwise.**

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## Non-maleficence

Non-maleficence means to "do no harm." Physicians must refrain from providing ineffective treatments or acting with malice toward patients. This principle, however, offers little useful guidance to physicians since many beneficial therapies also have serious risks. The pertinent ethical issue is whether the benefits outweigh the burdens.

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|----------------------|--|
| Autonomy             | - Patient's right to make a decision           |
| Beneficence          | - Physician action in best interest of patient |
| Non-maleficence      | - Do no harm                                   |
| Distributive Justice | - Treat everyone equally                       |
| Fairness             | - The decision making process is fair and just |

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A new guideline should help a physician to improve care and therefore raise beneficence. But, does it

- Improve a treatment
- Lessen side effects/harm
- Cost less to a population (insurance company)
- Cost less to the patient
- Trade off cost/health globally or individually

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### Cervical Cancer Screening

- 18 year old girl comes into the office with her mother, who is also your patient. The girl is off to college and “they” want all testing. When you say she doesn’t need a PAP, the mom replies, “she has been sexually active since age 14, I’d like a PAP.”

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The new guidelines for cervical cancer screening is to do less testing. Patient’s reasonable assumption is it will pick up less cancer but cost less.

- Autonomy
- Beneficence
- Maleficence

What is the downside of doing too many PAPs on a patient in your office?

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### Cervical Cancer

- Incidence has decreased 50% in the last 30 years
- 1975 rate was 14.8/100,000 women
- 2011 rate was 6.7 /100,000 women
- American Cancer Society in U.S.

2015	12,900 new cases
	4,100 deaths

- Worldwide 527,624 new cases  
265,672 deaths

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### Cervical Cancer

- 0.1% of cases of cervical cancer occur before age 20
- 1-2 cases per one million women age 15-19
- Screening in this group hasn't changed that number
- Of 10,090 PAP tests in 12-18 year olds, 422 had LSIL, 55 had HSIL.

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### USPSTF

- Created in 1984
- Volunteer panel of experts in prevention and evidence based medicine
- Since 1988 the Agency of Healthcare Research and Quality (AHRQ) has been authorized to convene the task force and provide support.
- 15 Members
  - One OB/GYN Maureen Phipps, Chair of OB/GYN, Brown U

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**Screening for Cervical Cancer: U.S. Preventive Services Task Force Recommendation Statement cont'd.**

Annals of Internal Medicine  
19 June 2012 Volume 156 Number 12

**Importance**

The age-adjusted annual incidence rate of cervical cancer is 6.6 cases per 100 000 women, according to data from 2008 (1–3). An estimated 12 200 new cases of cervical cancer and 4210 deaths occurred in the United States in 2010 (1). Cervical cancer deaths in the United States have decreased dramatically since the implementation of widespread cervical cancer screening. Most cases of cervical cancer occur in women who have not been appropriately screened (2–3). Strategies that aim to ensure that all women are screened at the appropriate interval and receive adequate follow-up are most likely to be successful in further reducing cervical cancer incidence and mortality in the United States.

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**Level A**

- **Women 21- 65**
  - Cytology every 3 years
- **Women 30-65**
  - Cytology & HPV every 5 years

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**Level D**

- Women younger than 30 & HPV testing
- Women younger than 21 – no screening
- Women older than 65 – no screening
- Women without a prior hysterectomy – no screening

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## Cervical Cancer

Who do we listen to:

- ACS            American Cancer Society
- ASCCP        American Society of Colposcopy & Cervical Pathology
- ASCP         American Society of Clinical Pathology
- USPSTF      U.S. Preventative Service Task Force
- SGO          Society of Gynecology Oncology
- ACOG         American College of OB/GYN

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## Cervical Cancer

- In 2011, ACS, ASCCP & ASCP issued a joint guideline.
- In 2011, USPSTF
- In 2015, ASCCP & SGO issued an interim guideline approved by the FDA

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Table 1. Screening Methods for Cervical Cancer for the General Population: Joint Recommendations of the American Cancer Society for Colposcopy and Cervical Pathology, and the American Society for Clinical Pathology

