Clinical preventive service recommendations from the US Preventive Services Task Force (USPSTF) are based on transparent, systematic, and rigorous methods that consider the certainty of the evidence and magnitude of net benefit. These guidelines aim to address the needs of diverse populations. Biological sex and gender identity are sources of diversity that are not often considered in studies of clinical preventive services that inform the recommendations, resulting in challenges when evaluating the evidence and communicating recommendations for persons in specific gender identification categories (man/woman/gender nonbinary/gender nonconforming/transgender). To advance its methods, the USPSTF reviewed its past recommendations that included the use of sex and gender terms, reviewed the approaches of other guideline-making bodies, and pilot tested strategies to address sex and gender diversity. Based on the findings, the USPSTF intends to use an inclusive approach to identify issues related to sex and gender at the start of the guideline development process; assess the applicability, variability, and quality of evidence as a function of sex and gender; ensure clarity in the use of language regarding sex and gender; and identify evidence gaps related to sex and gender. Evidence reviews will identify the limitations of applying findings to diverse groups from underlying studies that used unclear terminology regarding sex and gender. The USPSTF will use gender-neutral language when appropriate to communicate that recommendations are inclusive of people of any gender and will clearly state when recommendations apply to individuals with specific anatomy associated with biological sex (male/female) or to specific categories of gender identity. The USPSTF recognizes limited evidence to inform the preventive care of populations based on gender identity.

The US Preventive Services Task Force (USPSTF) makes evidence-based recommendations on clinical preventive services, including screening, behavioral counseling, and preventive medications. Frequently, USPSTF recommendations are sex-specific, most commonly based on the biological basis of the preventive service. For example, cervical cancer screening recommendations apply to females (individuals born with a cervix), and prostate cancer screening recommendations apply to males (individuals born with a prostate). However, many people have gender identities that differ from their sex assigned at birth. Transgender people, who were assigned male sex at birth but identify as women, or who were assigned female sex at birth but identify as men, are examples of such individuals, but there are also people with gender nonconforming or nonbinary identities who do not identify as either a man or a woman. A synthesis of data from 12 surveys involving 1,232,667 participants suggested that in the US, about 1 in 250 individuals, or about 1 million people, self-identify as transgender or gender nonconforming.1 Moreover, in the anonymous Behavioral Risk Factor Surveillance System survey conducted in 2014 among 151,456 US adults, 0.53% of respondents self-identified as transgender. Among these individuals, about 53% self-identified as male-to-female transgender, 31% as female-to-male transgender, and 17% self-identified as gender nonconforming.2

Although data are limited,3 transgender, gender nonconforming, and gender nonbinary people report barriers to health care, including negative experiences in health care settings, and report avoiding health care because of concern about being mistreated.4 Moreover, disparities in preventive care, such as cancer screening, have been demonstrated for transgender and gender-nonconforming people.5 Therefore, the USPSTF recognizes that the language used in sex-specific recommendations (specifically related to the sex assigned to a person at birth) needs to be clear and consistent so clinicians and patients can effectively and respectfully apply these recommendations in practice. The purpose of this report is to describe the methods that the USPSTF used to identify recommendations that have sex or gender components and clarify the populations for which the recommendations should apply and also to present a proposed approach to making recommendations that are respectful of gender diversity and that identify when biological sex assigned at birth has limitations as a factor for whom should receive recommended services. This report builds on previous USPSTF methods for developing evidence-based recommendations for diverse populations.
Definitions
It is critical to be able to use terminology with clear definitions. The word sex describes particular biological attributes commonly associated with specific chromosomes, the effect of particular endogenous hormones, and reproductive anatomy. Although individuals can change their hormonal levels and anatomy through medical or surgical approaches, sex is meant to identify those individuals who would likely have been assigned a sex at birth of either female, male, or intersex. Sex is commonly dichotomized into female or male, but this dichotomy is not inclusive of individuals who are intersex—ie, those who have reproductive anatomy that is inconsistent with usual definitions of female or male. For example, an individual with external female genitalia but internal male reproductive organs would be intersex but may be identified by the individual or clinician as male, female, or intersex.

The USPSTF uses gender terms to refer to identities that reflect how individuals generally perceive themselves with regard to social or cultural norms as men, women, gender nonbinary, or gender nonconforming. Gender identity is not specifically confined to a binary categorization and can exist as a continuum; additionally, it can change over time. How individuals identify themselves can differ from how others perceive them based on traditional stereotypes of gender presentation. Assumptions about sex assigned at birth or gender may not be aligned with a person’s biology or personal identity. The use of cis- and trans-prefixes are sometimes used to indicate whether an individual has a gender identity that aligns with their biological sex assigned at birth (cisgender) or does not (transgender).

