9:45 – 10:45 am Screening and Prevention Update 2015 SPEAKER Gary J. Martin, MD

primed

Presenter Disclosure Information

- The following relationships exist related to this presentation:
 - ► Gary J. Martin, MD: No financial relationships to disclose.

Off-Label/Investigational Discussion

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Screening and Prevention Update - 2015

Gary J. Martin, M.D. Professor of Medicine Northwestern University Medical School

Principles of screening

- Find early while curable.
- Common problem, burden of illness, long latency.
- Cost/benefit issues
- ?does it make a difference?
- Train tracks w/ binoculars? (example: lung/prostate cancer??)

Lifetime Cumulative Risk

- Breast cancer for women 10%
- Colon cancer 6%
- Cancer of the cervix for women 2%
- Domestic violence for women $\sim 15\%$
- Hip fracture for white women 16%
- Prostate 10 > 20% but still 3% mortality

In Summary:13 years of FOBT

- US study average age 57 y/o (50-75)
- Deaths from colorectal cancer: 5.88/1000 vs 8.83/1000
- 30% decrease (15% in European)

Colon Cancer Screening

- Flex sig decreases colon ca deaths by 60%
- Minimal data on marginal gain of combination (70 vs 75% yield for polyps)
- Family hx helpful (doubles esp if younger) but
- 80% of colon ca in pts w/o FH

Colon Cancer Screening

- What about those right sided lesions?!
- VA Study 1,765 pts w/out distal polyps
- Pts 50-75 y/o about twice as likely to have + FH (males)
- 2.7% had "advanced" proximal lesion (mostly benign adenomas)
- 10% were invasive cancer (73% potential cures)
- Age and distal lesions predicted proximal ones (Odds Ratio =3.4)
- .3% serious complications (AMI/CVA/GI bleed etc.) NEJM 2000;343:162.

Colon Cancer Screening/Colonoscopy

- 1,994 pts screened
 7 proximal cancers (2-3/7 had distal lesion)
- 23/1,564 w/out distal polyps had proximal lesion (1.5%; 22% cancer)
- Male sex, age, distal lesions predicted proximal ones (2-7 fold increase)
- About half the proximal lesions were seen in distal negative pts.

<u>NEJM</u> 2000;343:169.

Cervical Cancer Using the Pap Smear *			
Interval between pap smears†	Increase in life expectancy‡	Program costs§	
Year	Days	\$	
1	67.08	315.10	
2	64.55	149.39	
3	61.56	95.61	
4	58.00	69.65	
5	53.99	54.54	

Colon cancer screening

- Flexible sigmoidoscopy: if polyps found >>colonoscopy
- If negative, 97-98.5% of the time the right side of the colon will be negative too.
- In somewhat higher risk pts 3/1000 will have a cancer on the right side.
- Serious complication rate is also 3/1000.

Pap smear strategy

- Screening women ages 21 to 65 years every 3 years with cytology provides a reasonable balance between benefits and harms.
- HPV testing combined with cytology (co-testing) every 5 years in women ages 30 to 65 years offers a comparable balance of benefits and harms

Mammography

- HIP Study: 5 days or 30% decrease
- Overview of 5 Swedish trials
- 282,777 women, 12 yrs f/u, 40-74y/o
- No benefit for women 40-49
- For group as a whole ~30% decrease
- After 12 yrs, 3.9/1000 breast ca deaths vs 5 1/1000

Recent analysis

- # needed to invite for screening of 1904 to prevent 1 breast cancer death in women aged 39 to 49 years, counterbalanced by false positives
- # for other age groups:1339 for 50-59 v/o and 377 for 60-69 y/o

PSA screening RCTs

- 20% reduction in European study (but screened q 3.5 years).
- Over 9 yrs: 0.71 death per 1000 men less. 1410 men would need to be screened and 48 addl cases of prostate ca would need to be treated to prevent one death from prostate cancer.
- No impact in US study. Small sample size and 50% screened vs 85%.
- 5 alpha-reductase inhibitor ?!

PSA screening RCTs

- Goteborg Swedish study: 20,000 men 50-64 y/o. PSA q 2 years
- Used 2.5-3 ng/ml threshold
- 12.7% screened group Dx'd w/ P Ca
- 8.2% P Ca in control group
- At 14 years, .9% died from P Ca vs .5%
- 293 NT Screen, 12 Dx'd to prevent one prostate ca death.

