

# The Pelvic Examination in Asymptomatic, Average-risk Women: *To Do or Not To Do...?*

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# Objectives

- Introduction – The Pelvic Exam
  - Components of the pelvic exam
  - Reasons why we perform the pelvic exam
- The evidence:
  - The pelvic exam as a screening tool
  - Benefits and harms
- Guidelines/Recommendations:
  - USPSTF, ACP, AAFP, ACOG
- US Physician beliefs about the pelvic exam
- Conclusion



# Introduction

- The **routine pelvic exam** has been a usual part of the preventive care for women for decades.
- The exam consists of:
  - Inspection of the external genitalia
  - Speculum examination of the vagina and cervix
  - Bimanual examination
  - Sometimes rectal or rectovaginal examination
- Approximately **30.02 million** pelvic examinations are performed in the US every year.
- The annual cost: **\$1.17 billion**





# Introduction

Why physicians routinely perform a screening pelvic exam:

- Screening:
  - Malignancy (cervical, ovarian, uterine, vaginal or vulvar)
  - Infections (Chlamydia, Gonorrhea, warts, candidiasis, bacterial vaginosis)
  - Other pathology: atrophic vaginitis, cervical polyps, uterine prolapse, fibroids, etc.
- Prior to the provision of hormonal contraception
- As part of the Well-woman exam

# The Big Question...

Should we perform routine pelvic examinations in **asymptomatic, average risk, adult women** or is this unnecessary?





# The Big Question...

- Several organizations have tried to answer this question:
  - USPSTF – 2017
  - ACP – 2014
  - AAFP – 2014
  - ACOG – 2012 (Reaffirmed in 2016 after USPSTF Draft Recommendation)
- Consensus on many reasons NOT to do a screening/routine pelvic exam in healthy women.
- Jury still out on others.



# Opportunity for Education

Many physicians in the US perform the routine pelvic examination in asymptomatic, average-risk women when **not indicated** based on established guidelines for which there is consensus.





# POP QUIZ!

## Case 1

A healthy 19-year old university student has been sexually active for 4 months and requests oral contraceptive pills. She has no complaints.



## Case 2

A 40 year old woman with 3 children, married for 16 years, underwent tubal sterilization. She has no complaints. She has been undergoing cervical cancer screening every year for the past 18 years with no abnormal pap smears recorded.



**Which patient should receive a pelvic examination?**



# Let's look at Current Guidelines and Evidence

The role of the pelvic exam in the following:

- ✓ Screening for cervical cancer
- ✓ Screening for sexually transmitted infections (STIs) and PID
- ✓ Screening for ovarian cancer
- ✓ Screening for other GYN conditions
- ✓ Prior to hormonal contraception
- ✓ As part of the well-woman exam

# Cervical Cancer Screening

	ACOG 2016	ACS/ASCCP/ASCP 2012	USPSTF 2016
Starting Age	21	21	21
Pap Interval	Age 21-29 q 3 yrs ≥Age 30 q 3 yrs if no co-testing q 5 yrs if HPV co-testing	Age 21-29 q 3 yrs ≥Age 30 q 3 yrs if no co-testing q 5 yrs if HPV co-testing	Age 21-29 q 3 yrs ≥Age 30 q 3 yrs if no co-testing q 5 yrs if HPV co-testing
After TAH (no cervix)	Stop unless CIN 2 of greater present	Stop unless CIN 2 of greater present	Stop unless CIN 2 of greater present
Age to discontinue	65 after 3 negative Paps or 2 neg pap with co-testing in past 10 yr	65 after negative prior screening	65 after appropriate screening

*A bimanual examination is not indicated for cervical cancer screening*

Approximately **4.7 million women younger than 21 years** have a pap test **annually** in the US  
Cost: **\$500 million** per year.