Methods
Overview
To consider incorporating meaningful sex and gender terminology into its recommendations, the USPSTF created an internal workgroup of USPSTF members, evidence-based practice center (EPC) researchers, and Agency for Healthcare Research and Quality staff supporting the USPSTF program. The workgroup reviewed all USPSTF recommendations published by September 2021 (from September 7, 2015, to September 16, 2021) and identified all USPSTF recommendations with sex- and gender-specific language, performed an environmental scan of how other guideline-making bodies approach the use of the terms describing sex and gender, interviewed experts and leaders in the care of transgender persons, and pilot tested an approach on multiple individuals. No recommendation found sufficient evidence to make a specific recommendation for transgender, gender nonbinary, or gender nonconforming populations. One recommendation identified individuals who were not cisgender as a risk factor (preexposure prophylaxis for HIV), 2 recommendations called for more evidence in transgender and gender nonbinary persons (preexposure prophylaxis for HIV and behavioral counseling to prevent sexually transmitted infections), and 1 recommendation stated that there were no screening data for transgender and gender nonbinary persons.

Environmental Scan
Workgroup members reviewed publicly available guidance and methods documents from other national and international guideline bodies to identify (1) approaches to making guidelines based on sex and gender and (2) specific guidelines for transsexual, transgender, and gender nonconforming people. This effort was supplemented with a nonsystematic literature search (August 13, 2013, to
<table>
<thead>
<tr>
<th>Topic</th>
<th>Recommendation</th>
<th>Primary basis for recommendation</th>
<th>Potential changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal aortic aneurysm screening,14 2019</td>
<td>One-time screening for abdominal aortic aneurysm (AAA) with ultrasonography in men aged 65 to 75 years who have ever smoked. (B) Against routine screening for AAA with ultrasonography in women who have never smoked and have no family history of AAA. (D)</td>
<td>Biological</td>
<td>Clarify population under consideration (done) and consider evidence gaps (needed)</td>
</tr>
<tr>
<td>Asymptomatic bacteria screening,13 2019</td>
<td>Screening for asymptomatic bacteria using urine culture in pregnant persons. (B) The USPSTF recommends against screening for asymptomatic bacteria in nonpregnant adults. (D)</td>
<td>Biological</td>
<td>Use neutral language (done)</td>
</tr>
<tr>
<td>Bacterial vaginosis screening,16 2020</td>
<td>Against screening for bacterial vaginosis in pregnant persons who are not at increased risk for preterm delivery. (D)</td>
<td>Biological</td>
<td>Use neutral language (done)</td>
</tr>
<tr>
<td>BRCA testing,17 2019</td>
<td>Women with a positive result on the risk assessment tool should receive genetic counseling and if indicated after counseling, genetic testing. (B) Against routine risk assessment, genetic counseling, or genetic testing for women whose personal or family history or ancestry is not associated with potentially harmful BRCA1/2 gene variants. (D)</td>
<td>Biological</td>
<td>Clarify population under consideration (done) and consider evidence gaps (needed)</td>
</tr>
<tr>
<td>Breast cancer medications,16 2019</td>
<td>Clinicians offer to prescribe risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, to women at increased risk for breast cancer and low risk for adverse medication effects. (B) Against the routine use of risk-reducing medications in women who are not at increased risk for breast cancer. (D)</td>
<td>Biological</td>
<td>Clarify population under consideration and consider evidence gaps (needed)</td>
</tr>
<tr>
<td>Breast cancer screening,11 2016</td>
<td>Biennial screening mammography for women aged 50 to 74 years. (B) The decision to start screening mammography in women before age 50 years should be an individual one. (C)</td>
<td>Biological</td>
<td>Clarify population under consideration and consider evidence gaps (needed)</td>
</tr>
<tr>
<td>Breastfeeding,19 2016</td>
<td>Provide interventions during pregnancy and after birth to support breastfeeding. (B)</td>
<td>Biological</td>
<td>Use neutral language (needed)</td>
</tr>
<tr>
<td>Cervical cancer,20 2018</td>
<td>Screening for cervical cancer every 3 years with cervical cytology alone in women aged 21 to 29 years. For women aged 30 to 65 years, screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting). (A) Against screening for cervical cancer in women younger than 21 years, older than 65 years, or who have had a hysterectomy. (D)</td>
<td>Biological</td>
<td>Clarify population under consideration and consider evidence gaps (needed)</td>
</tr>
<tr>
<td>Chlamydia and gonorrhea,21 2021</td>