Population	Recommended Screening Method	Comment
Women younger than 21 years	No screening	
Women aged 21-29 years	Cytology alone every 3 years	
Women aged 30-65 years	Human papillomavirus and cytology co-testing (preferred every 5 years) Cytology alone (acceptable) every three years	Screening by HPV testing alone is not recommended
Woman older than 65 years	No screening is necessary after adequate negative prior screening results	Women with a history of CIN2, CIN3, or adenocarcinoma in situ should continue routine age-based screening for a total of 20 years after spontaneous regression or appropriate management of CIN 2, CIN 3, or adenocarcinoma in situ
Women who underwent total hysterectomy	No screening is necessary	Applies to women without a cervix and without a history of CIN2, CIN 3, adenocarcinoma in situ, or cancer in the past 20 years
Women vaccinated against HPV	Follow age-specific recommendations (same as unvaccinated women)	

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**The Beneficence  
vs  
Maleficence Argument**

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**Benefits and Harms of Cervical Screening From Age 20 Years Compared with Screening at Age 25**

Landy, R et al  
Br J Cancer 2014

Conclusions:

- To prevent one frank invasive cancer, one would need to do between 12,500 and 40,000 additional screening tests in the age group 20-24 years and treat between 30 and 900 women.
- For every 100,000 women starting at 20 not 25
  - Prevent 3 to 9 cancers
  - 8,000 unnecessary colposcopies
  - 3,000 unnecessary treatments

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**Increased Cervical Cancer Risk Associated With Screening at Longer Intervals**

Kenny W, Wright TC, Dinkajorn H, DeFranco M, Thomas Cox J, Huh W  
Obstet Gynecol, Feb. 2015

**Abstract**

The 2012 national recommendations for cervical cancer screening will produce a lower level of cervical cancer protection than previously afforded by annual cytology or 3-year co-testing. After a single negative co-test result, the risk of cervical cancer is twice as large at 5 years as it is at 3 years. Modeling published since the 2012 guidelines were drafted indicates that extending the co-testing screening interval from 3 to 5 years at ages 30-64 years will result in an additional 1 woman in 369 compliant with screening receiving a cervical cancer diagnosis during her lifetime, and an additional 1 in 1,639 dying of cervical cancer. The authors believe that a significant number of patients and providers would not choose to accept these additional risks if they understood them, despite the recognition of potential harms associated with more intensive screening.

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What are the “risks” of too much vs too little testing:

- Psychological
- QALY
- Cost

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**Abnormal outcomes following cervical cancer screening: event duration and health utility loss.**

Insinga RP<sup>1</sup>, Glass AG, Myers ER, Rush BB.

**Abstract**

**BACKGROUND:**

For decision analytic models, little empirical data are available from which to model the amount of time women spend with various cervical cytologic and histologic diagnoses following an abnormal Pap smear or the associated loss in quality-adjusted life-years (QALYs).

**METHODS:**

The authors retrospectively examined administrative and cytopathology data for women with abnormal routine cervical smears within the Kaiser Permanente Northwest (Portland, OR) health plan during 1998. Data were examined through the conclusion of follow-up, with final outcomes categorized as cervical intraepithelial neoplasia (CIN) grades 1 to 3 (n = 201) or a false-positive result (n = 722) if no CIN or cancer was detected on follow-up. CIN outcomes were assigned according to the initial grade of dysplasia observed during the care episode in the primary analysis. The number of months spent with various cytologic and histologic diagnoses during the course of follow-up was tabulated, and utility weights were assigned using data from a prior study reporting time tradeoff scores for cervical health states.

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**Abnormal outcomes following cervical cancer screening: event duration and health utility loss, cont'd.**

**RESULTS:**

The average total duration of follow-up was between 18 and 22 months for women with CIN, compared with 10 months for a false-positive Pap smear. The number of months spent with either an abnormal cytologic or histologic diagnosis was greater (P = 0.01) for women with CIN 1 (12.6 months) than CIN 3 (9.2 months), although this relationship was reversed for time spent receiving negative follow-up Pap smears and biopsies to rule out the presence of CIN and cancer. Total QALY losses per episode of care were estimated to be 0.11 for all 3 grades of CIN and 0.04 for a false-positive Pap smear.