Approximate **3 million women** (1 million are 65 years or older) **s/p TAH undergo pap testing annually**  
Cost: **\$350 million** per year



# Screening for Sexually-Transmitted Infections (STI's)

- The USPSTF, the CDC and other professional organizations recommend routine periodic screening for **Chlamydia** for all sexually active women under 25 years of age and older women at high-risk since screening decreases the incidence of PID
- Nucleic amplification tests (**NAATs**) using urine or self-collected vaginal swabs are highly sensitive and specific
- **Self-collected vaginal swabs**
  - Preferred Chlamydia screening test for women.
  - At least equal sensitivity and specificity compared to clinician-obtained swabs
  - Most cost effective when compared with urine or physician-collected cervical specimens
  - Preferred by patients

*A pelvic examination for the purpose of specimen collection for STI screening is no longer necessary*



# Screening for Ovarian Cancer



## Ovarian cancer:

- Highest mortality rate of all types of GYN cancer
- 5<sup>th</sup>-leading cause of cancer death among women
- The 5-year survival rate
  - Localized disease: >90% but only 15% of all patients are diagnosed with localized cancer
  - Advanced stage: 30%
- Infrequent (13 cases per 100,000 women.)
- Positive predictive value of screening for ovarian cancer – which directly depends on the prevalence of disease- is low, and most women with a positive screening test result will have a false-positive result.



# Screening for Ovarian Cancer



## The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial

- Large-scale, multicenter (10), randomized controlled trial
- Developed to evaluate the effect of screening for ovarian cancer on mortality.
- Enrolled more than 68,000 women ages 55-74 from the general US population
- Planned f/u, 13 yr.
- Bimanual ovarian palpation (BOP)
  - Initially offered annually but discontinued after 4 yrs. because no ovarian cancer was detected solely by BOP.
  - Low sensitivity: 5.1%.
  - Positive predictive value of 1%
  - False positive rate: 2%
  - BOP-only positives (negative TVU and CA-125)
    - Triggered diagnostic workups for false-positive exams
    - About 4% of this group received surgery (oophorectomy or TAH/oophorectomy)
- The PLCO trial found that **even annual ultrasound did not reduce ovarian cancer specific or all-case mortality**. Thus, it seems unlikely that the pelvic examination, a much less sensitive test, would be able to have any impact on mortality.



# Screening for Ovarian Cancer

- Pelvic exam is not an effective screening test
- Screening leads to important harms, including major surgical interventions in women who do not have cancer.
- **Most major professional and government groups recommend against screening for ovarian cancer** in asymptomatic average risk women.



Over 1/3 of US physicians continue to screen for ovarian cancer



# Screening for Other Conditions

Condition	Finding
<b>Bacterial Vaginosis, Herpes, and Trichomonas</b>	There is no evidence or guidelines supporting the screening for these conditions
	No studies examining the overall effectiveness of the pelvic examination in improving health outcomes for these conditions
<b>Fibroids and Ovarian Cysts</b>	Studies have shown the screening pelvic exam to be of no clinical benefit
<b>Vaginal and Vulvar Neoplasms</b>	Currently no practice of screening for these conditions in the general population or evidence that early detection of these rare conditions would change clinical outcomes

# Prior to Hormonal Contraception



- FDA, WHO, ACOG, Planned Parenthood Federation of America (PPFA):
  - **A pelvic examination is not required** asymptomatic women for the initiation of systemic hormonal contraceptives
  - Only need medical history and blood pressure measurement to rule out contraindications
- Applies to:
  - Contraceptive implants, injectable, pills, patches, or emergency contraceptive pills



# As part of the Well-Woman Exam

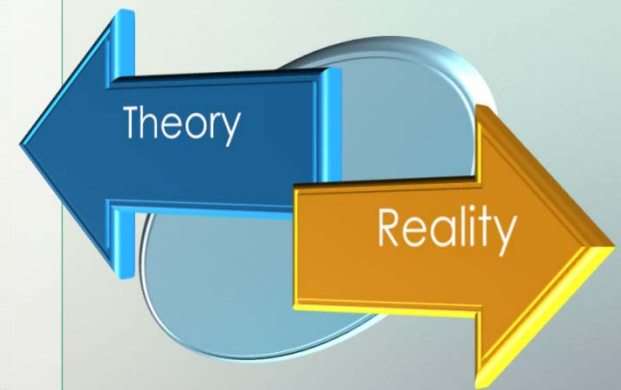
- No consensus exists on the appropriate content of preventive visits or Well Woman Visits
- Especially true with the lengthening of the screening intervals for pap tests
- It has been suggested that the opportunity for an annual pelvic examination might serve as an incentive for women to access the healthcare system and thereby receive recommended preventive services:
  - Screening for STD's
  - Screening for cervical cancer
  - Immunizations
  - Blood pressure check
  - Weight measurements
  - Cholesterol measurements
  - Colon cancer screening
  - Risk factor assessment and counseling