<td>Screening for chlamydia and gonorrhea in all sexually active women, including pregnant persons, who are 24 years or younger and in women 25 years or older who are at increased risk for infection. Persons should consider their sex at birth and current anatomy (especially presence of a cervix/vagina) to determine which recommendation best applies to them. Studies are needed to better understand the benefits and harms of screening specific populations at risk such as men who have sex with men, members of the LGBTQ+ community, and persons with nonbinary gender identity. (B)</td>
<td>Biological</td>
<td>Clarify population under consideration and consider evidence gaps (done)</td>
</tr>
<tr>
<td>Depression in adults,22 2016</td>
<td>Screening for depression in the general adult population, including pregnant and postpartum women. (B)</td>
<td>Biological and gender identity</td>
<td>Use neutral language (needed)</td>
</tr>
<tr>
<td>Folic acid,23 2017</td>
<td>Recommends that all women who are planning or capable of pregnancy take a daily folic acid supplement. (A)</td>
<td>Biological</td>
<td>Use neutral language (needed)</td>
</tr>
<tr>
<td>Gestational diabetes,24 2021</td>
<td>Screening for gestational diabetes in asymptomatic pregnant persons at 24 weeks of gestation or after. (B) Insufficient to assess the balance of benefits and harms of screening for gestational diabetes in asymptomatic pregnant persons before 24 weeks of gestation. (I)</td>
<td>Biological</td>
<td>Use neutral language (done)</td>
</tr>
<tr>
<td>Periodic pelvic examination,25 2017</td>
<td>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. (I)</td>
<td>Biological</td>
<td>Clarify population under consideration (done), use neutral language (done), and consider evidence gaps (done)</td>
</tr>
<tr>
<td>Hepatitis B in pregnant women,26 2019</td>
<td>Screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit. (A)</td>
<td>Biological</td>
<td>Use neutral language (needed)</td>
</tr>
<tr>
<td>Hormone therapy,27 2017</td>
<td>Recommends against the use of estrogen alone or with progesterone for the primary prevention of chronic conditions in postmenopausal women. (D)</td>
<td>Biological</td>
<td>Clarify population under consideration and consider evidence gaps (needed)</td>
</tr>
<tr>
<td>HIV preexposure prophylaxis,28 2019</td>
<td>Offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. (A) Persons who engage in transactional sex, persons who are trafficked for sex work, men who have sex with men and women, and transgender women and men who are sexually active can be at high risk. (B)</td>
<td>Gender identity</td>
<td>Clarify population under consideration (done)</td>
</tr>
<tr>
<td>HIV screening,29 2019</td>
<td>Screen for HIV infection in all pregnant persons. (A) Screen for HIV infection in adolescents and adults aged 15 to 65 years and younger adolescents and older adults who are at increased risk. (A)</td>
<td>Gender identity</td>
<td>Use neutral language (done)</td>
</tr>
</tbody>
</table>

Green shading indicates recommendations to which updated US Preventive Services Task Force methods for sex and gender have been applied. BRCA indicates breast cancer susceptibility gene.  

* Recommendation abbreviated, some letter grades excluded, or both, to highlight use of sex and gender language.  

Text from body of recommendation statement, not topline recommendation.
Many medical professional societies also have policies regarding the use of inclusive language on health care forms, demographic questionnaires, handouts, and paperwork. 

Pilot Testing
Over a series of 6 meetings, the workgroup considered revisions to the USPSTF processes and methods and defined guiding principles to strengthen sex and gender inclusivity when communicating recommendation statements. The EPC and USPSTF members were asked to apply preliminary changes throughout the process of updating 2 recommendations—screening for abdominal aortic aneurysm (AAA) and risk assessment and genetic counseling for BRCA-related cancers.14,17 Additionally, the EPCs and USPSTF members have prospectively applied the revised approach to subsequent topics to guide further insight and adaptation.
To advance its methods, the USPSTF tested (1) prospectively and explicitly determining whether the preventive service was expected to have a biological (sex) or identity (gender) basis, (2) conducting the evidence review based on the biological or identity basis, (3) identifying whether specific populations based on sex or gender were disproportionately affected by the condition, and (4) developing language to make a clear recommendation for sex and gender. The 2 topics reviewed (AAA screening and BRCA-related cancers) had multiple recommendations that were thought to be based on sex, not gender. However, the primary studies supporting these topics used gender-based language (eg, man, woman) when referring to study populations, without further clarification of these terms.60,61 For these 2 topics, no studies that addressed transgender, gender nonbinary, gender nonconforming, or intersex populations met inclusion criteria. Thus, when assessing the available evidence, the USPSTF could not determine whether the findings could be applied to these specific populations and could only make recommendations based on sex assigned at birth for both AAA screening and BRCA counseling.