Lancet Oncol 2010, 11, pp 725-32

Lung Ca screening

- 53,500 smokers (>30 PY) age: 55-74 y/o
- 3 annual helical CT's vs CXR-followed 5 years
- 442 vs 354 lung ca deaths (20.3% less)
- 7% decreased overall mortality
- Lung Ca deaths represented $\sim 25\%$ of overall deaths
- 20-60% of screened pts show abnormalities

Estimated average increase in life expectancy for a population

- Mammography:
- Women 40 50 years old: 0-5 days
- Women 50 70 years old: 1 month
- Pap smears age 18-65:
- 2-3 mo's • Screening treadmill for a
- 50 y/o asymptomatic man: 8 days

Estimated average increase in life expectancy for a population

- PSA + digital rectal exam for a Man > 50 y/o: up to 2 wks
- Getting a 35-year-old smoker to quit: 3-5 yrs
- Beginning regular exercise for a 40 y/o man (30 min 3 x's/wk):9mo-2yrs

Selected Screening and Prevention Interventions

- Pap test (age 21 or sexually active) every 1-3 years
- Chlamydia (sexually active women < age 25)? HIV/gonorrhea based on risk. Hep C (1945-65)
- Colon cancer screening (fecal occult blood annually and/or sigmoidoscopy every 5 years or colonoscopy every 10 years) age 50 or earlier, depending on family history
- Mammography +/- clinical breast exam (age 40/50 every 1-2 years)

Selected Screening and Prevention Interventions

- Blood pressure, height, and weight
- Total blood cholesterol
- General counseling and prevention (seat belts, helmets, STD prevention, hand guns, smoke detector, diet, alcohol, and tobacco)
- Osteoporosis screening (DEXA at age 65 or age 60 if at increased risk)
- AAA: One time screening with ultrasound (accredited facility) in men age 65-75 who have ever smoked
- CAD? Grey zone for higher risk?

Screening for AAA – USPSTF

- Recommendation: One time screening with ultrasound (accredited facility) in men age 65-75 who have ever smoked
 - No need to repeat if normal aortic diameter (10 yrs)
- \$14,000-20,000/QALY (FH drops the cost)
- Consider <u>competing</u> risks and smoking/FH
- They modeled this strategy for 100,000 men in this age group: 138 deaths prevented/5yrs

Screening for AAA USPSTF Relative impact in your practice

- To prevent one AAA related death over the next 5 years:
- Screen 500 men, 65-74 y/o, who have ever smoked
- Screen 1783 men, 65-74 y/o who have never smoked

Mammography 1000 women x 12 yrs: 1.2 less breast cancer deaths (~5 vs 4/1000)

Occult blood testing ~5 vs 8 colon cancer deaths/1000 pts screened for 13 years

Update of Screening and Prevention Issues 2015

Gary J. Martin, MD Northwestern University

Table 1. Principles of screening

- Find disease early while curable (long latency)
- Focus on common problems, major burden of illness
- Consider cost/benefit issues
- Does it make a difference, or did you just find out about it earlier?

Table 2. Lifetime Cumulative Risk

Breast cancer for women	10%	
Colon cancer	6%	
Prostate cancer	10>20% but mortality remains 3%	
Cancer of the cervix for women*	2%	
Domestic violence for women	up to 15%	
Hip fracture for white women	16%	
*Assuming an unscreened population w/o HPV vaccine		

Table 2 lists the lifetime cumulative risk of a number of conditions that we screen for. This helps put into perspective what the potential yield is and why, as the number gets smaller, false positives become a significant counter-balancing factor for benefit. One should also remember that tobacco use, diet and activity, and alcohol use represent the vast majority of factors for preventable deaths and close to half of all deaths. That is why general counseling noted in table 5 is an important preventive measure in addition to the screening tests. In fact, probably the single greatest accomplishment a physician can do for a patient is to help them quit smoking.