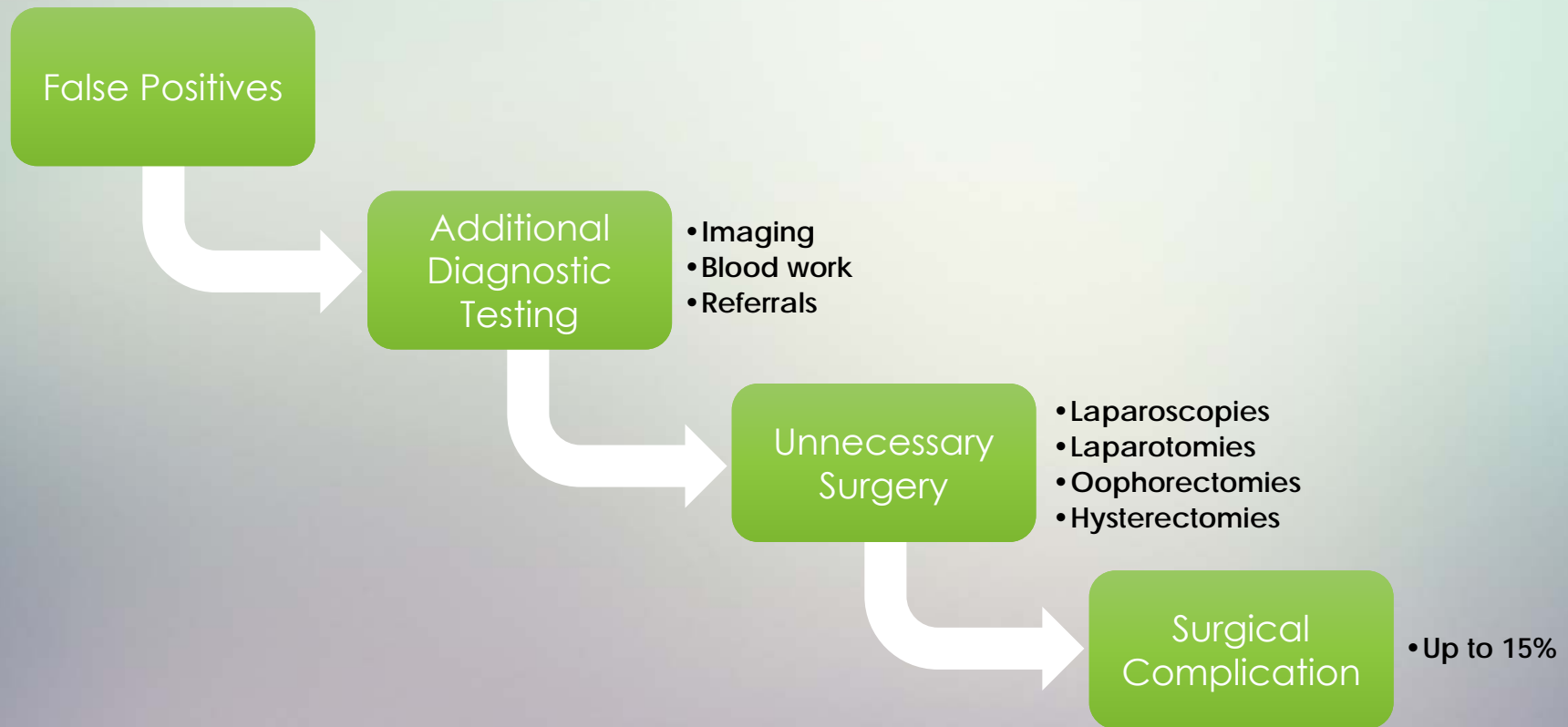
# Theory vs. Reality

- Most mammograms and pap smears are obtained during preventive gynecological examinations.
- Most counseling services occur outside of preventive health visits
- Fear and/or anxiety about the pelvic examination is associated with reduced compliance with pap visits.
- There is no data indicating that the performance of the routine pelvic examination in asymptomatic average risk women reduces morbidity or mortality from any condition





# Harms of the Screening Pelvic Exam





# Harms of the Screening Pelvic Exam

## Cost

- A large percentage of the **30.02 million** pelvic examinations/**\$1.17 billion dollars** per year in the US are **unnecessary**.
- False positive work ups and unnecessary surgeries + complications add to the cost
- **Opportunity costs:**
  - Preparing room and supplies
  - Patient disrobing and putting on a gown
  - Clinician finding a chaperone
  - Chaperone taking time away from other duties

Adds at least 10 minutes to an office encounter





# Harms of the Screening Pelvic Exam



- False Reassurance
- Psychological Harms:
  - Approximately 1/3 of women experience pain, discomfort, fear, anxiety and or embarrassment related to the pelvic exam
  - Less likely to return for another visit.
- Delay in Services and Obstruction of efforts to:
  - Increase appropriate cervical cancer screening
  - Reduce unwanted pregnancy
  - Prevent infertility through early treatment of chlamydia infections.



What are the Current Guidelines for the Screening Pelvic Examination?





- Independent, volunteer panel of 16 nationally recognized **experts in prevention, evidence-based medicine and primary care.**
  - Fields of practice/expertise include: behavioral health, family medicine, geriatrics, internal medicine, pediatrics, OB/GYN, and nursing
- Makes **recommendations about clinical preventive services** based on a rigorous review of existing **peer-reviewed evidence**