**CONCLUSIONS:**

The health and psychosocial burdens associated with follow-up for abnormal Pap smears translate into tangible QALY losses in a decision analytic context, with women receiving many months of follow-up and a variety of cytologic and histologic diagnoses over the course of a care episode

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### Breast Cancer Screening

- 44 year old wants a mammogram

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### Breast Cancer Screening

14% of women born in USA will get breast cancer

- Age 40-99 probability is 1 in 69
- Age 50-59 probability is 1 in 38
- Age 60-69 probability is 1 in 27

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### Breast Cancer Screening ACOG

- 40-49      Yearly
- 50 & older      Yearly
- BSE      Recommended
- CBE      Yearly, starting at age 19

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## Breast Cancer Screening ACS

- 40-44 Give patient a choice
- 45-54 Yearly
- 55 & older Yearly by choice or every two years
- BSE CBE ( ? ) recommended

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USPSTF Summary of Recommendations

Population	Recommendation
Women, Age 50-74	The USPSTF recommends biennial screening mammography for women 50-74.
Women, Before the Age of 50 Years	The decision to start regular biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.
Women, 75 Years and Older	The USPSTF concludes that the current evidence is insufficient to assess the benefits and harms of screening mammography in women 75 years and older.  Go to the Clinical Considerations section for information on risk assessment and suggestions for practice regarding the I statement.
All women	The USPSTF recommends against teaching breast self-examination (BSE).
Women, 40 Years and Older	The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years of older.  Go to the Clinical Considerations section for information on risk assessment and suggestions for practice regarding the I statement.
All Women	The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer.  Go to the Clinical Considerations section for information on risk assessment and suggests for practice regarding the I statement.

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## USPSTF ASSESSMENT

- The USPSTF concludes with moderate certainty that the net benefit of screening mammography in women aged 50 to 74 years is moderate.
- The USPSTF concludes with moderate certainty that the net benefit of screening mammography in the general population of women aged 40 to 49 years, while positive, is small.
- The USPSTF concludes that the evidence on mammography screening in women age 75 years and older is insufficient, and the balance of benefits and harms cannot be determined.
- The USPSTF concludes that the evidence on DBT as a primary screening method for breast cancer is insufficient, and the balance of benefits and harms cannot be determined.
- The USPSTF concludes that the evidence on adjunctive screening for breast cancer using breast ultrasound, MRI, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram is insufficient, and the balance of benefits and harms cannot be determined.

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### Breast Cancer Screening USPSTF

- Age 40 to 49 – net benefit is small
- Benefit of screening patients between 40 to 49 and 50 to 59 is the same
  - The incidence is much lower in the 40 to 49 year range

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### USPSTF META ANALYSIS

Over 10 years screening 10,000 women

60-69	21 fewer deaths
50-59	8 fewer deaths
40-49	3 fewer deaths

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### Breast Screening by Others

- ACS                      Start age → 40
  - Mammo
  - CBE
  - no BSE
- AMA                      Same + BSE
- Canadian Task Force    Start age → 40
  - Mammo
  - CBE
  - no BSE

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### Breast Screening by Others cont'd.

- ACOG Mammo every 1-2 years @ age 40  
Annually at age 50
  - CSE
  - BSE - recommended
  
- WHO Mammo every 1-2 years age 50 to 69
  - no CBE
  - no BSE

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### Breast Cancer Screening USPSTF

**The precise age at which the benefits from screening mammography justify the potential harms is a subjective judgement and should take into account patient preferences.** Clinicians should inform women about the potential benefits (reduced chance of dying from breast cancer), potential harms (for example, false positives results, unnecessary biopsies) and limitations of the test that apply to women their age. Clinicians should tell women that the balance of benefits and potential harms of mammography improves with increasing age for women between 40 and 70.

