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Developing Recommendations for Evidence-Based Clinical Preventive Services for Diverse Populations: Methods of the U.S. Preventive Services Task Force

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The U.S. Preventive Services Task Force (USPSTF) summarizes the principles and considerations that guide development of its recommendations for diverse U.S. populations. It uses these principles through each step in the evidence-based guideline process: developing the research plan, conducting the evidence review, developing the recommendation, and communicating to guideline users. Three recent recommendations provide examples of how the USPSTF has used these principles: the 2015 recommendation on screening for abnormal blood glucose and

type 2 diabetes; the 2016 recommendation on screening for breast cancer; and the recommendation on screening for prostate cancer, which is currently in progress. A more comprehensive list of recommendations that includes considerations for specific populations is also provided.

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The U.S. Preventive Services Task Force (USPSTF) works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services, such as screening, counseling, and use of preventive medications (1). To achieve this goal, we pay particular attention to how our recommendations can be most effectively applied to specific segments of the U.S. population with patterns of disease or the effectiveness of a preventive service that may differ from the general population. These specific populations may be identified by demographic characteristics (for example, age, race/ethnicity, or sex) or other factors (for example, biology, behavior, or heredity).

In this article, we outline the principles and considerations that guide the development of our recommendations for specific U.S. populations. We discuss 3 recent recommendations as examples: the 2015 recommendation on screening for abnormal blood glucose and type 2 diabetes (2); the 2016 recommendation on screening for breast cancer (3); and the recommendation on screening for prostate cancer, which is currently in progress (4). A more comprehensive list of recommendations that includes considerations for specific populations is provided in the Table.

DEVELOPING RESEARCH PLANS AND CONDUCTING THE EVIDENCE REVIEW TO INCLUDE DIVERSE POPULATIONS

We consider diverse populations starting with the first step in our process—development of the research plan. This plan defines the types of evidence that will be gathered and reviewed by the Evidence-based Practice Center (EPC) team and used by the USPSTF to develop the recommendation. The research plan routinely includes a means to identify evidence on whether specific segments of the U.S. population may be dis-

proportionately affected by a condition or susceptible to variation in the effectiveness of the preventive service. In consultation with the USPSTF, the EPC investigators have developed a comprehensive approach to incorporating the evidence for diverse populations throughout all phases of the systematic review process, including determination of the scope of the topic, data abstraction and critical appraisal, data analysis and synthesis, and reporting and interpretation of the evidence (13). Additional input about subpopulations comes from outside review and public comment on the draft research plan to further refine our process. For example, the draft and final research plans on screening for prostate cancer (Supplement 1, available at Annals.org) highlight additional clarifications from the USPSTF on consideration of African American men and men with family history of prostate cancer, which were added in response to public comments.

The research plan guides the systematic evidence review conducted by the EPC team, and the resulting evidence report routinely includes information on the epidemiology across all relevant populations (for example, incidence, prevalence, and mortality).

Supplement 2 (available at Annals.org) shows the draft and final research plans for the 2015 recommendation on screening for abnormal blood glucose and type 2 diabetes. The analytic framework depicts the intent to review literature and consider variation in benefits and harms by risk status (high vs. average) and to examine additional variability by age, sex, and race/ethnicity at each stage in the framework. The subse-

See also:

Web-Only
Supplement

Table. Selected Examples of USPSTF Recommendation Statements That Incorporate Evidence on Specific Populations