- All recommendations are published on the Task Force's website and/or in a peer-reviewed journal.
- Recommendations apply to **asymptomatic** adults and children
- Assign letter grade recommendations (A, B, C, or D or an I statement) based on the strength of the evidence and the balance of benefits and harms of a preventive service.
- Criteria for Evaluating Screening Tests:
  - Burden of suffering from target condition
  - Accuracy of test: Sensitivity, specificity and positive predictive value
  - Effectiveness of early detection
  - Relationship of benefits to harm
- Supported by the US Department of Health and Human Services (AHH) through AHRQ (Agency for Healthcare Research and Quality)





U.S. Preventive Services

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## Gynecological Conditions: Periodic Screening With the Pelvic Examination

Release Date: March 2017

### Recommendation Summary

Population	Recommendation	Grade (What's This?)
Asymptomatic, nonpregnant adult women who are not at increased risk for any specific gynecologic condition	<p>The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of performing screening pelvic examinations in asymptomatic women for the early detection and treatment of a range of gynecologic conditions.</p> <p>This statement does not apply to specific disorders for which the USPSTF already recommends screening (ie, screening for cervical cancer with a Papanicolaou ["Pap"] smear, screening for gonorrhea and chlamydia). See the <a href="#">Table</a> for more information.</p>	<b>I</b>

To read the recommendation statement in *JAMA*, select [here](#).

To read the evidence summary in *JAMA*, select [here](#).

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## Screening Pelvic Examination in Adult Women: A Clinical Practice Guideline From the American College of Physicians FREE

*Amir Qaseem, MD, PhD; Linda L. Humphrey, MD, MPH; Russell Harris, MD, MPH; Melissa Starkey, PhD; Thomas D. Denberg, MD, PhD; for the Clinical Guidelines Committee of the American College of Physicians (\*)*