Table 3. Methods of Measuring Health Benefits

- 1. Number of patients needed to screen in order to prevent one event
- 2. Absolute and relative impact on morbidity and mortality
- 3. Cost per year of life saved
- 4. Increase in average life expectancy for a population

Some examples of these different measures follow. Using a DEXA machine to screen for osteoporosis, and then appropriately treating patients, one would have to screen 731 women aged 65 to 69 in order to prevent one hip fracture. The related number of absolute impact can be exemplified by looking at breast cancer screening. A meta analysis of all of the Swedish mammography trials for breast cancer noted that approximately **1.2 fewer women per thousand** would die from breast cancer with screening for women aged 40 to 70 if they were screened over a twelve year period. Although it is a different population, it is interesting to compare this to the approximately **three lives per thousand** saved from colon cancer death in a population of 50 to 75 year olds screened with annual fecal occult blood testing (8.8/1000 versus 5.9/1000). Based on this, colon cancer screening may actually save more women's lives than mammography. The relative impact often sounds more impressive, but both figures are important. The relative impact for occult blood testing from the same data can be stated as a 30% reduction in colon cancer deaths. Cost per year of life data has been estimated for many screening and prevention strategies. Typically, strategies that cost less than \$30 - 50,000 / year of life saved are considered "cost effective". One example that is at this threshold of approximately \$30,000/year of life saved is using alendronate for a 65-year-old woman with osteoporosis.

Table 4. Estimated average increase in life expectancy for a population

Mammography:	
Women $40 - 50$ years old	0-5 days
Women $50 - 70$ years old	1 month
Pap smears age 18-65	2-3 months
Screening treadmill for a 50 year old	
(asymptomatic) man	8 days
PSA and digital rectal exam for a	
Man over 50 years old	up to 2 weeks
Getting a 35-year-old smoker to quit	3-5 years
Beginning regular exercise for a 40 year	
old man (30 minutes 3 times a week)	9 months to 2 years

Table 4 lists the increases in life expectancy for a population for a number of screening procedures. There are two important things to keep in mind while looking at this list. The first is that the actual average time increase applies to virtually no one. In reality, the vast majority of people screened will not derive any benefit, or possibly a slight negative from false positives. There will be a small subset of patients who benefit a great deal from being screened. These numbers average out to the reported value. One example is cervical cancer where pap smears cannot benefit the 98% of women who will never get cancer of the cervix, but for the two percent who would develop cervical cancer, pap smears may lead to preventing invasive cervical cancer and adding as much as 25 years onto those individuals' lives. The other important point to remember with this data is that although the average numbers appear modest, they are averaged over the entire population so that the number of patient months is a fairly large number. Some have recommended that the gain of a month for a preventive strategy aimed at the general population represents an important intervention.

The U.S. Preventive Services Task Force has attempted to rigorously balance all of these issues and table 5 lists the great majority of their recommendations. However, there are additional procedures to consider for individuals at higher risk for a given disease than the general population. In general, family history and social history can identify these patients and are illustrated in the Task Force report, which is available on their web page www.ahrq.gov/clinic/uspstfix.htm. Screening for many conditions begin at age 50 however, for those with a significant family history, starting ten years earlier than when the youngest family member developed a cancer is also prudent (i.e. if the patient's mother had colon cancer diagnosed at age 55, one would start as early as 45 for the patient). This ten-year advance is also reasonable for breast and prostate cancer screening (although prostate cancer screening with PSA is not recommended by the task force). Some interventions that the U.S. Preventive Services Task Force feels are of uncertain value because of lack of data, other groups recommend. Three examples worthy of consideration are screening for diabetes in the general population (with fasting blood sugars), screening for domestic violence and screening for depression.

Table 5Clinical Preventive Services for Normal-Risk Adults Recommended by the U.S. Preventive Services TaskForce

Screening

- -

Blood Pressure, Height and Weight: Periodically, 18 years and older *Cholesterol*:

Men, Every 5 years, 35 years and older.

Women, Every 5 years, 45 years and older

Diabetes: Periodically, adults with hypertension or hyperlipidemia

Pap Smear: Women, Every 3 Years 21-65 y/o, or spaced every 5 yrs for women >30 with HPV testing *Chlamydia*: 18-25 years HIV consider for all 15-65, gonorrhea, syphilis, Hep C, based on risk/1945-65 *Mammography*: Every 1 to 2 Years, 40? 50 years and older

Colorectal cancer: Periodically, 50 years and older (fecal occult blood annually and/or sigmoidoscopy every 5 years or colonoscopy every 10 years) depending on family history

Osteoporosis: Women, routinely, ≥ 65 years or ≥ 60 years at increased risk for fractures

Alcohol Use: Periodically, 18 years and older

Vision, Hearing: Periodically, 65 years and older

Immunization (http://www.cdc.gov/vaccines/schedules/hcp/adult.html)

HPV Females (males ≤ 21) $\leq 26y/o 3$ doses

Tetanus-Diphtheria (Td): Every 10 Years, 18 years and older. (Substitute one Tdap) *Varicella* (VZV): Susceptibles only—Two doses, 18 years and older.