Subpopulation, by Preventive Service	Recommendation	Consideration
Screening for abnormal blood glucose and type 2 diabetes mellitus (2)		
African Americans, American Indians or Alaskan natives, Asian Americans, Hispanics or Latinos, and native Hawaiians or Pacific Islanders	B (moderate net benefit): Recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40–70 y who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity. The target population includes persons who are most likely to have glucose abnormalities that are associated with increased CVD risk and can be expected to benefit from primary prevention of CVD through risk factor modification. Persons who are members of certain racial/ethnic groups (that is, African Americans, American Indians or Alaskan natives, Asian Americans, Hispanics or Latinos, or native Hawaiians or Pacific Islanders) may be at increased risk for diabetes at a younger age or lower body mass index. Clinicians should consider screening earlier in persons with ≥1 of these characteristics.	Higher than average prevalence of type 2 diabetes mellitus in African Americans, American Indians or Alaskan natives, Asian Americans, Hispanics or Latinos, and native Hawaiians or Pacific Islanders.
Screening for breast cancer (3)		
Women aged 50–74 y	B (moderate net benefit): Recommends biennial screening mammography.	Randomized, controlled trial evidence of benefit for mammography screening in women aged 40–74 y; combined with observational data and modeling, this indicates smaller net benefit for women in their 40s than at older ages.
Women aged 40–49 y	C (small net benefit): The decision to start screening mammography in women before age 50 y should be an individual one. Women who place a higher value on the potential benefit than the potential harms may choose to begin biennial screening between age 40–49 y.	
Women aged ≥75 y	I statement (insufficient evidence): The current evidence is insufficient to assess the balance of benefits and harms.	No trial evidence in older women. I statement represents a call for more research and not a recommendation against screening. Clinicians and patients must determine the appropriate course in the absence of evidence; the recommendation statement includes discussion of comorbidity and limited life expectancy as potential considerations.
Women with a family history of breast cancer	C (small net benefit): Women with a parent, sibling, or child with breast cancer are at higher risk for breast cancer and thus may benefit more than average-risk women from beginning screening in their 40s.	Observational studies suggest that women in their 40s with a family history of breast cancer have a risk similar to that of women in their 50s. These women may be more likely to benefit from initiating screening in their 40s. Included in the top line of the recommendation for women in their 40s.
African American women	No specific separate recommendation; discussed in the Clinical Considerations section.	Recommendation statement discusses higher mortality rates in African American women, with mixed evidence for what contributes to higher mortality. In the Research Needs and Gaps section, the USPSTF states, “Direct evidence about any differential effectiveness of breast cancer screening is lacking for important subgroups of women, such as African American women, who are at increased risk for dying of breast cancer, and older women, for whom balancing the potential benefits and harms of screening may become increasingly challenging with advancing age.”
Behavioral counseling to promote a healthful diet and physical activity (5, 6)		
Adults who are overweight or obese and have additional CVD risk factors	B (moderate net benefit): Recommends offering or referring adults who are overweight or obese and have additional CVD risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.	Robust evidence base (moderate certainty) for counseling for healthy lifestyle in each population, which allows for assessment of different magnitude of net benefit in each and a separate recommendation reflecting different magnitude of net benefit.

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Table—Continued

Subpopulation, by Preventive Service	Recommendation	Consideration
Adults without a known diagnosis of hypertension, diabetes, hyperlipidemia, or CVD	C (small net benefit): Although the correlation among healthful diet, physical activity, and the incidence of CVD is strong, existing evidence indicates that the health benefit of initiating behavioral counseling in the primary care setting to promote a healthful diet and physical activity is small. Clinicians may choose to selectively counsel patients rather than incorporate counseling into the care of all adults in the general population.	
Screening for colorectal cancer (7)		
African Americans	No specific separate recommendation; discussed in the Clinical Considerations section.	African American adults have the highest incidence and mortality rates compared with other racial/ethnic subgroups. The reasons for these disparities are not entirely clear. Studies have documented inequalities in screening, diagnostic follow-up, and treatment; they also suggest that equal treatment generally seems to produce equal outcomes. This recommendation accordingly applies to all racial/ethnic groups, with the clear acknowledgment that efforts are needed to ensure that at-risk populations receive recommended screening, follow-up, and treatment. In the Research Needs and Gaps section, the USPSTF states, "Empirical data about the effectiveness of different screening strategies for these at-risk populations are not available."
Screening for abdominal aortic aneurysm (8)		
Male smokers	B (moderate net benefit): Recommends 1-time screening for abdominal aortic aneurysm with ultrasonography in men aged 65-75 y who have ever smoked.	Several randomized, controlled trials of screening provide high certainty of at least a moderate net benefit.
Male nonsmokers	C (small net benefit): Recommends selectively offering screening in men aged 65-75 y who have never smoked rather than routinely screening all men in this group.	Lower prevalence in epidemiology studies. Extrapolation of trials of male smokers to male nonsmokers suggests a potential net benefit that is smaller in magnitude.
Female smokers	I statement (insufficient evidence): The current evidence is insufficient to assess the balance of benefits and harms.	Lower prevalence (similar to male nonsmokers). Single trial with female smokers showed no benefit. Extrapolation from trials in men results in mixed body of evidence that is insufficient to make a recommendation.
Female nonsmokers	D (no benefit): Recommends against routine screening for abdominal aortic aneurysm in women who have never smoked.	Single trial with women showed no benefit. Extremely low prevalence among female nonsmokers makes benefit unlikely.
Screening for hepatitis B virus infection (9)		
Adolescents and adults at increased risk	B (moderate net benefit): Recommends screening for hepatitis B virus infection in persons at high risk for this condition.	Risk groups with prevalence $\geq 2\%$ based on epidemiologic evidence.
Behavioral and pharmacotherapy interventions for tobacco smoking cessation (10)		
Adults	A (large net benefit): Recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and U.S. Food and Drug Administration-approved pharmacotherapy for cessation to adults who use tobacco.	Evidence of benefit for both behavioral counseling and pharmacotherapy for smoking cessation.
Pregnant women	A (large net benefit): Recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco. I statement (insufficient evidence): The current evidence is insufficient to assess the balance of benefits and harms.	Evidence specifically in pregnant women showing behavioral counseling has benefits, including abstinence, increase in infant birthweight, and reduced risk for preterm birth. Insufficient evidence for use of pharmacotherapy for smoking cessation.