# SUMMARY OF THE AMERICAN COLLEGE OF PHYSICIANS GUIDELINE ON SCREENING PELVIC EXAMINATION IN ADULT WOMEN

<b>Disease/Condition</b>	Cancer, pelvic inflammatory disease, other benign gynecologic conditions
<b>Target Audience</b>	Internists, family physicians, other clinicians
<b>Target Patient Population</b>	Asymptomatic, nonpregnant, adult women
<b>Interventions</b>	Pelvic examination
<b>Outcomes</b>	Mortality; morbidity; harms, including overdiagnosis, overtreatment, and diagnostic procedure-related harms
<b>Benefits of Screening</b>	None identified
<b>Harms of Screening</b>	Unnecessary laparoscopies or laparotomies, fear, embarrassment, anxiety, pain or discomfort, avoidance of necessary care
<b>Recommendations</b>	<i>Recommendation: ACP recommends against performing screening pelvic examination in asymptomatic, nonpregnant, adult women (strong recommendation, moderate-quality evidence).</i>
<b>High-Value Care</b>	ACP found no evidence that routine pelvic examination in asymptomatic, nonpregnant, adult women provides any benefit. With the current evidence, we conclude that performing pelvic examination exposes women to unnecessary and avoidable harms with no benefit. In addition, these examinations add unnecessary costs to the health care system. These costs may be compounded by expenses incurred by additional follow-up tests, including follow-up tests as a result of false-positive screening results, increased medical visits, and costs of keeping or obtaining health insurance.
<b>Clinical Considerations</b>	<p>Clinicians do not need to perform pelvic examination before prescribing oral contraceptives.</p> <p>Screening for sexually transmitted disease can be performed with urine testing or vaginal swabs and does not require a pelvic examination.</p> <p>Evaluation is often indicated in women with such symptoms as vaginal discharge, abnormal bleeding, pain, urinary problems, and sexual dysfunction.</p> <p>When screening for cervical cancer, examination should be limited to visual inspection of the cervix and cervical swabs for cancer and HPV.</p>





The American College of  
Obstetricians and Gynecologists  
WOMEN'S HEALTH CARE PHYSICIANS

## COMMITTEE OPINION

Number 534, August 2012

(Reaffirmed 2016)

### Committee on Gynecologic Practice

*This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.*

[PDF Format](#)

### Well-Woman Visit

“ACOG recommends annual pelvic examinations for patients 21 years of age or older. However, the College recognizes that this recommendation is based on expert opinion, and limitations of the internal pelvic examination for screening should be recognized.”

“Annual pelvic examination of patients 21 years of age or older is recommended by the College. At this time, this recommendation is based on expert opinion, and limitations of the internal pelvic examination should be recognized.”



The American College of  
Obstetricians and Gynecologists  
WOMEN'S HEALTH CARE PHYSICIANS

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## ACOG Statement on USPSTF Draft Recommendations on Pelvic Exams

June 28, 2016



# Summary of Guidelines

## Screening Pelvic Exam

	Recommendation	Rationale
USPSTF (2017)	Neither for nor against	Not enough evidence.
ACP (2014)	Against	No evidence to support. Significant harms.
AAFP	Against	No evidence to support. Low likelihood of benefit and increased risk of harm.
ACOG	Yearly after age 21	Expert opinion.



# Are US Physician Practices following the guidelines?

Adherence to guidelines is poor

	IM (%)	FP (%)	GYN (%)
Prior to hormonal contraception	40	68	72
As part of Well Woman Exam	54	90	98
Younger than 21			87
s/p TAH			96
Older than 65			98
Subsequent pap earlier than recommended	67	94	99
To screen for ovarian cancer	30	55	95
To screen for other GYN cancers	41	68	96
To screen for STIs	39	73	92