Measles, Mumps, Rubella (MMR): One dose, 18-50 years if not given series as child or born before 1957. Women of childbearing age **caution.**

Pneumococcal: One dose, 65 years and older. Influenza: Yearly, 50 years and older. All adults in 2010.

Meningococcal, Hep A and B can be considered based on risk.

Chemoprevention

Discuss aspirin to prevent cardiovascular events: CV risk needs to be enough to justify it Men, Periodically, 40 years and older. Women, Periodically, 50 years and older (especially > 65) *Discuss breast cancer chemoprevention with women at high risk*

Counseling

Calcium Intake: Women, Periodically, 18 years and older.

Folic Acid: Women of childbearing age, 18-50 years.

Tobacco cessation, drug and alcohol use, STDs and HIV, nutrition, physical activity, sun exposure, oral health, injury prevention (loaded handgun, seat belts, bicycle helmet), and polypharmacy: Periodically, 18 years and older Upper age limits should be individualized for each patient.

Notes:

- 1.) In the elderly some measures become the priority. For example: vision, hearing, dental evaluations, immunizations (pneumococcal, influenza) fall prevention, hot water heater at less than 120 degrees, and avoidance of polypharmacy.
- 2.) Adapted from the U.S. Preventive Services Task Force Guide to Clinical Prevention Services 2nd and 3rd editions (www.ahrq.gov/clinic/uspstfix.htm)

Commonly Encountered Issues

The Agency for Healthcare Research and Quality and the CDC have numerous flow sheets available that can be helpful as part of their "Put Prevention Into Practice" program (http://www.ahcpr.gov/clinic/ppipix.htm). There is much less data available about when to "sunset" some of these services. Certain cancers like cancer of the cervix actually become less common in older populations and the age of 65 has been offered for consideration as a stopping point assuming the previous recent pap smears have been negative. For breast,

colon, and prostate cancer an age of approximately 75 may be a reasonable time to reevaluate the need for some of these procedures. Because of co morbidities and since so many screening procedures' benefits set in approximately 10 years after screening, a useful approach is estimating the patient's life expectancy. For some older patients with advanced co morbidities, such as severe COPD, congestive heart failure, or immobility, the benefit of some screening procedures are likely to be close to zero and other priorities emerge if the patient's life expectancy is less than 10 years. This type of shift in focus needs to be done tactfully, so the patient doesn't receive the wrong message. The fact that greater attention will be paid to functional capacity, activities of daily living, and optimizing their co morbidities can be explained to both patients and families.

Screening for lung cancer and other cancers as well as coronary disease with CT/MRI scanning has been commercialized. Lung cancer screening in uncontrolled studies offer mixed results. The 50,000 patient NIH controlled study has just reported, using CT scanning for lung cancer screening, that showed a 20% reduction in lung cancer deaths and a 7% overall mortality reduction. It is still being debated if it's the best use of health care dollars and the large number of false alarm nodules that are detected that need follow up. http://www.cancer.gov/clinicaltrials/noteworthy-trials/nlst Use for abdominal cancers is quite unproven. Screening for CAD with CT is very controversial and unproven but is also the subject of an ongoing 10 year long MESA trial funded by the NIH.

Cervical Cancer

Most all authorities agree that screening for cancer of the cervix is valuable. For most women, the frequency may be as little as every three years because increasing the frequency adds little benefit and has risks of triggering off unnecessary procedures. The latest guidelines encourage a three year interval or spacing out the interval after age 30 to five years when combined with HPV testing. Using a cyto-brush to collect cells in the cervical os markedly increases the yield of some practitioners' abilities to collect endocervical cells. The use of the liquid based tests as part of the cervical cancer screening collection technique has become a first line approach in many parts of the country, although it's primary benefit is for women who have borderline cytology. Both the ACS and USPSTF still recommend the traditional collection as acceptable. The USPSTF feels more data is needed before routinely using the liquid-based technologies.