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Table—Continued

Subpopulation, by Preventive Service	Recommendation	Consideration
Screening for latent tuberculosis infection (11)		
Adults at increased risk	B (moderate net benefit): Recommends screening for latent tuberculosis infection in populations at increased risk.	Epidemiologic evidence showing that populations at increased risk include persons who were born in, or are former residents of, countries with increased tuberculosis prevalence and persons who live in, or have lived in, high-risk congregate settings (e.g., homeless shelters and correctional facilities).
Screening for intimate partner violence and abuse of elderly and vulnerable adults (12)		
Women of childbearing age	B (moderate net benefit): Recommends that clinicians screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services.	Trial evidence on screening specifically in women of childbearing age.
Older adults	I statement (insufficient evidence): The current evidence is insufficient to assess the balance of benefits and harms.	No studies on screening in older adults and vulnerable adults.

CVD = cardiovascular disease; USPSTF = U.S. Preventive Services Task Force.

quent systematic evidence review revealed the higher prevalence of diabetes and younger age at disease onset in African Americans, American Indians or Alaskan Natives, Asian Americans, Hispanics or Latinos, and Native Hawaiians or Pacific Islanders than in white populations. Obesity was identified as the defining factor in the high-risk group, for which screening and treatment showed a benefit, but the evidence also showed that Asian Americans had an increased risk for diabetes at a lower body mass index (14). The review revealed limited data on the effectiveness of screening or interventions specific to these racial/ethnic subpopulations.

USING THE EVIDENCE TO DEVELOP RECOMMENDATIONS RELEVANT TO SPECIFIC POPULATIONS

The USPSTF uses the systematic evidence review to develop a recommendation and follows a rubric for assigning grades based on the magnitude of net benefit anticipated for the preventive service (that is, benefits minus harms) and the certainty of that estimate. When a decision to issue a recommendation for specific segments of the population is being made, the ability to clearly and easily identify the factors that define the specific population is important (for example, age, easily measured risk factors, or self-identified race/ethnicity). Although many features may distinguish a specific population under consideration, the final decision to issue a separate graded recommendation for that population is primarily based on whether a difference in magnitude of net benefit can be confidently identified.

Evidence That Supports Differences in Magnitude of Net Benefit

Sometimes a robust evidence base across different segments of the population allows for determination of corresponding differences in magnitude of net benefit,

such as the evidence on mammography screening for breast cancer. Multiple randomized, controlled trials show the effectiveness of screening in women aged 40 to 74 years, with evidence of smaller net benefit at younger ages. The USPSTF issued a grade B recommendation for women aged 50 to 74 years and a grade C recommendation for those aged 40 to 49 years. Both grades favor screening, with grade B signifying moderate net benefit and C indicating a small net benefit.