Further, there was no specific evidence for the effect of treatment with gender-conforming therapies (eg, hormonal, surgical) for transgender, gender nonbinary, gender nonconforming, or intersex individuals and its potential effects on the biological basis for these recommendations. For example, for a person assigned female sex at birth who had transitioned during or shortly after puberty to a transgender man and who received maintenance exogenous testosterone, it is unclear whether their risk for AAA or breast cancer would be that of someone born female or male, or if their risk was somewhere on a continuum. Thus, more research is needed to make specific evidence-based recommendations. Still, until such evidence is available, it will be essential to take an inclusive, respectful approach to making preventive service recommendations to avoid further marginalization of these populations.

Very early in the pilot process, the concept emerged of using neutral language in recommendations whenever possible. The first example adopted was using the term “pregnant persons” instead of referring to pregnant women. The USPSTF used this language in several recommendations not included in the planned pilot8,9 and received no comments, criticisms, or concerns with the transition in the language in their public comment periods or thereafter.

When not possible to use neutral language, the USPSTF decided it was more appropriate to use gender terms throughout the recommendation statement, even when the service was based on biology. However, the USPSTF developed explicit language in the Patient Population Under Consideration section to make the USPSTF intent clear to readers. This addition was first piloted in a 2019 AAA screening recommendation statement in which the recommendation stated, “the recommendations are stratified by "men" and "women," although the net benefit estimates are driven by biologic sex (ie, male/female) rather than gender identity. Persons should consider their sex at birth to determine which recommendation best applies to them.” Similar language was used for the recommendation statement on BRCA-related cancer.17 The USPSTF received no comments or feedback, positive or negative, about using this language during the public posting periods for the draft recommendation statement or when the final recommendation statements were published.

**Position Statement**

The USPSTF is committed to promoting health equity for diverse populations, including based on sex and gender, and ensuring both the specificity and inclusivity of its recommendations. Therefore, the USPSTF will advance its methods and language in every step of its recommendation development process, as outlined in the Box.

**Developing the Research Plan**

When making a new recommendation or updating an existing recommendation, the USPSTF collaboratively creates a research plan with an EPC. The research plan defines the key questions that need to be answered with evidence for the USPSTF to make a recommendation and defines the types of evidence and populations included in the review. At the outset of this process, the USPSTF will consider whether the preventive service is expected to be applied according to biological or physiologic sex characteristics, gender identity, or potentially both. This consideration will be guided by whether specific populations have a higher prevalence or experience worse outcomes from a condition or if there are unique considerations for risk assessment or service delivery based on sex or gender identity.6 If specific sex or gender populations are not called out in the research plan for inclusion or exclusion, the research plan will be considered inclusive of all populations. Once a draft research plan is created, the USPSTF will seek review by transgender, gender nonbinary, gender nonconforming, and intersex individuals and groups with specific expertise in representing these populations, as appropriate. Input will be incorporated into the final research plan.

**Evidence Review**

Based on the research plan, EPC investigators will conduct the systematic review. Each systematic review provides background on the epidemiology across all relevant populations (eg, incidence, prevalence, and mortality); systematically searches the literature for evidence to address each key question in the research plan; conducts data abstraction, critical appraisal, data analysis, and synthesis; and summarizes the evidence in a report. The full systematic review is available and published with each USPSTF recommendation. Throughout this process, EPC investigators will aim to describe the gender of participants from the included studies accurately. They will also note when the terminology used in the underlying evidence is unclear or based on assumptions about gender or the biology of participants. The language will be included in the EPC report to acknowledge the absence or incompleteness of information on gender and biological sex and its implications for the interpretation and applicability of the evidence. EPC investigators also will seek review by transgender, gender nonbinary, and gender nonconforming individuals and groups with specific expertise in representing these populations for services with unique considerations for these communities.