There is a lifetime cumulative risk of approximately ten percent of developing breast cancer. Pooled data from the Scandinavian studies demonstrate a reduction in breast cancer deaths of approximately 1.2 women / 1000 screened over a twelve year period. Approximately 5.1 / 1000 women who are not screened will die of breast cancer over a twelve-year period, versus 3.9 / 1000 women who are screened with mammography.

Mammography between the ages of 40 and 50 has always been controversial, but in the United States it has become generally accepted. The absolute benefit in this age group is quite small and the number of false positives that lead to unnecessary biopsies is relatively large. Recently the USPSTF made 40-50 a grey zone that can be individualized. Mammography is particularly difficult in this group because 1.) Breast cancer is less common (only about 1 - 1.5 % of women will get breast cancer between age 40 and 50), 2.) The density of premenopausal breast tissue makes the interpretation of mammography more difficult, and 3.) It may be a faster growing tumor cancer in this premenopausal age group when it does occur and spread earlier. Postmenopausal breast cancer, however, may be a slower growing tumor. Although an overall frequency between one and two years is recommended, it probably makes some sense to use the shorter interval for women between 40 and 50 if one is going to screen this age group.

Colon Cancer

A person's lifetime cumulative risk for colon cancer is approximately 6%. This is lower for those without a family history and higher for those with first-degree relatives who have had colon cancer at younger ages. There are three accepted screening techniques for colon cancer. Fecal occult blood testing annually has led to a 15 to 30% reduction in colon cancer deaths in controlled studies. Based on case control studies, flexible sigmoidoscopy is thought to reduce colon cancer deaths by approximately 40-60%. Its benefit may last for up to ten years, but most experts would recommend a screening sigmoidoscopy every five years. Randomized data

suggests a smaller benefit but are diluted by large rates of screening in the "usual care" control groups. Although colonoscopy has not had as much data regarding a mortality benefit, it is generally felt that it offers at least the potential benefit of flexible sigmoidoscopy. Ironically, colonoscopy seems to have less impact on right sided cancers in part because they may be harder to detect (flat). Colonoscopy does, however, have additional costs and risks. No head to head comparisons between these techniques have been performed in the same population but the most important point is that some type of colon cancer screening be offered to patients. Screening generally starts at age 50, however, for those with a significant family history, starting ten years earlier than when the youngest family member developed colon cancer is also prudent (i.e. if the patient's mother had colon cancer diagnosed at age 55, one would start as early as 45 for the patient). Studies using colonoscopy have compared the findings of what flexible sigmoidoscopy would have found (i.e. the distal 55 cm) versus colonoscopy. Some patients who have a flexible sigmoidoscopy may go on to have a colonoscopy because of polyps that are found. For those who have a flexible sigmoidoscopy that is negative for polyps, only one and a half to three percent of patients will have a benign polyp on the right side of the colon that would be otherwise unrecognized. Up to three per thousand patients may have a cancer on the right side of the colon that would otherwise be missed. However, this needs to be counter balanced by the increased expense and complication rate of colonoscopy. In the same studies, approximately three per thousand patients have a serious complication related to colonoscopy (i.e. major bleeds, perforation, cardiovascular event). Most of these complications are related to polypectomy, but some are seen with just the screening portion. Either endoscopic technique may offer more benefit than fecal occult blood testing and the choice between them should be based on the patient's preferences and family history. "Virtual" colonoscopy with imaging techniques is evolving, misses mucosal lesions and cannot deal with polyps even if they are seen. Newer DNA based stool sample tests are promising and being evaluated.

Prostate Cancer

The lifetime cumulative risk of prostate cancer in men in the United States is approximately 15-18% with threefourths of those being diagnosed after age 65. The likelihood of a man in the United States dying from prostate cancer is only about 3%, so it should be clear that many men diagnosed with prostate cancer would die from other causes, particularly older men. It is also well known that at autopsy an even higher percentage of men have occult prostate cancer that did not lead to any morbidity during their lifetime. Many experts, including the U.S. Preventive Services Task Force, recommend an individualized discussion between physicians and their patients about prostate cancer screening since the risk benefit ratio is complicated and therefore personal utilities weigh highly. The USPSTF recently recommended against routine use of the PSA. Although the early detection of prostate cancer seems desirable, the risks include false positive results, unnecessary anxiety, biopsies, and even potential complications from treating some early cancers that may never have affected a patient's health or well being. These include erectile dysfunction, urinary incontinence, and bowel dysfunction from surgery and radiation treatment. Two recent randomized studies showed mixed results, one with a modest benefit that may not be worth the downside risks. A third study from Sweden showed some promising results but also noted substantial "over-diagnosis".