Variability in Quality or Volume of Evidence Supporting a Difference in Magnitude of Net Benefit

Sometimes evidence supports a difference in the net benefit of a preventive service for a particular segment of the population, but the quality or volume of the direct evidence is not sufficiently robust to formulate a separate recommendation. For example, a specific population may be studied in randomized, controlled trials, but the highest evidentiary standard is lacking (for example, subgroup hypotheses were not specified a priori, the trial did not have sufficient power to find an effect in the subgroup, or trial results were not analyzed for statistical heterogeneity among subgroups). In this case, the USPSTF may call attention to a clearly identifiable group for whom the net benefit may differ from that of the average population, even if a separate recommendation is not issued.

In the breast cancer screening recommendation, modeling studies suggest that women in their 40s with a mother, sister, or daughter with breast cancer have a risk similar to that of average-risk women in their 50s. We singled out family history as a factor that might lead a woman to consider screening in her 40s at the beginning of the grade C recommendation for women in their 40s, and we called attention to this in the Summary of Recommendations and Evidence section. Despite the higher risk and theoretically increased likelihood of benefit from earlier mammography screening

in women with a family history of breast cancer, the absence of studies directly testing the efficacy of such screening prevented us from issuing a separate recommendation.

Differences in Disease Epidemiology and the Question of Difference in Magnitude of Net Benefit

We often have evidence of differences in the epidemiology of disease patterns between populations (for example, differences in incidence, mortality, or competing risks). Although this evidence may be important to communicate to patients and clinicians, differences in epidemiology alone usually do not allow us to make a separate, population-specific recommendation. When assessing the need for a separate, population-specific recommendation, we consider whether the preventive service could reasonably be expected to result in a difference in magnitude of net benefit in the specific population based on this epidemiology. In the absence of this evidence, the recommendation for the general population may reasonably be assumed to apply to that specific population in most cases.

For example, African American women have higher rates of breast cancer mortality but the extent to which differences in screening efficacy contribute to this outcome is unclear. In fact, some evidence suggests that less breast cancer treatment is an important contributor to the higher mortality rates in these women. Our recommendation statement called attention to this fact and the importance of screening African American women, but we did not issue a separate recommendation because it is unclear whether more intensive or earlier screening in these women will affect mortality rates. The recommendation statement called for more research to address this question.

Younger or older age at disease onset in a particular population may suggest that initiating the preventive service at a different age is indicated. Most screening trials provide little direct evidence on the optimal age for screening initiation or periodicity; therefore, at times we have used modeling to address these questions. Mathematical modeling may help estimate the effects of earlier or more frequent use of a preventive service in a population segment with an underlying disease epidemiology that differs from that of the general population.

Differences in Certainty of the Evidence

The USPSTF often reviews evidence of a preventive service that has been studied in one population and considers whether the potential of net benefit can be extrapolated to another segment of the population. This extrapolation may decrease the certainty of the effectiveness of the preventive service in that population segment, thereby resulting in a different recommendation grade. One example is screening for abdominal aortic aneurysm (8); studies were primarily conducted in male smokers, so we extrapolated the evidence to estimate effectiveness in male nonsmokers and female smokers. We may also give a population-specific rec-

ommendation when a preventive service is studied in a narrow spectrum of higher-risk patients, and we must decide whether these results can be applied to lower-risk populations. If the evidence does not reasonably apply to such populations, we may issue a recommendation for only those at higher risk (for example, screening for hepatitis B virus infection only in persons at high risk for infection) (9).

Applicability of Recommendations for Children, Pregnant and Postpartum Women, and Older Adults

In general, USPSTF recommendations are routinely stratified for children and adults. Unless otherwise specified, pregnant and postpartum women are generally included in recommendations that apply to adults, but considerations related to health outcomes in women and the developing fetus or infant may result in a specific recommendation for these groups (for example, behavioral and pharmacotherapy interventions for tobacco cessation) (10). Older age is usually an important factor that increases the risk for a particular condition (thus making it more likely that a preventive service will have net benefit, if benefits are realized in the short term), but older adults also have a higher likelihood of competing risks that may reduce potential benefits. Because these adults are often not included in trials of preventive services, we frequently highlight the need for more research in this important population.