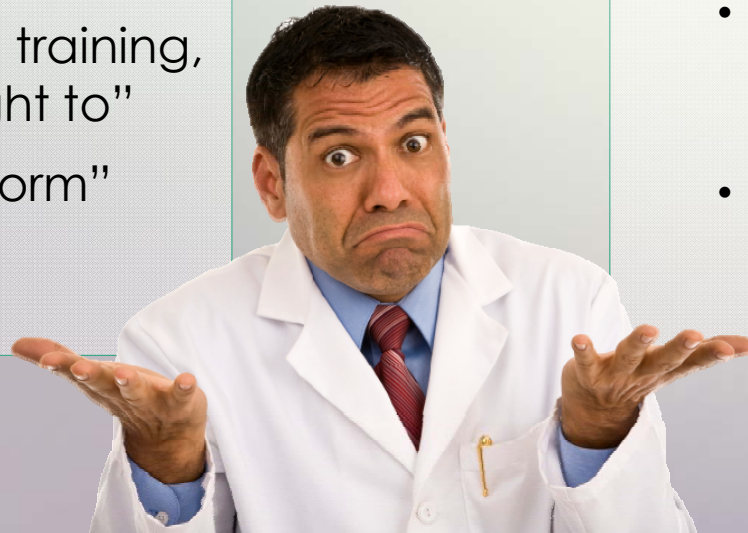
Most physicians indicate they are unlikely to change their practice despite evidence regarding the lack of utility of the pelvic examination as a screening tool.



# Why are US Physician Practices poorly adhering to guidelines?

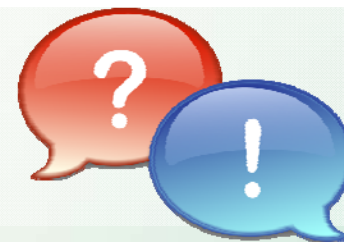
- Clinician preference
- Out of habit
- Legal concerns
- Financial incentives/reimbursement
- Influence of medical training, “because I was taught to”
- “Documenting the norm”
- “For completeness”

- To honor patients' request
- Patient reassurance
- False belief that the pelvic exam is a useful GYN cancer screening tool
  - Useful GYN cancer screening tool (75% FP, 79% IM and 84% of GYNs).
  - Effective screening tool for ovarian cancer (49% FP, 50% IM and 70% of GYNs).





# To Be or Not To Be...?



## Physicians “at risk”

- Solo practice
- In practice >10 years
- GYN specialty
- Female
- Personal hx of cancer
- NIH as top 3 organizations influencing their practice

## Improved Guideline Compliance

- Group practice
- <10 years in practice
- Internal Medicine specialty
- USPSTF as one of the top 3 organizations influencing their practice





## *POP QUIZ! - REVIEW*



Which patient should receive a pelvic examination?

# *POP QUIZ! - REVIEW*



## **Case 1**

A healthy 19-year old university student has been sexually active for 4 months and requests oral contraceptive pills. She has no complaints.

- Pap smear not indicated before the age of 21.
- Neither a pap nor a pelvic exam is necessary to start oral contraceptive pills.
- Blood pressure and medical history to r/o contraindications.
- Needs self-collected swab or urine test for Chlamydia.



# ***POP QUIZ! - REVIEW***

## **Case 2**

A 40 year old woman with 3 children, married for 16 years, underwent tubal sterilization. She has no complaints. She has been undergoing cervical cancer screening every year for the past 18 years with no abnormal pap smears recorded.

- Healthy, monogamous woman with multiple negative cervical cancer screens. Her lifetime risk of developing cervical dysplasia is very low.
- Pap every 3 years (every 5 if co-testing for HPV).
- Tubal ligation appears to decreased the lifetime risk of ovarian cancer by at least 33%.





# The Bottom Line



- The routine pelvic examination
  - Is not useful for GYN cancer screening.
  - Is not required for STI screening.
  - Is not necessary to provide hormonal contraception.
  - Harms outweigh benefits in asymptomatic, average-risk women.
- Time spent performing screening pelvic exams in asymptomatic women may be better spent delivering clinical preventive services that have been proven effective



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# US Physician Practices – Do we follow the guidelines?

- Adherence to guidelines in the US is poor
- DocStyles survey of US physicians
  - Web based survey
  - Administered by the public relation agency Porter Novelli
  - Sample drawn from 156,000 US physicians
    - Treated at least 10 patients/week
    - Worked in individual, group, clinic or hospital
    - Practiced for at least 3 yrs
- 1000 PCPs (Internists and FPs) and 250 OB/GYNs