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Cervical cancer: http://www.uspreventiveservicestaskforce.org/uspstf/uspscerv.htm

Mammography

U.S. Preventive Services Task Force recommendations now suggest routinely screening women with no risk factors starting at age 50, performing biannual screening until age 74, and no longer teaching breast self-examination. (*Ann Intern Med.* 2009;151:716-726.)

Gøtzsche PC, Jørgensen KJ. Screening for breast cancer with mammography. Cochrane Database Syst Rev. 2013;(6):CD001877 If we assume that screening reduces breast cancer mortality by 15% and that overdiagnosis and overtreatment is at 30%, it means that for every 2000 women invited for screening throughout 10 years, one will avoid dying of breast cancer and 10 healthy women, who would not have been diagnosed if there had not been screening, will be treated unnecessarily. Furthermore, more than 200 women will experience important psychological distress including anxiety and uncertainty for years because of false positive findings.

Prostate cancer

Back-to-back studies detailing the efficacy of screening for prostate cancer. Mixed results. (*N Engl J Med.* 2009;360;1310-1320 and *N Engl J Med.* 2009;360;1320-1328) Hugosson J, Carlsson S, Aus G, Bergdahl S, Khatami A,

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ONE PAGE SUMMARY FOR POCKET

Clinical Preventive Services for Normal-Risk Adults Recommended by the U.S. Preventive Services Task Force

Screening

Blood Pressure, Height and Weight: Periodically, 18 years and older Cholesterol: Men, Every 5 years, 35 years and older. Women, Every 5 years, 45 years and older Diabetes: Periodically, adults with hypertension or hyperlipidemia Pap Smear: Women, Every 3 Years 21-65. For women >30 q 5yrs if combined w/ HPV testing Chlamydia: 18-25 years HIV consider 15-65, gonorrhea, syphilis, Hep C, based on risk/1945-65 Mammography: Every 1 to 2 Years, 40? 50 years and older Colorectal cancer: Periodically, 50 years and older (fecal occult blood annually and/or sigmoidoscopy every 5 years or colonoscopy every 10 years) depending on family history Osteoporosis: Women, routinely, \geq 65 years or \geq 60 years at increased risk for fractures Alcohol Use: Periodically, 18 years and older Vision, Hearing: Periodically, 65 years and older Lung cancer > 30 pack yr; 55 yrs old and up still smoking or quit < 15 yrs ago. Low dose CT. AAA with ultrasound one time in men who have smoked > 100 cigs, 65-75 yrs old.

Immunization (http://www.cdc.gov/nip/recs/adult-schedule.htm)

HPV Females (males ≤ 21) ≤ 26 y/o 3 doses

Tetanus-Diphtheria (Td): Every 10 Years, 18 years and older. (Substitute one Tdap) *Varicella* (VZV): Susceptibles only—Two doses, 18 years and older.

Measles, Mumps, Rubella (MMR): One dose, 18-50 years if not given series as child or born before 1957. Women of childbearing age **caution.**

Pneumococcal: One dose, 65 years and older (both 13 and 23 valent vaccines). *Influenza*: Yearly, traditionally 50 years and older. All adults in 2010.

Meningococcal, Hep A and B can be considered based on risk.

Chemoprevention

Discuss aspirin to prevent cardiovascular events: CV risk needs to be enough to justify it Men, Periodically, 40 years and older. Women, Periodically, 50 years and older (especially > 65) Discuss breast cancer chemoprevention with women at high risk

Counseling

Calcium Intake: Women, Periodically, 18 years and older.

Folic Acid: Women of childbearing age, 18-50 years.

Tobacco cessation, drug and alcohol use, STDs and HIV, nutrition, physical activity, sun exposure, oral health, injury prevention (loaded handgun, seat belts, bicycle helmet), and polypharmacy: Periodically, 18 years and older Upper age limits should be individualized for each patient.