When the Evidence Is Insufficient to Make a Recommendation

When the evidence is lacking, the USPSTF highlights this insufficiency, summarizes the limited available evidence, and calls for more research to address the gaps. The USPSTF's evidence-based methods generally preclude it from making a recommendation based solely on epidemiologic evidence (often the only type available). We recognize that clinicians must act even if sufficient evidence is not available, and by providing information on the epidemiology of disease and the guidelines of other organizations, we hope to provide the tools that will help them make decisions until the research gaps are filled.

COMMUNICATING RECOMMENDATIONS FOR SPECIFIC POPULATIONS

The USPSTF recommendation statements extend beyond the section that reports the recommendation grade. In the body of these statements, particularly in the Clinical Considerations section, we discuss evidence relevant to specific populations, including variations in epidemiology or effectiveness of the preventive service, as well as what is known about the nature of these differences. For prevention of conditions that disproportionately affect minority and vulnerable populations, we strive to include information beyond simple descriptions of demographic risk factors by offering more detailed contextual information on the potential behaviors or exposures related to the increased risk experienced by these groups. A recent example is our

recommendation on screening for latent tuberculosis infection in adults (11), which disproportionately affects some racial/ethnic minority populations mainly through differences in the likelihood of exposure; these differences were the focus in the recommendation statement (Table). In our recommendation on screening for abnormal blood glucose and type 2 diabetes, the evidence pointed to stark differences in the prevalence and age at onset of diabetes across racial/ethnic subpopulations in the United States, but these populations lacked specific screening and intervention studies. This evidence gap prevented us from issuing a separate, population-specific recommendation. Instead, we issued a general recommendation that was followed by specific information about the differences in epidemiology across diverse U.S. populations. The general recommendation reads: "The USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity (B recommendation)" (2). To ensure that the information on specific populations is accessible to patients and clinicians, we highlighted this particular statement on the topic page of our Web site:

Persons who have a family history of diabetes, have a history of gestational diabetes or polycystic ovarian syndrome, or are members of certain racial/ethnic groups (that is, African Americans, American Indians or Alaskan Natives, Asian Americans, Hispanics or Latinos, or Native Hawaiians or Pacific Islanders) may be at increased risk for diabetes at a younger age or lower body mass index. Clinicians should consider screening earlier in persons with 1 or more of these characteristics.

We are also starting a new section in the Clinical Considerations section that focuses on specific populations. This section will appear in relevant recommendations in which more direct communication about how we considered the evidence on a specific population is needed. Our recommendation statements routinely include information on implementation and research gaps; this new section will highlight these points for specific populations, including more information that may help clinicians and patients better understand what evidence we considered, how we arrived at our decisions, gaps in the evidence for a specific segment of the population, and what clinicians and patients may want to consider when making decisions based on limited information.

The USPSTF engages its partners in implementation and dissemination to ensure broader circulation and to help reach the communities that may be disproportionately affected by the condition addressed by each recommendation. Disparities are often associated

with less use of evidence-based preventive services in communities at increased risk, and improving awareness of and access to recommended services and indicated treatment in these groups is important to a national strategy to eliminate disparities (such as higher rates of cervical cancer mortality in Hispanic and African American women, and less receipt of treatment once detected) (15). For screening for abnormal blood glucose and type 2 diabetes, our dissemination partners helped to circulate the recommendation and communicate its applicability to the specific racial/ethnic minority populations at higher risk for diabetes.

CONCLUSION

The USPSTF is dedicated to improving the health of all Americans and works to formulate recommendations to meet the needs of all segments of the diverse U.S. population. Limitations in the available data present challenges to the science of developing recommendations for specific groups. The USPSTF continues to develop rigorous and transparent methods to use the best evidence; highlight critical research gaps; and communicate effectively to clinicians, patients, and other stakeholders how its work might best serve our diverse population.

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