**Assessing the Evidence**

When assessing the evidence to make a recommendation, the USPSTF will consider the sex or gender identity basis of the evidence; applicability of evidence to transgender, gender nonbinary, and gender nonconforming populations and to intersex persons; variability in the quality of evidence based on sex or gender; and whether the net benefit varies based on sex or gender. Consistent
Box. USPSTF Methods for Considering Sex and Gender in Recommendations

Developing the Research Plan
Prior to developing the research plan for a new or updated recommendation, the USPSTF will consider potential sex and gender issues, including:

- How biology (sex) and identity (gender) inform the risks, outcomes, and provision of the preventive service;
- Whether certain populations based on sex, gender, or both may be disproportionately affected by a condition or susceptible to variation in the effectiveness of the preventive service; and
- Whether there is potentially adequate evidence to consider a specific review and recommendation for transgender, intersex, gender nonbinary, and gender nonconforming populations.

Based on the above considerations, the USPSTF will develop a research plan to guide the systematic evidence review. Unless explicitly stated, the research plan will be inclusive to identify available evidence applying to diverse populations based on sex and gender. As appropriate, specific sex and gender, including transgender, intersex, gender nonbinary, and gender nonconforming populations, will be identified explicitly in the inclusion and exclusion criteria.

Prior to finalizing any research plan, the USPSTF seeks additional input from outside review and public comment. All public comments are considered.

As appropriate, the USPSTF will seek input from topic experts with knowledge related to sex and gender if applicable to the recommendation.

Conducting the Systematic Evidence Review
The EPC will conduct the evidence review based on the defined research plan.

As appropriate, the EPC will seek out sex- and gender-specific evidence, including:

- Incidence and prevalence of target condition;
- Outcomes of the preventive service;
- Benefits from the preventive service; and
- Harms from the preventive service.

Prior to finalizing the evidence review, the EPC will solicit external input, including topic input related to sex and gender as appropriate.

Assessing the Evidence to Make a Recommendation
When considering the evidence, the USPSTF will assess

- How biological sex, gender identity, or both, pertain to the evidence;
- Applicability of evidence to transgender, intersex, and gender nonconforming populations;
- Variability in the quality of evidence based on sex, gender, or both; and
- Whether the net benefit varies based on sex, gender, or both.

Per the USPSTF methodology, all recommendations, including sex- and gender-based recommendations, will be based on (1) the certainty of the evidence and (2) the magnitude of net benefit.

The USPSTF will consider recommendations to be inclusive unless evidence is not applicable to specific populations.

The USPSTF will make specific sex and/or gender recommendations when there is at least moderate certainty that there is differential magnitude of net benefit for a preventive service.

(continued)
Considerations section, the USPSTF will review the evidence supporting the basis for a recommendation focused on a specific population defined by biological sex or gender attributes. When the USPSTF finds important evidence gaps for transgender, gender nonbinary, and gender nonconforming persons, the USPSTF will call for more evidence in the Research Needs and Gaps section of the recommendation.

Conclusions

The USPSTF intends that these new approaches for developing recommendations attuned to sex and gender diversity will improve the clarity of its statements and help clinicians and their patients make informed decisions about preventive care. The USPSTF plans to continue its engagement with individuals and groups with specific expertise in representing these populations to learn how best to formulate recommendations that are gender inclusive, more clearly communicate with regard to sex and gender diversity, and improve understanding of the research gaps. This policy statement should be viewed as a first step in advancing the task force’s methods on these issues. The USPSTF updates its recommendations for each preventive services topic, with a goal of approximately every 5 years. As topics are updated, the approaches outlined above will be applied during the updates. The process is underway or complete for several topics and will continue over the next several years for all others.

It is common for the USPSTF to identify evidence gaps for specific populations of patients—even when there is evidence that these populations are more likely to be diagnosed or experience specific preventable conditions.6,2 The evidence gaps for preventive services are substantial for transgender, gender nonbinary, gender nonconforming, and intersex persons, limiting the ability of the USPSTF to make a specific recommendation. As science and understanding evolve, the USPSTF will remain committed to advancing its processes and methods to further promote equity for all persons regardless of sex or gender. However, until primary studies that inform USPSTF recommendations adopt more nuanced approaches to assessment and reporting on the sex and gender of study participants, there will continue to be gaps in the evidence and challenges to formulating and communicating inclusive clinical recommendations.

ARTICLE INFORMATION

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