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### USPSTF

The USPSTF concludes that while there are harms of mammography, the benefit of screening mammography outweighs the harms by at least a moderate amount from age 50 to 74 years and is greatest for women in their 60s. **For women in their 40s, the number who benefit from starting regular screening mammography is smaller and the number experiencing harm is larger compared with older women. For women in their 40s, the benefit still outweighs the harms, but to a smaller degree; this balance may therefore be more subject to individual values and preferences than it is in older women.** Women in their 40s must weigh a very important but infrequent benefit (reduction in breast cancer deaths) against a group of meaningful and more common harms (over diagnosis and overtreatment, unnecessary and sometimes invasive follow-up testing and psychological harms associated with false positive test results, and false reassurance from false-negative test results). Women who value the possible benefit of screening mammography more than they value avoiding its harms can make an informed decision to begin screening.

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## USPSTF

In addition to false-positive results and unnecessary biopsies, all women undergoing regular screening mammography are at risk for the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to their health, or even apparent, during their lifetime (known as "over diagnosis"). Beginning mammography screening at a younger age and screening more frequently may increase the risk for over diagnosis and subsequent overtreatment.

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## USPSTF Harm of Screening

- 1975 to 2011 - 50% increase in cancer detection.
- 1975 to 2011 - mortality declined from 31 to 22 cases per 100,000

➡ If over diagnosis is only explanation of the 50% increase one could conclude that

➡ 1/3 women diagnosed with breast cancer are being treated for cancer that would never be discovered or caused health problems

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The current recommendation from ACOG is not to test you. That is because cervical cancer is extremely rare in your age group. More common is being exposed to HPV and your body's immune system being able to knock it out. If I test you and you are positive to HPV you may end up with more treatment which may be unnecessary. I really don't think you need to be tested.

## AUTONOMY

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### Crossing the Quality Chasm – A New Health System for the 21<sup>st</sup> Century

IOM 2001

Patient – centeredness is a fundamental attribute of health care alongside:

- safety
- effectiveness
- timeliness
- efficiency
- equity

Providing care that is respectful of and responsive to individual patient preferences, needs and values.

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### Patient Centric Care

The Picker Institute 1987

- Request patient values
- Coordination and integration of care
- Information, communication, education
- Physical comfort
- Emotional support
- Involve family and friends
- Continuity of care

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### Physician Communication: Barriers to Achieving Shared Understanding and Shared Decision Making with Patients

Brenda Lovell, MEd, Raymond T. Lee, PhD, Celeste M. Brotheridge  
J Participat Med. 2010; 2:e12

- 278 Physicians – Manitoba, Canada
  - family & internal medicine specialty
  - a mean of 16.49 years in practice
  - mean time with a patient is 19 minutes
- Participants were asked to indicate problems they had communicating with patients
- Shared understanding and shared decision making

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## Affordable Care Act

- Provision of SDM
  - Patient decision aids
    - Written materials
    - Videos
    - Interactive electronic presentations

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A recently updated Cochrane review [16] has synthesized the body of evidence about different interventions that can be used to help healthcare professionals about their health. In this review of studies testing interventions to help healthcare professionals adopt practices to better involve their patients in the process of making decisions, five studies were identified. This review found that education meetings, giving healthcare professionals feedback, giving healthcare professionals learning materials, and using patient decision aids are some techniques that have been tried and might be helpful. However, the review could not determine from the available studies which of these were best.

Legare et al  
Cochrane Database review 2014

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## Decision Making Process

- Be educated as to guidelines
- Supply patients with that information
- Drill down on those guidelines to understand the risk/benefit modeling
- SDM should be your practice model

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**GAIN PATIENT TRUST**

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**What to Do When The Government Tells You to Do Less Testing**

- You understand the new guidelines
- You explain it to the patient
- You explain its benefits (Beneficence)
- You explain the risks (Maleficence)
- You answer patient concerns with an understanding of her social/financial/religious beliefs with and understanding of her psychological make-up (Autonomy)

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**SHARED DECISION**

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